Assisted Reproductive Technology in India: A Need to Regulate

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Abstract

Surrogacy is an ancient practice and may be defined as one woman-referred to as the mother-having intercourse or medical treatment in order to achieve pregnancy for the purpose of another woman. In the later decade of the twentieth century, though, surrogacy underwent a significant revival. In the past, the only way for surrogate mothers to produce children was to engage in sexual relations with the prospective father. With artificial insemination however, conception was removed from sex, making it possible for a man to impregnate a surrogate without sexual intercourse. Artificial insemination also made surrogacy more feasible, allowing infertile couples to procure sperm and eggs outside. Commercial surrogacy is questionable because it defines a baby as a commodity, up for sale at the prevailing market price. Surrogacy, is the most controversial issue in ART, because, both the sperm and egg donors are paid, and surrogates may receive a considerable amount. Defenders of surrogacy deny that it constitutes baby-selling, claiming instead that a surrogate is simply relinquishing her right as a parent to have a relationship with the child. The payment should be seen as justification for the risks, sacrifice, and discomfort the surrogate undergoes during pregnancy. The ART guideline in India contains specific provision relating to surrogacy.This paper is an analysis of the risks related to surrogacy in India in general and legal, ethical and health related risks in particular. The paper aims to advocate for protection of Human Rights of surrogate mother at national as well as international level.

Introduction

Although the birth of Louise Brown, world's first test-tube baby, was England's singular achievement, Assisted Reproductive Technology (ART) is now a fast growing global industry. Advances in scientific facilitation of conception offer infertile couples and individuals a lot of options, ranging from the low-tech process of artificial insemination (AI) to the more complex high- cost process of *in vitro fertilization* (IVF) and surrogacy. The growing industry of fertility-enhancing therapeutics has led the development of markets in gametes, surrogates, and advanced clinical techniques. There are social, scientific, and commercial components associated with ART, and, as a result, there are a wide variety of players involved in the practice of ART, including clinics, hospitals, and related facilities; egg and sperm donors and surrogates; intended parents; and attorneys. This development and use of human reproductive technologies is continuously raising a range of complex and profound social, legal and ethical issues: now the question is how should we react toward these developing markets? Do we appreciate our growing power over the "natural" processes of reproduction, or fear its hubris? Do we seek to expand every individual's capacity to achieve biological parenthood, or view reproductive potential as appropriately bounded? What role should the state play in providing individuals and families with access to reproductive technologies? What criteria should be used to determine

who deserves to have medically assisted reproduction? What restrictions should be placed on ARTs? Definitely these are some questions which cannot be answered in isolation. The law always plays an important role to determine the role of state, public or private agencies and individual also. This paper will try to find out the more specific answers to these questions through analyzing the legal provisions at national and international level.

History of Regulation

Six years after the first test tube baby was born in the UK in 1978, the Indian government established an IVF project within its contraceptive research establishment, at the Institute for Research in Reproduction (now national Institute for Research in Reproduction or NIRR) in Mumbai. NIRR is an institution of the Indian Council for Medical Research. In August 1984, the NIRR set up an IVF programme in collaboration with the King Edward Memorial Hospital, a tertiary care center of the Bombay Municipal Corporation. The technology-essentially replicating a procedure established in the West-was tested on poor women seeking infertility services in this government hospital. The world's first IVF baby, Louise Brown, was born on July 25, 1978, in the UK through the efforts of Dr. Robert G Edwards and Dr. Patrick Steptoe. The world's second and India's first IVF baby, Kanupriya, alias Durga, was born 67 days later on October 3, 1978, through the efforts of Dr. Subhas Mukherjee and his two colleagues in Kolkata. The techniques used by Mukherjee were markedly different from those used by Edwards and Steptoe. Mukherjee was the first person in the world to use (a) gonadotropins for ovarian stimulation prior to ovum pick-up in an IVF treatment cycle; (b) the transvaginal route by colpotomy for harvesting oocytes; and (c) freezing and thawing of human embryos before transferring them into the uterus that led to the successful birth of Durga. 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). This work was executed after being approved by the Scientific Advisory Committee of the ICMR's Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of the KEM Hospital. Births of IVF babies were reported subsequently during the same year by two other clinics in India. There are an estimated 250 IVF clinics in India today.[1]

On August 6, 1986, the first documented "test tube" baby in India was born to the wife of a municipal employee.[2] Since then, its slow expansion has been a gradual but steadily increasing phenomenon. ICMR supported National Institute of Reproductive Research to take up ART research and later to bring it in the Family Welfare Programme and tertiary care service institutions in the Ninth Five year Plan. The ICPD declaration at Cairo on reproductive rights and choices emphasized expanding the scope of reproductive health and thus promoted ARTs in

[1] National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, Indian Council of Medical Research National Academy of Medical Sciences (India), New Delhi, 2005at 4

[2] Sandhya srinivasan, Making babies: Birth markets and assisted reproductive technologies in India, Zubaan, New Delhi,2010, at xvi

the name of women's choices and rights.[3] Finally, India's Ninth Five Year Plan introduced management of sterility in its comprehensive RCH Programme but not in the "Essential" package of RCH. It was said that given an estimate of 5-10 percent sterility, it is essential that couples who do not have children get access to essential clinical examination, investigation, management and counseling. It was proposed that while the expertise would be made available at the tertiary hospitals, basic services to detect causes and carry out preliminary investigations like sperm count, diagnostic curettage, and tubal patency tests will be done at the CHC to screen cases and refer them to appropriate institutions. ICMR guidelines also mention that the scope of providing infertility services in the public sector needs to be explored. It is interesting that, while the Five year Plans committed to ARTs, the National Public Health Standards evolved for CHC under the NRHM did not included the simple test facilities. This commitment was repeated almost verbatim in the Tenth Five Year Plan yet, the Broad framework for Implementation of the NRHM, while enumerating guaranteed services, talked only of treating RTI and ignored the simple tests for infertility at the CHC level. Thus, in the public sector these services are confined to the tertiary sector and therefore not accessible to the majority. We see then, that ARTs are a part of the glamour technologies projected by India to establish its international standards. It is however confined primarily to the private sector and tertiary public sector institutions accessible to a select few. The basic services have no strategy to deal with infertility. The intent of this neglect can be gauged only when we examine the prevalence of infertility and its causes.[4]

Need for Regulation

The idea of the government restricting what scientists can or cannot research, or what treatment a doctor can offer a patient, are seen in some countries as improper government interference. Nevertheless the U.K's regulation of this area is well established and is regarded by many countries in the world as a model system.[5] The advantage of regulation is that it provides a flexible approach to this controversial area. In 1982, four years after birth of Louise Brown the committee into Human Fertilization and Embryology chaired by Mary Warnock was commissioned to make recommendation on the regulation of fertility treatment and embryo research. Its report was published in 1984 and although it was debated in the House of Commons shortly afterward, the Human Fertilization and Embryology Bill, which was based upon Warnock Committee recommendations, was not introduced to parliament until 1989. The Act covers three main activities: any fertility treatment that involves the use of donated eggs or sperm (for example, donor insemination) or embryos created outside the body (IVF – in vitro fertilization); the storage of eggs, sperm and embryos; and research on early human embryos. The Human Fertilization and Embryology Authority (HFEA) was created under the Act to oversee the licensing and compliance of treatment clinics and research centers in the UK, and to keep under review all new developments in the field. The Act provides a legal framework for

[3] Imrana Qadeer, p.14
[4] Imrana Qadeer, p.15
[5] Jonathan Herring, Medical Law and Ethics,3rd edition 2010 at P. 354.

everyone involved in fertility treatments. It defines the rights of donors, patients and the children who may result from the treatment. There has been a much debate in the Indian medical community in the last 10 years about whether there is any need for legislation in relation to the provisions of ARTs. 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 of gametes and embryos. ART is quite different from other medical treatments because the process involves the formation of a family and of course the interest of child born through this complex process.

Children created through ART now have the option of at least eight different "parents" : two intending parents; a sperm provider (with a partner); an egg provider(with a partner); and a surrogate (who may have a partner) who carries the egg.[6] There are many other Martine Johnson has listed the parties whose interests regulation needs to protect: i) the embryo in vitro ii) children deriving from these embryos iii) patients (especially women, but also partners, donors, surrogates), iv) society (the public interest), v) the health team (doctors, counsellers, nurses, biomedical scientists). Johnson is concerned that the interest of the embryo has come to dominant the issue of regulation, without proper thought being given to what regulation is seeking to achieve and how the different interest can be balanced.[7]

ICMR submitted the country's first national guidelines for accreditation, supervision and regulation of Assisted Reproductive Technology (ART) to the Union Ministry of Health and Family Welfare. These important guidelines will now form the foundation of any legislation to be introduced by the Government and provide standardized "treatment". The guidelines submitted by ICMR deal with areas including minimal requirement for opening an ART clinic, essential qualifications of the ART team and ART procedures that have to been followed in a three-tier prescribed system. The guideline also deals with the screening of patients for ART, patient selection and categories of infertility care units that they should be referred to.[8] A section has been dedicated to the code of practice, ethical considerations and legal issues which includes responsibilities of the clinic, information and counseling provided to the patient, requirement for sperm donors, oocyte donor and surrogate mother. Important sections that the guidelines has addressed in the submitted document are legitimacy of the child born through ART, adultery in case of ART, rights of an unmarried woman to artificial insemination with donor semen and posthumous artificial insemination with husband's semen through a sperm bank.

After the ICMR guideline and on the law commission report in 2009, Indian Parliament proposed to pass a bill known as ART (Regulation) Bill, 2010. It is still pending. The bill contains 50 Sections which divided in nine chapters. The bill seeks to regulate the Assisted Reproductive Technology as well as practice of surrogacy. On the whole, it is well written and avoids some of the pitfalls of the ICMR guidelines on the same question.

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[6] Naomi R. Cahn, Test Tube Families: why the fertility market needs legal regulation, 2009, New York and London, New York University Press. P.17.
[7] Supra note 27.
[8] Bindu Shajan Perappadan, Guideline for ART, The Hindu, Online Edition 17 Feb.2005.

Scheme of the *Draft Assisted Reproductive Technology Bill & Rules 2010*

The *Draft Assisted Reproductive Technology Bill & Rules 2010* has divided into two sections- Bill and Rules. The nine chapters covered under the Bill include details on various aspects of the regulation of ART clinics, semen banks and research on embryos. In chapter I-III dealing with Registration and Regulatory Authorities, the Bill proposes that a National Advisory Board be set up to recommend modifications in the regulations regarding permissible ARTs, the minimum physical infrastructure of the ART clinics, guidelines for counseling, research on human embryos, and other policies on assisted reproduction. Moreover, all states are to establish State Boards, who may advice the state government to constitute a Registration Authority, monitor its functioning and hold enquiries. Chapter IV mentions the duties of an assisted reproductive technology clinic, which include general duties, the duty to obtain written consent and maintain accurate records, duties for clinics using gametes and embryos, and duties regarding pre implantation genetic diagnosis and sex selection. Chapter V deals with sourcing, storage and handling of gametes and embryos, records to be maintained by semen banks, and restrictions on sale of gametes, zygotes and embryos. Chapter VI mentions regulation of research on embryos, gametes, or other human reproductive material sourcing. Chapter VII elaborates on rights and duties of patients, donors, surrogates and determination of the status of the child, the right of the child to information about donors and surrogate mothers. Chapter VIII mentions offences and penalties and chapter IX covers certain miscellaneous provisions. The Bill is followed by the Rules, which seek to provide an explanatory background on the various clauses of the Bill.

The Assisted Reproductive Technology (Regulation) Bill 2008/2010 provides a national framework for married and unmarried couples and single parents seeking surrogacy in India. It also aims to regulate and supervise the Assisted Reproductive Technology procedure happening throughout the country. It will also mean that surrogate mothers will have to enter into a contract with the couple seeking surrogacy. The bill also recommends setting up State Boards and a National Advisory Board that will exercise the powers and duties conferred on them by the legislation. The ART bill also provides special guidelines for foreign nationals seeking surrogacy in India. The bill allows individuals and unmarried couples to avail of this way to have children. There is also a provision that conception by surrogacy shall not be considered by any clinic if it would normally be possible to carry a baby to term. There is also a restriction on ART clinics from providing any information 'about surrogate mothers or potential surrogate mothers to any person'. Parties seeking a surrogate mother thus have to either advertise or approach middlemen. The gay couples would have to adopt a child post-birth as there is no provision in the act for a gay couple to have a child. The example is of heterosexual couples who adopt children when one of the genetic parents happens to be an external donor. This bill does not seek to change that arrangement. It is clarify that while this arrangement will continue to hold for gay couples, the situation will change for heterosexual couples (both married and unmarried) should this bill pass to become law. Under S. 32(2), informed consent is mandatory for both partners (in case of a married or unmarried couple); S.35(1) and 35(2) would automatically render the child the

legitimate child of both parties. The bill also calls for the formation of both national and state advisory boards composed of Health Department workers, industry representatives, scientists, and other civil society members (including those from the human rights community). These boards are charged with operationalizing and enforcing the many guidelines enumerated in the bill.

Provisions for International Surrogacy

- India is emerging as a leader in international surrogacy and a destination in surrogacy-related fertility tourism. Indian surrogates have been increasingly popular with fertile couples in industrialized nations because of the relatively low cost. Indian clinics are at the same time becoming more competitive, not just in the pricing, but in the hiring and retention of Indian females as surrogates. Surrogacy in India is relatively low cost and the legal environment is favorable. In 2008, the Supreme Court of India in the Manji's case (Japanese Baby) has held that commercial surrogacy is permitted in India. That has again increased the international confidence in going in for surrogacy in India. The ART (Regulation) Bill 2010 provides the following guidelines for foreign couples or individuals or non-resident Indian couples or individuals entering in surrogacy agreements in India: Foreign or non-resident Indian couples or individuals must nominate a local guardian, who is legally responsible for taking care of the surrogate mother during the gestation and after delivery, until the child is delivered to the couple or the guardian. However, if the foreign couple does not take the delivery of the child within one month of its birth, the local guardian and surrogate mother are required to hand over the child to an adoption agency. This will entitle the baby to Indian citizenship.
- Foreign nationals must provide legal documentation to the ART clinic proving that the surrogate baby will be taken to the couple's home country after delivery. They must submit two certificates: one stating their home country's policy on surrogacy and the second stating that the child will be automatically given the couple's home country citizenship.
- Foreigners may have to register with their Embassy or High Commission in India (it is unclear as to the acceptance of this by those bodies) and provide signed and notarised agreement to the terms laid out by Indian ART legislation.
- Like others, foreign couples also have to bear the expenses, including those of insurance, related to the pregnancy of the surrogate, during the gestation and after delivery. This is applicable until the time the child is delivered to the foreign couple. Such proposals have been influenced by the few high profile legal battles that were a consequence of surrogate children born in India to foreign couples. For instance, surrogate babies Nikolas and Leonard had to undergo a two-year legal battle to get to their country, since their birth in January 2008 to an Indian surrogate mother. Born to German couple (surrogacy remains illegal in Germany) Susan Lohlad and Jan Balaz, the infants were stateless as they were given neither German nor Indian citizenship. Finally, the Supreme Court in India ordered

the grant of exit permits for the babies in May 2010. In a similar case, an Israeli gay couple was prohibited by a Jerusalem judge from taking their surrogate twins to their hometown. The twins were finally provided Israeli passports after a DNA test established that gay Dan Goldberg was indeed the biological father of babies Liron and Itai, born to a Mumbai-based surrogate mother.[9]

Criticism of the Draft Bill

Women's health groups and other human rights organizations in India have long demanded national regulation of ART due to concerns about the exploitation of surrogates and egg donors, and raised major concerns about previous drafts of the bill. SAMA, a New Delhi-based women's health resource group, submitted a letter to the Indian Health Ministry thoroughly detailing its concerns, objections and suggestions to the 2008 draft bill. These included a failure to address and regulate the role of new "players" in the ART industry (brokers, intermediary agencies, hospitals, advertising agencies and other media, etc.); failure to explicitly recognize surrogates' rights both to enter into contracts independently and have final say in medical procedures such as antenatal testing, abortion and fetal reduction; inadequate acknowledgment of medical risks to surrogates; and a general "apathy" for other social dynamics around commercial surrogacy and the marginalized women it tends to employ.

It is yet unclear to what extent the 2010 bill's language, and more importantly, its interpretation, implementation and enforcement if passed will address these and other social justice and health concerns. The implications for reproductive tourism are undoubtedly huge, and will certainly be shaped by the forthcoming responses from international commercial ART/surrogacy agencies, rights groups, and other civil society voices. Regardless of how the bill moves forward, there is an ongoing need to consider how the ART industry will interface with social realities of poverty, as well as gender and class inequality in India.[10]

The Law Commission of India described ART industry as a “Rs.25, 000/- crore pot of Gold”. It recommended only altruistic surrogacy arrangements and not commercial ones. But the Draft Bill legalizes commercial surrogacy as well. This present 2010 draft bill tries a middle path between the law commission report 2009 and the draft bill of 2008. The Draft of Assisted Reproductive Technology (Regulation) Bill 2010 is a step in the right direction. Make the entire process of surrogacy legal and bringing it under legal purview control in setting up ART Banks help to regulate the functioning of the In-Vitro Fertilization (IVF) Centre will protect surrogate mothers by making the contact legal help expectant parents protect their rights as well.[11]

The bill must ensure that the intended parents understand and agree that the surrogate has a right to physical integrity and bodily autonomy, i. e., she cannot be forced to abort the foetus,

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[9] http://www.indian-surrogacy.com/item/proposed-art-regulations-for-international-surrogacy-in-india.html last visited on 7/9/2012 at 2:39 P.M.

[10] http://www.psychologytoday.com/blog/the-age-biotech/201102/india-moves-toward-regulation-assisted-reproduction-and-surrogacy last visited on 7/9/2012 at 2:44 P.M.

[11] http://tnfwl.com/pdf/news_letter/Legalizing_Surrogacy_in_India.pdf last visited on 7/8/2012 at 2:49 P.M.

go through foetal reduction or be made to follow a certain diet and lifestyle. These decisions are for the surrogate, and no one else, to make. The MTP, 1971 Act guarantees women in India the right to abortion, while international human rights legislation guarantees her physical integrity. However, no sex-selection should be allowed even with the consent of the surrogate. The surrogate's right to privacy and physical integrity should be acknowledged in the bill.[12]

It is unclear as to why there is a separate listing of the legitimacy of a child born through ART to married, unmarried and single men and women. Moreover, the definition of legitimacy is premised on the assumption that only children born within wedlock are legitimate. Such an assumption is problematic firstly because a child should not be accorded legitimacy based on her/his birth within or outside "wedlock". This essentially violates the right of a child to live a life of dignity and respect. The bill makes provision for the child to seek information about donors and surrogate mothers on attaining 18 years of age. But at the same time it excludes information regarding personal identification and only in some cases (medical reasons) allows disclosing the information with prior consent of the donor(s) or surrogate. Clause 36(1) states that "A child may, upon reaching the age of 18, apply for any information, excluding personal identification, relating to his/her genetic parents or surrogate mother." But, since the semen banks, the ART clinics and the central database of the ICMR (where the details of the records will be transferred after expiry of 10 years) will keep the records of the donors and the surrogate mothers, it is not clear where the child should apply. By the time the child is 18 years old, the details would be with the Central Data of ICMR. It also falls short in the measures taken to ensure the welfare of the children born through ART. In fact there is no section, which talks about the welfare of the child. The only points mentioned in this regard are those granting legitimacy to the children born through ART and the right of the child to have non-identifying information about his/her genetic parents. Special measures need to be taken to ensure the welfare of the child and that the intended parents are of appropriate age and would be able to raise the child till he/she reaches adulthood.[13]

The distinguishing characteristics of this rapidly developing ART industry have been unregulated at national as well as international level. There is lack of ethical and legal regulation by both sides; the government as well as the medical scientists. Infertility is an approximately $3-4 billion-per-year business whose participants include surrogate mothers and major drug companies; families using donor gametes etc. By passing the natural method of conception, fertilizing more embryos than needed, discarding excess embryos, unnatural environment for embryos, freezing them and destroying them in research are the issues involved in misuse of technology. If during the time in which the embryos are in storage if the couple divorces what is to be done with it and by whom? The religious concepts believe

[12] Sama Team, Assisted Reproductive Technologies: For Whose Benefit?, Economic & Political Weekly EPW may 2, 2009 vol. xliv no 18 29

[13] Sama Team, Assisted Reproductive Technologies: For Whose Benefit?, Economic & Political Weekly, may 2, 2009 vol. xliv no 18

that life begins of at conception; it may amount to abortion which is contrary to both law and ethics. Since more embryos than required are fertilized in the lab, the spare embryos are frozen. In the process some of them are killed. The remaining embryos are human lives that, given a chance, would develop in to a man or women. They are used even for experimentation which can be fatal to them. Donation of sperms or ova involves separation of biological and social roles of parenthood and is equivalent to adoption. In this view there needs to be change into the adoption laws. In the existing legal framework there can be possibility of disputes relating to the property rights in view of the rights related to marriage, succession etc. Even the concepts of the mother, father, son, and daughter need to be reframed or redefined. National and international regulation may have a great impact to ART and stem cell research in the future, one way or the other. ART and research develop at a pace faster than legislation and to an unpredicted destination. Courts and authorities might be challenged with demands of licensing new interventions, but are not the right place to settle the basics of these issues. So, there is a strong need to regulate this complex issue through law.