Chapter IX Results, Suggestions and Recommendations

9.0 Overview of the Field Survey
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This chapter presents the results of the field survey conducted for the purpose of present study and further forwards suggestions and recommendations to be implemented by the Central and the State government for the best interest of infertile patients and children created by ART.

9.0. Overview of the Field Survey

In field survey, a close-ended scheduled printed questionnaire was prepared and distributed among the clinicians practicing ART in Mumbai city. The survey aimed at ascertaining certain facts like popularity of treatments offered, number of years of practice, cost of treatment, prevalent legal practices and for forwarding suggestions whether legislation is necessary for regulating Assisted Reproductive Techniques in India.

9.1. Challenges and Limitations

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

9.2. DATA ANALYSIS

The section below presents the results of the survey conducted arranged into following categories:

Section A: Socio-demographic Characteristics of the Clinic

Section B: Services rendered by the Clinic

Section A: Socio-demographic Characteristics of the Clinic

Experience in terms of years of practice being practiced by the clinic or practitioner

The results reveal duration of the percentage of clinics rendering their services. The highest percent for years of practice rendered by the practitioner or the clinic is 10-15 years (42%) whereas the lowest percent for years of practice is 20 years and above (3%), followed by 5-10 years (33%) and 15 to 20 years (8%). There was no response from 14 percent of the clinics. Thus, a striking percentage of clinics i.e., 75%, mushrooming in past decade of 5-15 years indicate the dire need for formulation of guidelines for licensing and accreditation of clinics.

![Experience of Practice by the Clinic or Practitioner](image)

Figure 1. Experience of Practice by the Clinic or Practitioner (n=36)
Section B: Services rendered by the Clinic
This section present the results related to several services rendered to the patients by
the practitioner or the clinic.

Clinics providing IVF Counseling to Patients
Many clinics provide counseling facilities with regard to IVF treatment to patients
such as the pros and consequences of the treatment and cost of the treatment. Some
clinics do offer counseling facilities (59%) whereas some clinics do not offer
counseling facilities (19%). Twenty two percent of clinics do not respond to the
query.

Special Services offered by the Clinics
Most of the practitioners are practicing intra uterine treatment on female patients. It is
done even without appropriate IVF set up. The cost of per insemination is
approximately up to Rs 3,000-3,500. Success rate depends upon the age of the female
patient and several other factors. Many clinics opt for the donor insemination [AIH]
or [AID]. In vitro fertilization is being practiced by clinics but for IVF and ICSI a
proper IVF set up is required.
Figure 3. Percentage of Clinics providing Special Services to the Patients (n=36)
Mode of Accessing Services (referred or voluntary).

The mode of accessing services are voluntary (5%), referred (0%), as well as both, referred and voluntary (87%). No response was obtained from 8% of clinics.

Figure 4. Mode of Accessing Services used by the Patients (n=36)

Basic Investigations for Infertile Patients
The basic investigations conducted on the infertile patients are blood tests, USG (ultrasonography), semen analysis, HIV, Hepatitis, screening of infections, identification of timing of ovulation, ECG, ESR are some which are prioritized
among the few. The results show hundred percent screening for blood tests, ultrasonography and semen analysis by the clinics studied.

![Basic Investigations for Infertile Patients](image)

**Figure 5. Basic Investigations conducted on the Patients (n=36)**

**Clinics providing Counseling for Adoption of Children**

About 24 clinics provide counseling for adoption of children before advising them for going for infertility treatment. This is mainly for the couples who are older in age for the infertility treatment but as adoption have its own pros and cons related to legal formalities, couples go in for the infertility treatment most of the times.

![Clinics providing Counseling for Adoption of Children](image)

**Figure 6. Clinics providing Counseling for Adoption of Children (n=36)**
Clinics providing Screening for Donors

The clinics provide screening tests for the eggs as well as sperms. They screen for any kind of infections or diseases that can be transmitted to the child. A high rate, 41.67% of clinics however do not screen the donors which may result in transmission of the deadly diseases to the unborn child.

![Clinics providing Screening for Donors](image)

Figure 7. Clinics providing Screening for Donors (n=36)

Suggestions for Egg Sharing and Egg Donation

Almost equal number of clinics provides suggestions for egg sharing and egg donation. The egg sharing and donation may result in helping a couple to conceive or can also reduce the cost of the treatment for the donor as well as the recipients.

![Suggestions for Egg Sharing and Egg Donation](image)
Figure 8. Clinics providing Suggestions for Egg Sharing and Egg Donation (n=36)

Provisions applicable for Screening of Donors

About 30 clinics follow the ethical standards of screening for donors, that is, age restrictions (18 – 45 years), and HIV positive status and hepatitis tests. However, 6 clinics do not follow these restrictions implying the need for strict regulations of these ethical standards.

Types of Equipments used by clinicians / practitioners for Assisted Reproductive Techniques

Almost all equipments are used by the clinicians / practitioners for ART such as ultrasonography machines, pathology services, deep freezers for sample preservation and standard IVF laboratory.

Technical Collaboration of Indian IVF clinics with Foreign Institutes

Only 11 clinics have established collaborations with foreign institutes for machinery, equipments, medical consultancy or expertise. About 20 clinics work on their own establishments whereas no response was obtained from five clinics.

Figure 9. Clinics having Technical Collaboration of Indian IVF clinics with Foreign Institutes (n=36)
Details for Further Surveillance
Several clinics (29) affirmed for further surveillance whereas five clinics denied for further communication in this regard. Two clinics did not respond to the query.

Reporting for Live Birth Rate by the Clinics

![Live Birth Rate Reporting Pie Chart]

Figure 10. Clinics reporting Live Birth Rate (n=36)
About fifty percent clinics do not provide live birth reporting from IVF Technique whereas 33% clinics do provide the service.

Cost of the ART Treatment

![Cost of ART Treatment Pie Chart]
Figure 11. Cost of the ART Treatment estimated by the Clinics (n=36)

The cost of the treatment lies anywhere between INR 50,000 to 2,00,000 depending on various factors such as type of treatment chosen, fees of the practitioner, type of technical investigations required. About 44% of clinics charge INR 1-1½ lacs for the treatment followed by 25% charging INR 1½ – 2 lacs, and 17% INR 50,000 - 1 lac.

Consent Seeking from the Patients

The figure below describes the categories of consent forms to be filled by the patients. They include several forms such as consent seeking from the couples, donors as well as recipients, and consent forms for several processes like freezing of embryos, AI, egg donation and surrogacy. Consent seeking is priority for couples, donors and for AI (n more than 33), followed by consent for PESA/TESA and embryo transfer (n more than 20).

Figure 12. Categories of Consent Form filled by the Patients (n=36)

Note. This is a multiple frequency table. Responses may exceed n.
9.3. SUGGESTIONS AND RECOMMENDATIONS

Introduction

Assisted reproductive technologies have rapidly changed the concepts of reproduction. Reproduction is no longer a matter of chance encounter between an egg and spermatozoa. An egg can now be forced to fertilize outside the body by ICSI, develop into an incipient embryo and lead to a pregnancy and a live birth following the transfer of the early embryo from the Petri dish into the mother's womb. It has been stressed by the Indian Council for Medical Research that clinics handling such important events in the procreation of our species need to be accredited, to be provided with guidelines and their work to be supervised by an independent body established by the State. Britain, the European Union and United States, among other developed countries of the World, have established mechanisms to achieve such goals India, like most of the developing countries, still lack these essential services. Nevertheless, there is growing awareness for such needs and steps are being taken to achieve such objectives. For example, the National Board of Examinations, Ministry of Health and Family Welfare, Government of India has taken steps to offer postgraduate degrees in Reproductive Medicine. The National Academy of Medical Science has initiated discussion on what needs to be done to draw up guidelines for the ethical practice of medically assisted reproductive techniques and to offer suggestions for establishing a national Accreditation and Supervisory Body for Infertility Clinics.

The development of assisted reproductive technologies (ARTs) in India began with efforts to create "test tube babies" with in vitro fertilization in the 1980s. But rather than commit public funding to advance such research, the Indian government withheld the use of government funds for research on human embryos, largely as a byproduct of the debate over population control. Without government funding, research on human embryos was outside of government regulation and oversight, and continues to take place in private settings with private investment, beyond governmental rules and public scrutiny. In addition to the absence of government oversight, scrutiny from health insurance companies were also absent, since till last year the only insurers were government owned monolithic companies and they do not cover assisted reproductive technologies. Whatever we might think about health
insurers, they perform the valuable function of determining the appropriate use of new and expensive technologies, by refusing to pay for services that do not meet certain standards. Since assisted reproduction is not usually covered, there is very limited third-party oversight. ARTS have slipped through the cracks in the oversight system that covers nearly every other area of clinical research and medical care. There is no good reason why assisted reproduction ought to be treated differently than other area of medicine, except for its unique history. Without insurance to pay for it, assisted reproduction became market-driven. New technology introduced by one clinic is quickly offered by others as a matter of survival. But unlike other areas of medicine, in which new therapies are developed after controlled research in humans, ARTs often are introduced directly from the lab as clinical services for patients. Data are collected as patients are treated with untested new approaches, creating the only area of medicine where patients come for treatment but in reality pay for the privilege of being research subjects. The irony is hard to ignore: The research protection policies applied elsewhere in medical research were driven by efforts to prevent exploitation of the vulnerable—yet patients confronting infertility are often the most vulnerable. There are few straightforward ways to bring assisted reproduction to the fold.

Research in assisted reproduction should receive the same sort of approval and oversight as government funded research. Such policies are long overdue. Bringing ARTs into the open will better serve patients and improve research oversight. In the process, it will go a long way toward convincing the public that this is a technology we can manage. Each society has approached the ethical and legislative aspects of IVF in its own particular way. A situation has now emerged in India, where increasing numbers of couples now utilize this approach to the alleviation of their infertility. As IVF expands worldwide, its ethical aspects enter into increasingly diverse societies. The demand for some sort of ethical control is also widened as new technologies are invented and applied, and as the number of IVF clinics continue their large-scale increase.

a. **Governments**- Expenditure on health as a percentage of gross domestic product differs significantly between different continents and different countries (World Health Statistics, 2007). The American (12.7%) and the European regions (8.6%) have the highest score compared with the African (6%), the Western Pacific (5.8%), the Eastern Mediterranean (5.0%) and the
South-East Asia regions (4%). Evidently, these discrepancies translate into gross inequalities with regard to global health care. From the perspective of reproductive health, political statements and commitments need to result in appropriate action in order to achieve ‘sexual and reproductive health for all’ by 2015 as agreed to by 179 governments at the United Nations International Conference on Population and Development in Cairo in 1994. More recently, health was recognized as one of the most important long-term foreign policy issues by the Ministers of Foreign Affairs of Brazil, France, Indonesia, Norway, Senegal, South Africa and Thailand. In a Ministerial declaration, the need for integration of health services was emphasized by stating that the well-functioning health systems that are needed to reduce maternal newborn and child mortality and to combat HIV/AIDS, tuberculosis and malaria will also help countries to cope with other major health concerns such as sexual and reproductive health. There are many reasons for fragile and fragmented health services in developing countries, which include political instability, poor quality governance, lack of workforce, inadequate drug supply and lack of functional information systems. It is thereby recommended to the government that – Research is urgently required on how to overcome these barriers and strengthen health systems in resource-constrained settings.

1. Health authorities should focus on primary health care such as the reduction of maternal mortality and the promotion of family planning.

2. Although prevention of STDs and pregnancy-related sepsis should be considered a reproductive health priority, public investment in infertility treatment must also become a subject for discussion.

3. Public funding of infertility-related health care for education and preventative care, substantially simplifying ART procedures.

4. We should consider the integration of infertility management into sexual and reproductive health-care programmes and reduction of costs a prerequisite in this regard.

5. Simplifying diagnostic procedures in the infertility work-up, simplifying ART, minimizing complication rates and organizing training courses for medical and paramedical personnel will be mandatory if new reproductive technologies are
becoming available and affordable, especially outside the private health-care sector.

b. Preventive strategies should be adopted The first priority should always be prevention rather than cure. Therefore, prevention of STDs and pregnancy-related sepsis should be regarded as the most important and cost-effective strategy to decrease infertility rates. Many variables influence the success of the different prevention strategies. These include a number of elements: the target group, the constraints to overcome and the right strategies for prevention. The importance of education was documented by Okumu et al. (1990) who studied the past reproductive and sexual characteristics of patients with tubal infertility. When compared with fertile controls, women with tubal disease were younger at first coitus, were more likely to have had first coitus pre-menarche, had more sexual partners, more abortions before marriage, more induced abortions, were more likely to have been diagnosed with STDs and had fewer years of schooling.

These data suggest that reproductive and sexual events during teenage years determine the future prospects of fertility and highlight the importance of education. Paradoxically, education will not only help to safeguard future fertility but will also reduce total fertility rates as studies have demonstrated that education, especially of women, is an important variable determining the desired number of children.

c. Simplifying diagnostic procedures An accurate history of couple's personal and medical details together with a simple light microscopy semen analysis will identify the majority of infertility problems related to ovulatory disorders and male subfertility. The diagnosis of tubal factor infertility can be made by hysterosalpingography (HSG) or hystero-salpingo-contrast-sonography. These techniques are simple, reliable and comparatively inexpensive Laparoscopic techniques have been simplified over the years and can now be conducted in a one step ambulatory approach. Even office mini-hysteroscopy can be done without major costs and side-effects, provided there have been appropriate training. Moreover, all of these procedures can be performed by a small team of health-care providers within a short period of time in an inexpensive setting. Future studies should assess the value and potential costs of 'one-stop infertility clinics' in different developing countries.
d. Simplified infertility treatment and non-IVF assisted reproduction

Fertility awareness programmes are an inexpensive and efficient first line approach to infertility management, provided tubal patency is demonstrated and severe male factor sub fertility has been excluded. In a prospective randomized study by couples were instructed about the meaning and detection of cervical mucus secretion, with good results. Fertility awareness counseling, which should also incorporate education on infertility prevention, can be given by nurses and paramedical staff working in existing reproductive health-care centers. For ovulatory dysfunction, representing almost 20% of female infertility, clomiphene citrate (CC) can initiate ovulation. This medication is very cheap, can be taken orally with minimal discomfort and the results are rewarding. Ovulation can be induced in 50–70% of cases and, together with timed intercourse, the pregnancy rate varies between 15 and 25% per cycle with a low multiple pregnancy rate of 6–8%. In case of resistance to CC, a low-dose ovarian stimulation regimen with gonadotrophins aimed at monofollicular growth is advisable, although this medication is more expensive. Alternatively, the use of aromatase inhibitors (AI) such as anastrozole and letrozole may be considered. Although more expensive than CC, success rates may be slightly higher when compared with CC, probably due to a better endometrial, receptivity.

In the case of unexplained and moderate male factor infertility and provided tubal patency has been documented, intrauterine insemination (IUI) with husband's semen in natural cycles or after CC-stimulation can be promoted as a first-line treatment without major costs and without expensive infrastructure. Cost-effectiveness studies showed that three IUIs were as successful, but much cheaper than one IVF/ICSI cycle. Moreover, IUI programmes can be run by well-trained paramedical staff, another advantage for resource-poor countries. Controlled ovarian hyperstimulation (COH), with or without IUI, is associated with the risk of multiple gestations, especially when gonadotrophins are used.

Infertility programmes in India can only be implemented and sustained if they are supported by local policy makers as well as the international community. A critical aspect of this process is funding, and this is likely to require input and collaboration from various role players.
Recommendations are –

- Importance of reproductive confidence.
- Infertility and increased genetic risk are serious health threats which deserve appropriate attention and action. The goal of assisted reproductive technology (ART) and genetic services is to restore reproductive confidence for couples facing these types of difficulties.
- Reproductive health is for value for the community. Prevention of infertility should be prior goal of health care, in addition to social measures to counter parental age, abuse of drugs sexually transmitted diseases, obesity and environmental factors.
- Parenthood should be made easier by societal changes to improve the possibility of combining children and career and encouraged by informing young adults of the impact of ageing on reproductive performance. Adoption should be promoted.
- A Special Task Force should be appointed by the government aimed to encourage more and affordable infertility diagnosis and treatment in India. The members to be included in this task force should be medical practitioners, health management stakeholders, policy planners, government administrators, NGOs, and patients. Optimizing a concurrent and affordable infertility diagnostic and treatment programme will be the most important challenge. One of the Study-Groups will also deal with health economics, quality-of-life and cost-effectiveness of ART in resource-poor settings. One of the questions will be how cost-effective fertility treatment will be in comparison with other measures aimed to improve health. Whether we are creating false expectations by introducing relatively expensive and sophisticated fertility treatment will be another important subject. Looking at the different strategies the researcher acknowledges this fact would the implementation of ART in developing countries result in relief or grief? should be discussed seriously all the way. STF should aim to document the problem of infertility in India, to develop and test the effectiveness of a simplified 'one-step clinic' for the diagnosis of infertility, to develop and test the effectiveness of simplified IVF-related procedures, to develop strategies for minimizing the risks of ART and to promote the linkage of family planning, maternal and neonatal care and infertility treatment. The STF also aims to search for the optimal management strategy for sub fertile couples in developing countries with emphasis on non-IVF
treatment and other (surgical or medical) options before starting IVF. Other plans for the STF are to organize expert meetings and training courses for fertility specialists and paramedical staff from developing countries, to approach the media and to work together with other non-profit organizations with common interests.

e. Patient Support Network

From a political point of view, it is very important that patient organizations claim the right to equitable access to infertility treatment all over the world. The International Consumer Support for Infertility is a global family of patient associations of 39 countries in all world regions. In sub-Saharan Africa, the Joyce Fertility Support Centre Uganda was founded in 1998 to bring forward the idea of providing a holistic approach to the problem of infertility. Joyce Fertility Support is breaking with tradition by openly talking about infertility, its causes and its treatment. This patient network tries to convince local people that infertility affects both men and women, and that methods to prevent and to treat it are available. Recently Joyce Fertility Support launched the African Infertility Alliance which brings together the countries of Uganda, Kenya, Zimbabwe and Israel to share issues concerning infertility. Patients' voices will be crucial when the issue of infertility has to be discussed with policy makers. It is necessary to have this kind of patient support network in India also in order to serve the best interests of the patients seeking infertility treatment.

f. The Role of Industry

It will be essential to convince industry of the value of infertility treatment in developing countries and to gain their support for Foundations and NGOs in this area of reproductive health. Apart from general support, the industry can make several relevant contributions. Providing cheap medication will be an important issue, as will be the manufacturing of basic ultrasound and laboratory equipment at low price. Industry has also become an important source of funding for clinical research and this source should be utilized in developing countries. As for all clinical research, ethics committees and review bodies are needed for the appropriate monitoring of studies.
The wish for a child is a basic need for all people. In developing countries, childlessness has important psychological, social and economic consequences as previously outlined. The question is not whether fertility care is ethically justified in resource-poor developing countries but whether we can propose the more widespread use of ART as a valuable strategy. In our view, reproductive autonomy and equity justify our efforts to make ART available and affordable worldwide subject to political stability and a basic level of medical infrastructure. This does not mean that fair access to scarce resources, non-malificence and treatment effectiveness are not equally important, of course.

Even if we succeed in implementing low-cost IVF, it remains however unlikely that treatment will become universally accessible. We may speculate that those who can afford treatment in low-resource settings are also able to raise a child in reasonable circumstances. In contrast, men and women living in extreme poverty cannot and should not access infertility treatment but require socio-political interventions, which improve their economical situation. Another controversial question is whether infertility treatment should be offered to HIV positive couples in countries with a high HIV-related mortality and morbidity. While the answer to this question is likely to centre on the availability of antiretroviral medication, all HIV-infected couples require in-depth counseling on the pregnancy-related risks as well as on different reproductive choices, including, where indicated and accessible, ART. Unilateral promotion of contraception contradicts the concept of reproductive autonomy. A cost-benefit analysis of simplified and affordable ART in developing countries does not exist and the subject is extremely difficult to study. The results will depend largely on the cost of the diagnostic procedures and the ART treatment itself.

Pilot studies are urgently needed to examine the precise cost of ART when the laboratory environment and equipment are available at minimal cost and when minimal stimulation protocols with cheap medication and minimal monitoring are used. The economic value of a newborn in developing countries has never been studied and will likely depend on the economic and demographic situation.

The infertility is a common reproductive health problem in developing countries, which frequently carries negative psychosocial implications. In many instances, infertility is caused by genital tract infections. This highlights the need for both
preventative health care measures and ART. New reproductive technologies can only be successfully introduced in developing countries if sociocultural and economic prerequisites are fulfilled and governments can be persuaded to support their introduction. We have to liaise with the relevant authorities to discuss the strengthening of infertility services, at the core of which lies the integration of infertility, contraceptive and maternal health services within public health-care structures.

Beyond this, the success and sustainability of ART in resource-low settings will depend to a large extent on our ability to optimize these techniques in terms of availability, affordability and effectiveness. It is our duty to give correct information to the governments, health-care providers and infertile couples to avoid the situation where couples would sacrifice everything they have or could borrow, for low-quality low success IVF. After a fascinating period of almost 30 years of IVF and 15 years of ICSI, only a small part of the world population benefits from these new technologies.

Time has come to give adequate attention to the issue of infertility in developing countries.

**The Scenario of ART in INDIA**

There has been much debate in the Indian medical community in the last ten years about whether there is any need for legislation in relation to the provision of ARTs. Undoubtedly, the law already has some influence in the way ART treatments are provided, to whom and on what terms. However, because of the relatively recent development of these technologies, the common law has had little opportunity to develop in this area. Accordingly, there is a great deal of uncertainty as to how the law may respond to disputes which arise in relation to ART, such as those involving the ownership and use of gametes and embryos. ART has been developed by the medical and scientific community primarily as a treatment for infertility. Thus, it is generally provided and, to some degree regulated, in the same manner as other medical treatments. However, like some other areas of recent scientific and medical technology, it has been argued that ART is in some way qualitatively different from other medical treatments. Rather than simply alleviating the medical condition of an individual through treatment which has consequences only to that individual, ART alleviates infertility by allowing for the birth of another person. Thus, the interests of
a third person (the child born as a result of the technology) are affected by the treatment. In some cases, ART is not used as a medical treatment for infertility at all, but as an alternative means of obtaining a pregnancy. Fertile persons who cannot, or do not wish to, for a variety of reasons, engage in coitus. The question arises as to whether ART is so qualitatively different from any other kind of medical practice that medical practitioners require a license from the State merely to carry out these treatments. India, like most of the developing countries, still lacks these essential services. Nevertheless, there is growing awareness for such needs and steps are being taken to achieve such objectives. For example, the National Board of Examinations, Ministry of Health and Family Welfare, Government of India has taken steps to offer postgraduate degrees in Reproductive Medicine. The National Academy of Medical Science has initiated discussion on what needs to be done to draw up guidelines for the ethical practice of medically assisted reproductive techniques and to offer suggestions for establishing a national Accreditation and Supervisory Body for Infertility Clinics. The desirability of constructive dialogue between regulators and regulated rather than the use of coercion and criminal sanctions. At current count, there are many “IVF clinics” in India mushrooming weekly!! The subcontinent has unfortunately witnessed unregulated and unsupervised growth of ART centers often serviced by untrained or poorly trained staff. A National weekly newsmagazine did an undercover investigation of IVF clinics (many run by quacks) and got into the "Laboratories" of some shady IVF centers which were booming with sex-pre selection advertisements in National newspapers—they photographed bare rooms with pigeons flying in and out through ventilator ducts!

On a scientific basis, there is no University-based ART teaching program and there is an obvious lack of training even in well-equipped centers. Most practitioners of infertility treatment are self-taught. Embryology and its attendant subjects, including gametogenesis, genetics, reproductive endocrinology, and other such related subjects, is hardly taught as a distinct discipline in any of the Indian colleges now days. The new term, "Clinical Embryologist," has been coined to include all those biologists (zoologists, microbiologists, biochemists, veterinarians, etc.) who assist the gynecologist in processing semen, screening follicular aspirates for selecting oocytes, inseminating them in vitro or by intracytoplasmic injection of spermatozoa (ICSI) and handing over the developing embryo to the attendant gynecologist. In some instances the gynecologist doubles up as the embryologist for want of trained staff.
There are no guidelines as yet; Mr. Prasad Rao, former Secretary to the Government of India, Ministry of Health and Family Welfare, released Draft Guidelines for the Accreditation, Regulation, and Supervision of Assisted Reproductive Technologies Clinics in India on September 4, 2002 at a public function held in New Delhi in the presence of the Director General of the Indian Council of Medical Research (ICMR) and the President of the National Academy of Medical Sciences (NAMS) (1). The Guidelines were prepared on the basis of several consultations and public debates held during the past two years. Professor R. G. Edwards participated in one of the early meetings where the need for national guidelines was discussed in Bangalore on November 4, 2000. Much more remains to be done in India with its pluralistic society. A national common law, acceptable to people belonging to different cultural and religious backgrounds, is yet to be established despite the long debates; personal laws still govern most Indians. The legal profession will have to be pressed to develop legal guidelines for the practice of ART to suit every Indian. All said and done, the altruism of Indian politics is that Indians want their politicians and regulators to stay out of the bedroom, but there maybe at least one good reason to legislate and regulate ARTs it could prevent the issue from being turned over completely to the lawyers.

The Present Research

For the field survey, a close-ended scheduled printed questionnaire was prepared and given to clinicians practicing ART in Mumbai city for ascertaining certain facts like popularity of treatments offered, number of years of practice, cost of treatment, prevalent legal practices and for forwarding suggestions whether legislation is necessary for regulating Assisted Reproductive Techniques in India.

It was difficult for the researcher to have access to these clinics as there is no registry for maintaining records of clinics practicing ART. The study aimed at studying 50 clinics. Given the limitations and nature of the study, only 36 doctors from clinics responded. Some assisted reproductive techniques like intra uterine insemination, artificial insemination with husband’s semen are commonly offered services to the patients. The data analysis throws insight into popularity of the treatment, cost of the treatment, prevalent legal practices, quality control for clinics, at par with international standards for services such as screening of donors, filling in consent forms, maintaining an equipped laboratory and service equipments. To ascertain the fact that whether legislation is necessary for regulating the practices of ART in India,
analysis of data is further presented by tables, designing graphs and pie charts in earlier part of this chapter.

Some techniques like IUI, AIH are practiced by KEM, Cama hospital and IRR. The government authorities in these hospitals refused to impart information on these techniques. In private clinics after several visits some doctors were kind enough to fill in the questionnaire. Information from the patients seeking infertility treatment could not be available because the doctors did not reveal the identity of the patients as it was ethically incorrect according to their procedures. Despite the researcher’s efforts to assure to maintain the secrecy and confidentiality of patients seeing the sensitive nature of the research, the doctors were not convinced and hence, the professional themselves acted as a hurdle in carrying out the research. Thus, the data from the IVF seeking patients was not collected. This also has an adverse affect on the recommendations as the patients themselves would have been a great resource in revealing what are their needs and where they face most of the problems, also telling us where the doctors may have had a lacuna in providing effective services. Moreover, by not allowing the researcher to talk to the patients, who are in fact the prime sources of information, we have shut ourselves from a part of data which would have otherwise been an integral part of the IVF policy recommendations and suggestions.

Often patients seeking such treatments feel guilty, ashamed and are not ready to respond at once to their experiences of being treated with IVF (personal communication, October 2009). This also indicates towards the dire need of research this area requires as it has adverse effect on the mental and emotional health of the individuals seeking IVF. However some questions still remained unanswered.

The few points in the draft guidelines that are being opposed tooth and nail by the ART fraternity in India are

(i) Disclosure of sperm donor’s identity to children conceived from donor insemination once they are adults.

(ii) Banning of egg donors from family and friends while encouraging commercial egg donation.

Indian society is relatively more conservative and third party reproduction is a taboo subject; cutting across all strata of society. Most of the donor egg IVF done today in India is with the help of family or friends or egg-sharers and we would not like to have the North American commercialization to creep into traditional Indian society
which would result in ART becoming even more expensive and out of reach of even the 10% populace in India that can afford it today.

This requires an informed and thoughtful response, not just from the scientists and clinicians who control the techniques and technologies but also from society and the law. Infertility and reproductive genetic risk are both increasing in our societies because of lifestyle, changes and various other factors. Owing to the magnitude of the problem they have implications not only at the individual and family level but also at the community level. The increasing application of genetics in reproductive medicine and vice versa requires closer collaboration between the two disciplines. ART and genetics are two evolving fields where new technologies are currently introduced without sufficient knowledge of their potential long term effects which need to be envisaged to make sure that the balance between benefit and risks is clearly on the benefit side.

Women who seek infertility treatment invariably receive blame regardless of causes. There is personal grief and frustration. They become targets of domestic violence and economic deprivation, ostracism and social stigma. Often male partners do not agree for basic investigations. Family, friends and health care providers must provide support for mental well being of infertile patients. Infertility programmes in developing countries can only be implemented and sustained if they are supported by local policy makers as well as the international community. A critical aspect of this process is funding, and this is likely to require input and collaboration from various role players.

Practitioners practicing ART support efforts taken towards safety standards, licensing and accreditation of clinics for improving safety standards while practicing ART but they are also concerned about the limitations such restrictions might introduce. While being in favor of guidelines that will protect patients, medical associations also have some concerns. The new ICMR guidelines must not be so cumbersome or expensive that they inhibit research or increase the cost of treatment—an especially important consideration because these treatments are still not covered by insurance. The issue of infertility should be looked upon by the government as socio economic issue. No doubt with huge population in India the Indian government has always advocated and adopted the family planning programmes but the apathy of childless couples cannot be ignored. People
irrespective of caste, creed, religion, rich or poor have the right to have biological offspring. It is the responsibility of the government that the interests of the patients seeking infertility treatment should be protected. Government, NGOs, public to come forward for having ART set up where treatment will be provided to lower strata of society. However infertility as such cannot be cured and for those couples who seek infertility treatments have to undergo through a hefty medical procedures which are expensive and time consuming in nature. Infertility treatment may further lead to technical problems for e.g. trauma and penetration of pelvic structures, anesthetic hazards, ovarian hyper stimulation, multiple pregnancy and ovarian cancer in the long run. Therefore, often success rate is low. Thus, as another option to the IVF patients, adoption should be encouraged by government and by social groups to the common masses. There should be uniform adoption laws with simple procedures to be legislated by the government so that common man can have access to child.

*Standard practices to be adopted by medical practitioners for the benefit of couples as recommended by National and International Medical Standards.*

1. In couples with documented infertility, it is a standard practice to explore the aetiology of their infertility for more information of the couple, particularly since it may have implications for treatment and genetic risks to the offspring. Based on the medical, family and reproductive histories, appropriate counseling should be offered and genetic testing should be implemented when indicated.

2. Couples should obtain evidence based information on the techniques and their implications as well as birth rates in that clinic in a standardized way. It is recommended that the performance of infertility clinic through clinical pregnancy rate per oocyte retrieval and through delivery rate per oocyte retrieval and the percentage of singletons should be presented.

3. Although the autonomy of couples should be respected, professionals have a duty to convey a wide perspective preserving the child’s interest.

4. Family and reproductive histories of female and male donors should be obtained and genetic tests should be performed only according to the family history or standard testing practices in the population or ethnic group from which the donor or recipient originates.
5. Any selection of donors should be evidence based. Donors should not be excluded because of heterozygosity for an autosomal recessive disease because they can be matched with suitable recipients.

6. In families with inheritable disorder, prenatal diagnosis should be offered as an alternative. Appropriate genetic work up is needed in PGD to ensure that a correct diagnosis has been established. All couples at high genetic risk due to structural chromosomal abnormalities or monogenic diseases and seeking PGD should first see a clinical geneticist or genetic counselor who will discuss with them the use of PGD for their particular disorder, then a clinical fertility specialist who will evaluate the couples as for routine IVF and discuss with them the different options, and explain the burden, invasiveness limited success rate and cost and unknown risks for those involved. PGD has to be considered in the context of all possible options, and the pros and cons have to be appropriately balanced.

7. Both pre PGD counseling and post counseling should be performed in a proper genetic counseling setting. Referral to a psychologist should be made when needed in the pre test period as well as in the post test period. PGD should be performed only if couples agree to know the results and accept all the implications of the test. If social sexing is to be considered, it should be limited to family balancing. Equal respect for both genders should be guaranteed.

8. There is evidence that pre implantation genetic screening has the potential to increase the pregnancy rate and to reduce the abortion rate by detection of number of chromosomal anomalies. However, randomized controlled trials are needed to establish the usefulness of this approach and to define the potential indications. If PGD is proposed, counseling should include information on the uncertainties of the indications and benefits of the procedure. Counseling should be given by trained fertility professionals.

**Research and Development**

Prior to introduction of new procedures, every attempt should be made to test the methods pre clinically on in vitro models and animals. It is recommended that new technologies and new practices be introduced as clinical research projects. This implies that protocols are in place, that they have received ethics approval that the data are collected in a way which will allow for rapid conclusion on the safety and efficacy of new technology or protocol that couples are informed that they are offered a technology / protocol not yet fully validated. Research on safety and efficacy can
only progress if large sets of data are collected in a standardized way. Large prospective collaborative multi centre efforts as well as cohort studies are strongly recommended to assess the long term effects and the possible trans generational effects. At present there is a conflict on one hand between the need for research on safety aspects and on the other hand the need to minimize the research on embryos. Attempts to resolve this conflict should be encouraged. Ethical, social legal and psychological research in this field is needed.

**Organization of Services**

- Availability and accessibility to ART services should be equal in India, which is not currently the case. Couples in need of this treatment are increasingly choosing to cross national borders, which may not provide conditions for treatment due to quality, language and economical issues. Shared protocols and counseling and laboratory protocols should be introduced to guarantee the quality of treatment in such cases.
- Any person involved in reproductive or genetic counseling has to have appropriate training.
- Although ART is considered to be of low priority in many countries, there are situations that should have high priority, like genetic fertility of young couples, and medical need of PGD. Appropriate funding is needed to treat such cases.
- Networking of PGD should be encouraged, especially in cases of very rare diseases.
- To improve free informed choice, it is strongly recommended that evidence based information leaflet be developed in style understandable for vast majority and to make them widely available on any appropriate support.
- Non medical use of ART has a much lower priority. Implications have to be clearly evaluated before being accepted and should respect human dignity.
- Multidisciplinary teams are needed to manage the multiple facets of this field.

There must be licensing and accreditation of clinics for supervision and regulation of clinics practicing ART in India. The reasons are -
- Licensing and quality assurance of services should be put in place to meet the expectations of consumers for reliable services.
• Quality standards have to be defined at European and at national level, including both laboratory procedures and other elements of care including counseling.
• It ensures that only persons who hold appropriate qualifications are able to gain a license and hence practice ART.
• It allows for the imposition of sanctions, such as the cancellation or suspension of a license, in cases of misconduct; it allows for the imposition of conditions upon the practice of ART (such as the keeping of records, the approval of research).
• It allows the Government to raise revenue for the purposes of regulating ART through the imposition of license fees. How a society regulates ART depends on cultural context.
• The challenge for the regulatory regime is to balance protection for patients and society with freedom for medico scientific creativity neither an exclusively market-regulated nor a peer-regulated approach is realistic politically, or desirable socially, ethically, and legally. Legitimate social issues that go beyond the exclusive expertise of doctors and scientists or market choice by patients need to be accommodated within the regulatory regime. Within this context, four key issues need to be thought of:
  • The lack of a shared social ethic that helps the needs of the community to be balanced against those of its individual members.
  • The negative impact of intrusive external regulation on scientists and doctors; the requirement for doctors and scientists to review their professional structures reflectively and critically if they are to be entrusted with peer-regulation.
  • The desirability of constructive dialogue between regulators and regulated rather than the use of coercion and criminal sanction.

The Guidelines released by the Government of India addresses the following issues.
  a. Ensuring the ethical practice of assisted reproductive technology.
  b. Maintain a national registry of all assisted reproductive technology clinics
  c. Accredit and license assisted reproductive technology clinics
  d. Supervise performance of assisted reproductive technology clinics regularly regulate functioning of assisted reproductive technology clinics and take punitive action against erring clinics.
e. Make assisted reproductive technology affordable to the economically weak
f. Draw up guidelines for the use of spare embryos
g. Support training and research in assisted reproductive technology.

There is a unique responsibility on the part of the physicians and scientists working in this area and even important considerations for society. Accreditation, regulation, and supervision of assisted reproductive technology clinics are not unique to the Indian situation; other countries have already trodden this path. However, there are two main alternative approaches to the problem reproductive technology practitioners.

Treatment should be provided to low income group.

In India, ethical and legal concerns that needs addressing are -

1. An important issue in the practice of ART in India is who should be the donor of semen for AID. The fact is that vast majority of population in India today still lives as a part of larger joint family.

2. The second major issues that the ART clinics in India are facing today pertain to donation of oocytes who should be an oocyte donor. As of today, in India it is almost always the close relative from the side of the man or the woman.

3. We need to have sperm banks that would also keep track (for example through appropriate advertisement) of possible oocyte donors against monetary compensation or egg sharing system should be encouraged in which an indigent infertile couple requiring financial help for ART treatment would agree to donate oocyte to rich affluent couple, wherein the wife can carry the pregnancy through but cannot produce her own oocyte, for in vitro fertilization with the sperm of the male partner of the affluent couple, for monetary compensation that would take care of the expenses of an ART procedure of the indigent couple.

4. The practice of surrogacy - Who can act as a surrogate mother - familial surrogacy or any other lady? The upper and lower age limit for germ cell donation or for surrogacy and number of times one can act as surrogate mother.

5. Then there is the question of the right of a child born through donation of a germ cell, to know who is the biological father or mother is, when the child attains adulthood assuming the sperm or egg donation has been anonymous. In Indian environment, it is impractical and unethical to give the right to the child, to the donor and to the couple who has brought up the child. (However the child has the right to know everything except the name and address of the person who donated the oocyte or the sperm).
6. The question as to what should be done by infertility clinics with spare embryos which would be the main source of totipotent embryonic stem cells. As of today there is no regulation in the country as to what should be done with such embryos. Ultimately under surrogacy contracts surrogates are exploited. In order to protect the interests of surrogate mothers the following suggestions should be taken into account.

- Surrogacy is a morally acceptable method of assisted reproduction of last resort.
  The last problematic indication is the absence of the uterus regardless of etiology. Other indication may include serious health risks and uncertainties for all parties involved; reluctance regarding the broadening of relative indication, is advisable.
- Payment of services is unacceptable only reimbursement of reasonable expenses and compensation for loss of actual income should be considered.
- All parties involved should be counseled and screened separately by independent specialists.
- The surrogate should be aged below the age of 35 years for partial surrogacy and less than 45 years for full surrogacy. In order to ensure free and well considered decision making by the surrogate / gestating woman, it is required that the woman has at least one child.
- A ‘cooling off period’ is recommended so that only one embryo should be replaced in order to prevent multiple pregnancies and to avoid unnecessary endangerment of the surrogate’s and the future child’s health. For special conditions, the replacement of a maximum of two embryos can be considered.
- Long – term – up follow up studies both of the resulting family and of the family of the gestating woman should be conducted, especially to gain insight in the psychological impact of the agreement on the (children).

The commissioning parents should be well aware that the surrogate has the legal right to make the decision about her pregnancy against her will and against the original agreement. The concept of surrogacy is well known and surrogacy is practiced in different communities throughout the world.

A surrogate mother carrying a child biologically unrelated to her must register as a patient in her own name. The birth certificate shall be in the name of the genetic parents and the surrogate mother.
The clinic should provide certificate to the genetic parents giving the name and address of the surrogate mother.

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. The child born through surrogacy would need to be legally adopted by the couple who has sought surrogacy. The birth certificate should show the couples as the legal parents and a provision could be made in the birth certificate stating the name of the surrogate mother as a mother. The ART clinic must not be a party to any commercial element in donor programmes or in gestational surrogacy. 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.

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.

**Medical Negligence and Accountability of Doctors practicing ART**

- 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 Protection Act and law of torts.

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iv Regulation of ART Clinics in India—Draft. New Delhi, India, National Academy of Medical Sciences (India), 2002, 92 pp.

v Rowland R; Living Laboratories ;women and reproductive technologies; Bloomington, Indiana University Press; (1992)
9.4. Latest Developments in the Field of Assisted Reproductive Techniques

Assisted Reproduction is one of the scientific disciplines has evolved faster in the last years. The main reason of the success offer by ART is the association of different research areas both medical and biological. The achievements allow couples to get the right of being parents. Today, we can say that assisted reproductive technologies (ART) have produced a dramatic change in social behavior, allowing pregnancy in non physiological conditions e.g. post menopauses ages, choosing the baby sex for religious, social or simple private reasons, delaying the motherhood age, stopping the inherited disease's transmission and also opening the possibilities for other familiar status: mono-parental families, lesbians couples, uterine subrogation, etc. Since the nature of research is exploratory, the researcher has attempted to incorporate the recent/current scientific developments in the field of Assisted Reproductive Technologies.

ART represents an emerging and dynamic biomedical market that stretches around the globe and encompasses hundreds of thousands of people. The fertility trade is in some ways analogous to the markets for personal computers, which were initially considered luxury items but migrated to the mass market. However, the introduction of property rights, rules, and institutional policies is making the marketplace more sensitive to the social, medical, and ethical issues that are emerging from the science. Owing this reasons, since beginning, assisted reproductive techniques were furiously criticised, and they were a matter of religious, political, sociological and economical concerts. IVF, initially indicated for the treatment of fallopian tube's pathology, is now the first line therapy, and almost ever the only one, for severe male factor, severe endometriosis, idiopathic long duration sterility, immunological sterility and some ovulatory disorders, and is currently considered as the most valuable tool for the treatment of such medical conditions.

The latest developments are;

1. The pregnancy rates are growing step by step since his beginnings and now are hundreds of medical teams around the world giving baby home rates 50% above in many cases with low multiple order pregnancy, a common complication in all the ART involving ovarian stimulation.
2. In fact, research is currently focusing on methods to improve IVF success rates while reducing twin and triplet pregnancies and their associated increased morbidity and mortality.

3. Development in field of assisted reproductive techniques and molecular biology techniques, such as polymerase chain reaction (PCR), fluorescent in situ hybridization (FISH), multiple displacement amplification (MDA) and others. PGD is a recently introduced technique, in the ART, involving screening for genetic and chromosomal disorders in the embryo prior to the transfer. Although PGD was offered initially to couples at risk, the scope of PGD has also been extended to infertile couples for recurrent IVF failure, repeated spontaneous abortions, advanced maternal age and extreme male factor.

4. Screening methods to identify the most viable embryos include optimizing culture conditions for prolonged culture and selection of a high quality blastocyst for transfer. The detection of molecular markers of embryonic viability in the culture medium, like the soluble human leukocyte antigen G, is another area of investigation towards the single embryo transfer.

5. The application of social sex selection uses the same technology as that used in the PGD for sex-linked diseases and has raised significant ethical issues. In some countries, "family balancing" is allowed. Moreover, the provision of "saviour" siblings by PGD has aroused fierce controversy. PCR protocols are used to provide an HLA type for each embryo, with the intention of matching an embryo to the sick child in the family.

6. This embryo is then transferred in the hope of establishing a pregnancy; hence, having stored cord blood stem cells and potentially bone marrow as material for treating the older sibling.

7. Micromanipulation techniques are now an integral part of an IVF laboratory and are now employed in the oocyte/embryo to perform assisted hatching, surgical methods to remove fragments or cytoplasm transfer. Micromanipulation has also been used in the development of nuclear transfer technique, a potential solution for creating "younger" oocytes for women of advanced maternal age and spermatozoa for azoospermic men.
8. However, the most relevant thing is the possibility of ending the transmission of hereditary diseases (Preimplantation Genetic Diagnosis, PGD) as results of combination of polar body/blastomere biopsy.

9. PGD cycles have allowed the possibility, with appropriate consent, for the creation of stem cell lines. These cell lines will provide an invaluable in vitro resource for studying the development and etiology of the phenotype arising from these single gene defects and chromosome abnormalities.

10. Beside scientific or technological aspects, Quality Management System is of great importance. Staff development and monitoring of staff performance in the IVF laboratory has to be considered in the next future.

11. Finally, the use of friendly drugs regimens, the ultrasound guide ovarian pick up and the drop of financial burden are changing the patient's point of view from an experimental approach as at the 80's was seen, to an accepted, well considered and safe treatment. Life cells powered by laboratory chemicals.

12. Dr Craig Venter and scientists of 'J Craig Venter Institute' for the first time have assembled full genetic code from laboratory chemicals and used it to create living organism. They did it by transplanting their synthetic DNA into the empty husk of microbe and watching it come to life. Venter's team maps entire genome of a common bacterium, Mycoplasma mycoides. This information is fed into a DNA synthesizer, which produces short strands of bacteria's DNA from 4 bottles of chemicals. The DNA strands are inserted into yeast and E coli bacteria. As a natural response, this bacterium stitches the strands together into longer DNA. This process is repeated till all letters of mycoplasm bacterium's genome are pieced together. Scientists had inserted 'biological water marks' at various places to distinguish. These are junk genes but carry messages which make sense to humans once decoded.

13. Finally, the synthetic genome is transferred into other bacteria. The bacteria multiply and some of its offspring carry only the lab made genome. (These bacteria are not clones of genetically modified organisms. They are 'synthetic bugs' which survive and reproduce entirely due to genome made by humans).
This research enables scientists to understand the manner in which a cell works as essential genes are required to making a functional cell. Synthetic biology and metabolic engineering which is in its basic stages will eventually help scientists to harness beneficial features from microorganisms that are otherwise intractable, thus allowing scientists to create a designer bacterium and cells that have pathways built in to make bio-fuels, antimicrobial compounds and vaccines.

**Recent challenges in Assisted Reproductive Technology**

- The growing international bias against surrogacy, particularly homosexual couples having and raising children could have a visible impact on India’s booming surrogacy industry. Whether adoptive parents are gay or straight experts feel that sporadic controversies like the case of Baby Manji from Japan, twins of Jan Balaz from Germany and Israel’s Dan Goldberg could impact medical tourism in short term. Israeli citizen Dan Goldberg had to delay his return home with his newborn after an Israeli Court declined to grant permission for a paternity test, vital for the child to get citizenship. The Indian Council of Medical Research (ICMR) does not maintain statistics of couples visiting India for IVF surrogacy, India being one among the cheapest centre for surrogacy, most couples opting for it are foreigners.

- A recent report carried by this newspaper on surrogacy agencies sourcing poor women from the slums of Mumbai also had a ripple effect. A gay rights’ group in Australia expressed shock at this practice, questioning the Bhandup clinic it has been recommending to its members. Incidentally the Australian Government is contemplating a ban on commercial surrogacy from India.

- Several nations are also witnessing a moral churning of sorts as far as the gestation of their future generations is concerned. Germany, Norway, Spain, Japan, France, Hungary and Saudi Arabia, either do not recognize surrogacy or are not amenable to the idea of gay couples raising babies.

- German freelance writer Jan Balaz’s twin boys have turned tow in Jaipur as they wait for that country to process their entry. Their grand mother has come to live in India while Jan’s wife visits now and then.
• After a two year legal battle, German couple Jan Balaz and Susan Anna Lohlad will now be in a position to take their surrogate sons Nikolas and Leonard home. German authorities who had refused visas to them on the grounds that state laws did not recognize surrogacy, agreed to provide necessary travel documents after the couple went through an inter country adoption process. The Indian government had refused the twins Indian citizenship, as they were surrogate children, agreed to give them exit permit. Solicitor General Gopal Subramaniam informed the Supreme Court on Wednesday.

• The Israeli Government has granted passports to the twin sons of Israeli gay father Dan Goldberg who were born of an Indian surrogate mother.

• The Draft bill on ‘Assisted Reproductive Technology Bill’ prepared by a 12 member committee headed by Dr P M Bhargava under the Indian Council of Medical Research which was submitted to the health ministry recently, clearly states that though gay and lesbian relations are legalized in India, gay couples would not be allowed to have children through a surrogate. According to Dr R S Sharma (member of panel which drafted the bill), under present laws, the definition of a couple is “persons living together and having a sexual relation that is legal in India”. The draft bill also says foreigners or outsiders coming to India to rent a womb will have to submit two documents – one confirming that their country of residence recognizes surrogacy as legal and second, it will give citizenship to the child through the agreement of an Indian mother.

• Foreign couples should identify a local guardian to take care of the surrogate mother during the gestation period till the child is handed over to the parents. However, if the foreign couple fail to take delivery of child born within one month of the child’s birth the surrogate mother will be legally obliged to hand over the child to an adoption agency.

• Shobhana Chavada 47 years, is all set to give her daughter Bhavika 26 years, the biggest gift of her lifetime – the birth of her triplet children. Shobhana has lent her womb to her daughter Bhavika. This unique kind of surrogacy was facilitated by Dr Purnaima Nadkarni of Surat.
- After the anguish of Israeli gay father in May, a French gay father is now similarly stranded with twins in Mumbai after their birth. However, since surrogacy is not legally accepted in France, the father now faces prosecution or losing his newborns altogether if he returns home. His desire to have a family with his partner of 14 years was finally realized when his twin boys were delivered at Hiranandani Hospital, Powai. He then took the birth certificates which the hospital gave him to the French consulate and asked for the names to be transferred to the French birth registry, a move that is necessary to get his newborns French passport. The embassy, however, yet to decide if the names are to be transferred as France does not approve of surrogacy, either commercial or altruistic. The French father of the stateless surrogate twins born in Mumbai is hoping that his government will take a sympathetic approach and allow his children French passport. Paul Augustine further informed that the Centre for Human Reproduction in Bandra failed to inform him about the problems faced by gay couples while returning home.

- **Women Freezing Eggs to wait for 'Mr Right' Technique Gives future Relationships Time to Bloom**

  Increasing number of women in their 30s and 40s are freezing their eggs as they continue their search for “Mr. Right”, say British doctors. This trend was brought to light by a study of women who had applied to have their eggs frozen at a Belgium clinic between July 2009 – May 2010. Highly educated and financially secured these women in their late 30s and early 40s and considered adoption or single motherhood before plumping to spend hundreds of pounds on IVF and egg vitrification and freezing. They told their doctors that they wanted to “take pressure of the search for the right partner” and “give future relationship more time” before bringing up the subject of kids. “Julie Nekkebroeck”, from the Centre for Reproductive Medicines at the University of Brussels, who headed this study further, informed that by preserving their eggs these women wanted to find right partner and to do everything to prevent age related infertility. Moreover, frozen eggs were considered precious goods, since even if they would meet Mr Right in the near future, they would use frozen oocytes in the last instance, after trying to conceive naturally.
www.e Magazine BIO forum.com (referred on 30th May 2010)

ii Experiment just genetic engineering ‘Times of India’ (22nd May 2010).

iii Bella Jaisinghani | TNN, Surrogacy Rows may hit Indian Centers. (11th May 2010).


iv Dhananjay Mahaputra | TNN “Germany relents to grant visas to German twins

v Vijaysingh Paramar | TNN “Mother carries triplets for daughter..(24th May 2010).

vi Sumitra Deb Roy | TNN “French gay surrogate dad in legal limbo” (9th June 2010)

vii The Times of India Mumbai Wednesday, June 30, 2010