Chapter-I

Introduction

In every society, family is rooted like a natural phenomenon. It has existed like an immutable and indispensable natural thing through the uncountable stories and non-transformed cultural roots. The family as a basic unit of society existed from the early history of human civilization. In every religion either in eastern society or in western society, the formation of family and procreation has been a sacred duty of human being. It is as fundamental as the existence of human being as no one can imagine a society where it can be ignored. The institution of family was also recognized in international instruments.¹

Besides it, God has bestowed human being with the natural instinct of reproduction. So, to fulfill this natural instinct, human being has established various institutions in the society. Marriage, being one such institution, facilitates this natural instinct among the human being in an acceptable manner. The couple is always encouraged to plan a baby immediately after the marriage. At this point of time the societal pressure is developed over the couple for the child bearing. Whosoever comes out of this pressure has been provided a due place in the society but who fails has been ascribed with a stigma of infertility.

Infertility is a worldwide problem affecting 8-12 percent couple (50-80 million) during their reproductive lives.² According to WHO multi centric studies in India, 40% women and 73% of men had no demonstrable cause of infertility.³ To overcome this grave problem of infertility, the couple goes to any large possible extent primarily from conventional method to advanced techniques of reproduction. The other viable alternative for the problem may be the concept of adopted children. The adopted children are permissible, from religious point of view, only on compliance of certain conditions. The concept of adopted children was confronted

¹ The United Nations Declaration of Human Rights, 1948 Article 16.1 recognizes that, “Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family”. The European Convention on Human Right also guarantees respect for family life and the right to found a family. Article 12 says: Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right. Article 10.1 and 11.1 of The International Covenant on Economic, Social and Cultural Rights provides the human rights about family.


with certain complications in social norms and invites litigations also. Moreover, besides the availability of these alternatives, the people are very much desirous for purity of blood line to perpetuate the system of inheritance.

To give vent to this manifestation of human mind, the medical sciences made an acute introducement by way of medically assisted human reproduction. Assisted reproductive technologies (hereinafter referred as ART)\(^4\) are a group of technologies, which assist in conception and pregnancy. It includes a range of techniques for manipulating eggs and sperms in order to overcome infertility. It includes In vitro fertilization (IVF), gamete intra-fallopian transfer, zygote-intra fallopian transfer, surrogacy, posthumous procreation and most recent techniques like, intra-cytoplasmic sperm injection, (ICSI), cryopreservation of donated oocyte/sperm, in vitro maturation, pre-implantation genetic diagnosis and microsorting. In general, ART procedures involve surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman. They do not include treatments in which only sperm are handled (i.e., intrauterine or artificial insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved\(^5\).

The ART has revolutionized the life of millions of infertile couple by satisfying the psychological desire of having genetically related sons and daughters. The promise of the reproductive technologies i.e. producing babies now goes beyond curing infertility and challenges our concept of family and parenthood. Creating a family, irrespective of whether you are an infertile husband and wife couple, a same-sex couples or a single person have deliberate choice. The possibility of choosing to form a family outside the traditional heterosexual married couple is controversial both practically and legally. Recognition of the legal relationship that results from the creation of families through ART has similarly developed in reaction to the stigma of illegitimacy.

The ART is the miracle of the new era where high-tech babies are produced through new reproductive technologies and genetic engineering. In vitro fertilization

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\(^4\) According to Section 2(c) of ART (Regulation) Bill, 2010 “assisted reproductive technology” (ART), with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or the embryo into the reproductive tract.

\(^5\) “Assisted reproductive technology” available on [http://www.cdc.gov/art/](http://www.cdc.gov/art/) visited on 01/02/2012
(IVF) started the science of assisted reproductive technology. Aldous Huxley introduced the term “test tube” babies in 1932 in his novel “Brave New World”, in which he described a world where children were fertilized and incubated in artificial wombs. The term “test tube” baby refers to fertilization that take place outside of the womb.⁶ Louise J. Brown, the first test tube baby was born on July 25, 1978, in Oldham, England.⁷ Since then, the field of medically assisted reproduction has taken off, bringing increasingly new and innovative ways to create children, as well as increasingly more complex family relationships and ethically fraught medical practices. The births of the first English, Australian, American and Indian IVF babies (Louis J Brown in 1978, Candice Reed in 1980, Elizabeth Carr in 1981 and Harsha⁸ in 1986) started a revolution in medical technologies and the creation of family. Infertility which was once considered incurable is now medicalized which can be treated through ART.

The development and use of ART continues to raise a range of complex social, ethical, legal and moral questions. The important issues confronted to ART are related to the legitimacy of child born through ART, the responsibilities of ART clinics, the rights and duties of parties including parents, surrogate mother and the doctor, the role of state in facilitating ART, criteria for determining the deserve couple to use ART, restrictions on the use of ART, the commercialization and comodification of human organs, the malpractices and misuse of ART etc.

However, from the last few years there is a great debate in the Indian medical community whether there is any need to regulate ART through law. The ART is quite different from any other medical treatments because the process involves the formation of the family and the interest of the child. Since there is lack of laws in the area and it has been left unregulated, therefore, there are maximum chances of misconduct, irregularity, exploitation and malpractices. However, there is a significant effort for regulating this highly complex area by Indian council of medical research (herein after referred as ICMR) through providing non-binding guidelines from time to time. The first effort appeared in 2000 in the form of Ethical Guidelines

⁸ India’s first scientifically documented IVF baby, Harsha, was born on August 6, 1986 in Mumbai, through the collaborative efforts of the ICMR’s Institute for Research in Reproduction and the King Edward’s Memorial Hospital (KEM).
for Biomedical Research for Human Subjects\(^9\). Subsequently in 2005 ICMR and National Academy of Medical Sciences (NAMS) framed National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproductive Technology Clinic.\(^10\) Recently ICMR and Ministry of Health and Family Welfare (MOHFW) have proposed the draft Assisted Reproductive Technology Bill and Rules 2008 which was later modified in 2010.\(^11\)

The legal issues in the field of ART in Indian scenario seem very remarkable and controversial. First time, it was the case of Baby Manji\(^12\) came before the apex court of India when the absence of law on ART in India was observed. This case, for the first time raised the ethical issues regarding commercial surrogacy and fertility tourism. Later, in the case of Jan Balaz\(^13\), again the nationality of the surrogate twins born through Indian surrogate was raised. These two cases arose unexpected problems where the foreign genetic parents have been restricted to bring the children in their own country. The reason was only lack of legal regulation in India.

The researcher has selected the topic because of popular acceptability of the ART in the society and the area has been left open without sufficient regulation. The non binding ethical and professional guidelines are not able to tackle the problem arising from the use of ART. Due to insufficiency of rule and regulation, there are every chance of misuse and exploitation. An attempt has been made under the study to make a critical study of huge unregulated ART industry in India. The study also examines the development and use of ART, legal issues attached with ART, and its commercialization. The ethical, moral, legal, religious and social issues surrounding the practice of ART have been also discussed.

**Aims and Objectives**

Through a qualitative research process, the study aimed:

- To discuss the historical background, conceptual framework and the causes of infertility and its treatment through various conventional and other methods.

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\(^10\) National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, Indian Council of Medical Research National Academy of Medical Sciences (India), (2005, New Delhi).


\(^12\) Baby Manji Yamada v. Union of India 2008, 13 SCC 518

\(^13\) Jan Balaz v. Anand Municipality 2010(2) ALL MR. (JOURNAL) 14
- To discuss in detail various techniques of ART and the procedures thereof.
- To analyze the development of ART by which, persons who have not been able to produce their child by natural means and by using these technologies they can procreate their own child who is biologically or genetically linked with them.
- To analyze the laws of different countries related to ART through which they regulate and manage the procedure of ART.
- To critically analyze the response of the judiciary in India and abroad towards the disputes arising out from the use of ARTs and also the role of judiciary in developing the law related to ART.
- To analyze the ethical, moral, social and religious issues involved in the ART.
- To analyze the commercialisation of ARTs and also to discuss the misuse and malpractices and exploitation by the parties involved in ART.
- To critically analyze the existing system of regulation of ART, especially the Draft Bill and Rules prepared by ICMR and MOHFW.
- To provide certain suggestions and recommendations for regulating ART through a comprehensive legislation. This will be highly beneficial for the society at large.

**Hypothesis**

In order to achieve the above mentioned objectives, the following hypothesis has been framed by the researcher:

- The problem of infertility is a social stigma in our Indian society and the use of new reproductive technology in the form of ART is very helpful to overcome the problem of infertility.
- The existing regulatory framework is not sufficient to solve complex legal issues arising out of the use of ART so there is an urgent need to regulate the ART through a comprehensive legislation.

**Research Methodology**

The methodology employed for this work is doctrinal. In particular, analytical and descriptive methods have been adopted to draw the inference and conclusions. Materials for the study have been collected from both primary as well as secondary sources. The existing literatures comprises of various books, articles, law journals, dictionaries, encyclopedia, law reports, newspapers, and other materials available at
websites have been used. Secondary data such as the Report of Law Commission of India, Ethical Guidelines of Indian Council of Medical Research, Five Year Plans of Government of India, Warnock Committee Report etc. has been consulted.

**Scheme of Chapters**

To obtain the aforesaid objectives the entire work has been divided into seven chapters:

Chapter I titled “**Introduction**” is as usual introduces the research topic and focuses on the genesis and development of assisted reproductive technology for infertility treatment. It also deals with aim and objectives put forth for the research. It also highlights briefly various issues confronting to ART.

Chapter II titled “**Conceptual Framework of Infertility and Assisted Reproductive Technology**” discusses the problem of infertility, its causes and consequences, its treatment through various means, the social construction of motherhood, treatment of infertility through medical technologies and the development and scientific understanding of medically assisted reproductive technology and its processes like in vitro fertilization, intra cytoplasmic sperm injection, sperm donation, egg donation, surrogacy, pre implantation genetic diagnosis, micro sorting, cryopreservation and posthumous procreation.

Chapter III titled “**Regulation of Assisted Reproductive Technology in India**” analyses the background of regulation of ART, need for regulation of this controversial area of law. Aspects such as the role state should play in providing individuals and families with access to reproductive technologies, the criteria to determine, who deserves to have medically assisted reproduction, the restrictions to impose on ARTs are some of the issues which cannot be answered in isolation. Law always plays a significant role in determining the role of state, public or private agencies and individuals. This chapter tries to find out the more specific answers to these questions through analyzing the Guidelines, Bills and Rules in India. It contains the critical analysis of *Ethical Guidelines on Biomedical Research 2000, National Guidelines on Accreditation, Supervision and Regulation of ART Clinics in India 2005*, and *Draft Assisted Reproductive Technologies (Regulation) Bill & Rules 2010*.

Chapter IV titled “**Laws in Different Countries on Assisted Reproductive Technology**” is a comparative study of the ART regulation in different countries such as UK, USA, Australia, Sweden, Israel, Italy etc. Scientific societies around the world, such as the ASRM, ESHRE and IFFS, have drawn up guidelines for the safe
and ethical practice of ART. The European Union and the Governments of several
countries like Australia, the UK and the USA have taken steps to accredit and
supervise the performance of infertility clinics. While most industrialized nations ban
commercial surrogacy others such as Brazil, Israel, and the U.K. have established
regulatory regimes or partial bans to control access to it. This chapter tries to analyze
comparatively the regulatory scheme at international level.

Chapter V titled “Ethical-Moral and other Issues in Assisted Reproductive
Technology” analyzes the social, medical, ethical, moral, religious and commercial
issues involved in ART. Ethical discussion of reproductive technologies began in the
early 1970s, when techniques such as in vitro fertilization became a real possibility.
Access to ARTs is available primarily to the wealthy, upper middle class, or those
able and willing to borrow the money required. Apart from obvious commercial, and
ethical concerns, ARTs entail potentially serious health risks for women, which could
even be life threatening. Such aspects of ARTs pose important challenges for us
today. Another controversial issue is use of genetic testing for tissue matching to
produce a savior sibling.

Chapter VI titled “Judicial Response and Assisted Reproductive
Technology” examines the response of the judiciary regarding assisted reproductive
technologies. Although access to ART is the first step in assisted reproduction, it
receives considerably less attention than issues of parentage or authority over
reproductive materials. Further, some complex legal issues relating to legitimacy and
paternity are involved in the use of oocyte/sperm donation and posthumous
reproduction. Gestational surrogacy also involves issues of international adoption and
compensation. The study of relevant case law is significant in this context. The
famous Baby Manji Case\textsuperscript{14}, Jan Balaj Case\textsuperscript{15}, K. Kalaiselvi v. Chennai Port Trust\textsuperscript{16}
and the most recent Shihabeldin v Union of India and Ors\textsuperscript{17} are discussed. Apart from
these, some leading American cases and British cases like A v. C (Baby Cotton
Case)\textsuperscript{18}, R v Sheffield HA ex p Seale\textsuperscript{19}, R v Ethical committee of st. Mary’s hospital
(Manchester) ex p Harriott\textsuperscript{20}, North Coast Women’s Care Medical Group. Inc. et al.

\textsuperscript{14} Baby Manji Yamada v. Union of India 2008, 13 SCC 518
\textsuperscript{15} Jan Balaz v. Anand Municipality 2010(2) ALL MR. (JOURNAL) 14
\textsuperscript{16} Judgment delivered on 04.03.2013, High Court of Madras.
\textsuperscript{17} CWP–15490/2013
\textsuperscript{18} F.L.R. 445 [1985] Fam. Law 241
\textsuperscript{19} (1994) 25 BMLR 1
\textsuperscript{20} (1988) FLR 512,HC
v. S.C.(Benitez)\textsuperscript{21}, Mrs. U v. Centre for Reproductive medicine\textsuperscript{22}, Evans v. Amicus Healthcare Ltd. And others\textsuperscript{23}, Hadley v Midland Fertility Services Ltd\textsuperscript{24}, R v. Human Fertilisation and Embryology Authority ex p blood\textsuperscript{25}, The Leeds Teaching Hospitals NHS Trust v. Mr. and Mrs. A and Others\textsuperscript{26}, U v W (Attorney General Intervening)\textsuperscript{27}, U.S. v. Mata\textsuperscript{28}, The case of A v. C\textsuperscript{29}, Re C (A minor) (Wardship: Surrogacy)\textsuperscript{30}, In Re an adoption application (surrogacy)\textsuperscript{31}, Johnson v. Calvert\textsuperscript{32}, In Belsito v. Clark\textsuperscript{33}, In Soos v. Superior Court of Maricopa\textsuperscript{34}, In Re Marriage of Buzanca\textsuperscript{35}, Briody v. st. Helens and Knowsley Area Health Authority\textsuperscript{36}, Re C (Application by Mr. and Mrs. X under s.30 of the Human Fertilization and Embryology Act 1990)\textsuperscript{37}, Baby M Case\textsuperscript{38}, In Re Q (Parental Order)\textsuperscript{39}, In re D (A Child Appearing by her Guardian ad Litem)\textsuperscript{40}, Davis v. Davis\textsuperscript{41}, Kass v. Kass\textsuperscript{42}, Roman v. Roman\textsuperscript{43}, Gillett-Netting v. Barnhart\textsuperscript{44}, R (on the application Bruno quintaville on behalf of pro life alliance ) v. secy for health\textsuperscript{45}, Elisa B. vs. Emily B\textsuperscript{46}, K.M. v. E.G\textsuperscript{47} etc. are also discussed among other cases.

Chapter VII titled “Conclusion and Suggestions” contains the conclusions and suggestions for regulating the practice and use of ART.

\textsuperscript{21} (2008) Cal. LEXIS 10756
\textsuperscript{22} [2002] EwcA Civ 565, [22]
\textsuperscript{23} ( 2004) 3 All ER 1025
\textsuperscript{24} [2003] EWHC 2161 (Fam)
\textsuperscript{25} [1997] 2A1IER 687 (CA)
\textsuperscript{26} (2003) 1FLR 1091.
\textsuperscript{27} [1997] 2 FLR 282, FD
\textsuperscript{28} 18 Phil. 490 (1911).
\textsuperscript{29} F.L.R. 445 [1985] Fam. Law 241
\textsuperscript{30} [1985]FLR846,HC
\textsuperscript{31} [1987] Fam. 81
\textsuperscript{32} 851 P.2d 776 (Cal. 1993).
\textsuperscript{33} 644 NF 2d 760 (Ohio Com Pl 1994)
\textsuperscript{34} 897 P2d 1356 (Ariz. App Div 1 1994)
\textsuperscript{35} 72 Cal. Rptr. 2d 280 (Cal. Ct. App. 1998).
\textsuperscript{36} [2001] EWCA Civ 1010, [2002] QB856
\textsuperscript{37} [1990] [2002] EWHC 157 (Fam.),
\textsuperscript{38} 537 A.2d 1227 (N.J. 1988).
\textsuperscript{39} [1996] 1 FLR 369
\textsuperscript{40} [2005] UKHL 33
\textsuperscript{41} 842 S.W.2d 588 (Tenn. 1992).
\textsuperscript{42} 696 N.E.2d 174 (N.Y. 1998).
\textsuperscript{43} 193 S.W.3d 40 (Tex. App. 2006).
\textsuperscript{44} 371 P.3d 595 (9th Cir. 2004)
\textsuperscript{45} (2002)2wlr550,ca
\textsuperscript{46} 117 P.3d 660 (Cal. 2005).
\textsuperscript{47} 117 P.3d 673 (Cal. 2005).