Centre for Legislative Research and Advocacy

SAMA: A Resource Group for Women and Health

Welcome Kit for Parliamentarians

Policy Brief

Assisted Reproductive Technologies (ARTs)

Introduction

Assisted Reproductive Technologies (ARTs) are a group of technologies, which assist in conception and pregnancy. They encompass various procedures ranging from the relatively simple Intra-Uterine Insemination (IUI) to other variants of *In-Vitro* Fertilization (IVF), more commonly known as "test-tube baby technology". Surrogacy, which is not a technique, but an arrangement, is also included under the umbrella term of ARTs.

Current ART Scenario in India

- Rampant use of unethical practices in the use of ARTs and no accountability of doctors providing ARTs
- Severe compromising of women's health and well-being
- Treatment of women's bodies as commodities
- No standardisation of the procedures and drugs used, lack of proper documentation
- Non-transparency and insufficient\incorrect information on success rates (a 'successful cycle' need not lead to a baby being born), costs etc.
- No rights to the users of ARTs
- Providers fleecing users of huge amounts of illegal money by cashing on their desperation for a child and the stigma around infertility
- India is fast becoming a destination for foreign health tourist shopping for ARTs, especially for surrogate mothers, who can be commissioned for much less price
- Use of Preimplantational Genetic Diagnosis (PGD) in the process of ARTs as a sex selective technique
- Non-regulation of a whole range of research activities around and arising out of ARTs, especially those using embryonic stem cells

In India, there has been an unprecedented and unregulated growth of ART clinics providing IVF procedures over the years. Within the framework of medical tourism, ARTs are the latest addition to the long list of medical services being offered. Low costs, easy access to the otherwise highly regulated technologies and easy availability of surrogate mothers and gamete donors have made India a favoured destination for these procedures. The resulting surge of the ART 'industry' in the country has posed a number of ethical, legal and social dilemmas, including amongst other things the increasing commodification and commercialization of women's reproductive tissues.

In such a context, stringent regulatory and monitoring mechanisms are the need of the hour. Laws and guidelines on Assisted Reproductive Technologies (ARTs) have been developed by many countries across the world to check unethical practices and prevent the proliferation of unsafe techniques. The recent Draft Assisted Reproductive Technology (Regulation) Bill and Rules-2008 by the Ministry of Health and Family Welfare (MOHFW) and the Indian Council of Medical Research (ICMR) is an important and welcome step in this direction. Although the Draft Bill attempts to incorporate many issues related to ART, it unfortunately carries on the vestiges of the drawbacks present in the National Guidelines on Accreditation, Regulation and Supervision of ART clinics in India (2005). The purpose of this policy brief is to highlight the concerns with regard to the Draft Bill amongst parliamentarians and policy makers, and to engage with them towards a more effective and comprehensive legislation. The fact sheet tries to highlight only certain concerns. However, there are many issues in the entire document which are not in the interest of women's rights, child rights and rather promote the interest of ART industry.

Assisted Reproductive Technologies

- Are highly invasive procedures
- Have low success rates
- Have serious risks and side effects
- Are very expensive
- Do not treat infertility, only assist in reproduction

Contradictions within the proposed draft ART Bill

The document lacks clarity at many levels and uses ambiguous language, which makes the effective implementation of the Draft Bill challenging. Moreover, different parts of the Draft Bill contradict each other leaving certain critical questions unanswered.

For example, regarding the issue of making payment to the surrogate, Clause 26 (6) of the Draft Bill states that

> *"A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.* But according to Clause 34(2) '*... the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate."*

Further, the Form of Contract between the Semen Bank and the Surrogate [Form- R2 (4)] mentions that

> *"...the consideration for the surrogacy is to be paid by the parent(s) and the Bank will not be responsible for any demand by the surrogate in the form of compensation. The Bank shall not be responsible for payment to the surrogate for any other expenses incurred during the surrogacy period."*

It is interesting to ponder upon how the law would perceive these contradictory clauses and the way their implementation would be brought about. In case of such contradictions, which clause would be given precedence?

Health Risks and Side Effects

The Draft Bill states that *"ARTs carry **small risks** both to the mother and the offspring"* (Rules 6.13) and at the same time mentions that the risks for women include health implications such as multiple gestation, ectopic pregnancy, spontaneous abortion and Ovarian Hyper Stimulation Syndrome (OHSS). These risks are not only serious by themselves which is not reflected in the Bill, they further entail serious implications, which also have not been mentioned in the Draft Bill. It is appalling how the MOHFW/ICMR have described life-threatening risks as '*small risks*'. It only reflects the extent of their concern for women's well-being in a document that actually seeks to regulate these technologies and ensure their safe usage.

Further, while the document at least mentions risks for the women, risks to the ***offspring*** *or children* born of ARTs especially those resulting from Intra-Cytoplasmic Sperm Injection (ICSI) a procedure used in cases of severe male infertility, are not mentioned at all, even though they are really substantial as revealed through studies:

Risks associated with Intra Cytoplasmic Sperm Injection (ICSI)

i) possible inheritance of genetic and chromosomal abnormalities including
   (a) inheritance of cystic fibrosis gene mutations
   (b) sex chromosome defects and the inheritance of sub-fertility
ii) abnormal numbers or structures of chromosomes
iii) novel chromosomal abnormalities
iv) possible developmental and birth defects
v) possible risks during pregnancy such as miscarriage

Ref: Human Fertilization and Embryology Authority's Code of Practice (6th Edition, Part 16

Surrogacy

Although the Draft Bill has specific clauses regarding the surrogacy arrangement, the rights and health of the surrogate are still compromised to a large extent. MOHFW/ICMR should take special measures for safeguarding the rights and health of the surrogates, especially those commissioned by foreigners . Further, the Draft Bill prohibits the surrogate from being the egg donor, thereby only permitting gestational surrogacy. This also indicates that the surrogate would have to undergo IVF even though her oocytes are viable and she can conceive through the much simpler procedure of IUI.

In addition to the broad concerns there are also specific concerns which have been left unaddressed or inadequately addressed in the Bill, some of which are:

- Eligibility and age for becoming a surrogate
- Contract between the surrogate and the couple
- Exploitative role played by 'middle-men' and intermediaries in surrogacy agreements
- Special safeguards and special terms of agreement, for surrogates commissioned by foreigners
- Role of the semen bank in the payments made to the surrogate
- Number of cycles or attempts for surrogacy
- Health risks that surrogates are vulnerable to
- Health insurance and legal aid for the surrogate
- Other rights of the surrogate and guardianship
- Screening of intended couples

Inadequate Coverage through Registration and Monitoring:

The Draft Bill in its present form focuses only on IVF clinics and semen banks, but ignores gynaecologists offering infertility 'treatments' and IUI procedures. Further, the Draft Bill does not take into consideration other consultancies, organizations, agents, private agencies and travel agencies involved in promoting IVF/ART techniques, egg donation and surrogacy. It is important that any piece of regulation should take into consideration the increasing numbers of 'players' and take measures to specify their roles and status. Further, the Draft Bill is limited in the sense that it does not extend to the public hospitals offering these technologies.

Age of women undergoing ARTs

The Draft Bill treats women's bodies and wombs merely as sites of reproduction, without any concern for other aspects of her life and well-being. It has left a substantial void in the regulation process by not specifying the maximum permissible age of women for undergoing ART procedures. Considering the serious health implications, the magnitude of which may increase with age, this lacuna needs to be addressed. There have been cases where women as old as 60 years or above have conceived through ARTs with serious implications to their health. Providers are glad to undertake such 'challenging' cases without analyzing the repercussions. It is important that this should be monitored by the MOHFW/ICMR, rather than left to the discretion of the providers. The number of embryo transfer and oocyte retrievals should also be specified corresponding to the age of the woman.

Eligibility

Though the Bill claims to be liberal by using the phrase married or unmarried couple as eligible for ARTs, it does not include within its ambit people who are not heterosexual and their accessibility to ARTs. The Bill clearly defines "Unmarried Couple" as a man and a woman, both of marriageable age, living together with mutual consent but without getting married [Clause 2(w)] and "Couple", as persons living together and having a sexual relationship that is legal in the country / countries of which they are citizens or they are living in. [Clause 2(e)]. Therefore, Indians who openly identify as homosexuals are not

eligible. As per both the above-mentioned definitions, only heterosexuals, irrespective of their marital status, are eligible to access these technologies in India.

Role and Regulation of Semen Banks:

The Draft Bill in its current form hands over a substantial part of managing and running of the ART process to the semen banks without providing any rationale. According to Clause 26(1)

> *"The collection, screening, storage and handling of gamete will be done by a semen bank"*

Without clear directions regarding mandatory equipment and personnel in the semen bank, the Draft Bill is not clear on how they are going to equip themselves for these responsibilities. The Draft Bill also does not lay down any clause specifying who can open and run a semen bank the qualifications and background of the person and the team necessary to run a semen bank, as has been specified for ART clinics. There needs to be a clear-cut demarcation of roles of the ART clinic and the semen bank, which at present, is one of the weakest points in this Draft Bill. In the present scenario left unchecked, there is a greater risk of manipulation, entry of intermediaries and breach of anonymity of donors and surrogates making them vulnerable to exploitation.

New and Emerging ART Procedures, and Embryonic Stem Cell and other Researches around ARTs not covered:

The Draft Bill appears narrow in its approach by trying to regulate only a specified number of procedures. However, with the everyday advancement of these technologies, a number of new procedures have also been introduced in some of the IVF clinics. The Draft Bill does not mention any of the new procedures in the entire draft. By not doing so, the legislation is limiting itself to only the ART procedures the aspects of which are so far well understood.

Further, having included a chapter on research on embryos, it is surprising that the Draft Bill does not mention human embryonic stem cell research or issued any regulations related to it. Considering the fact that the source of embryonic stem cells is generally the spare embryos developed during IVF, the document should make efforts to regulate this aspect. In lieu of the rapid pace of advancement being made in this field, scope should be left in the legislation for the inclusion of new technologies, researches, and the possible debates resulting from their potential use.

Continuing with its limited approach, the Bill lists Artificial Insemination with husband's sperm and Artificial Insemination with donor's sperm as two different procedures [Clause 13 (3)a], when technically both the procedures are the same. It is expected that the Bill should describe the techniques objectively without qualifying these with the social connotations attached.

Advertisements

The Draft Bill allows couples to advertise for surrogates without mentioning '*details relating to the caste, ethnic identity or descent of any of the parties*' and prohibits ART clinics from seeking surrogates for its clients [Clause 34(7)].However, advertisements for egg donors or surrogates by advertisement agencies, tourism departments, surrogacy agents, women's magazines, medical tours and travel agencies are not covered in the Draft Bill at all. Advertisements from couples looking for surrogates and women intending to be surrogates can be found regularly in newspapers and magazines like Sarita and Woman's Era mentioning the desired age, religion, caste and even the skin colour of the donors. Similarly there are many advertisements by women wanting to become surrogates. The Draft Bill only prohibits the clinics from advertising but does not foresee the establishment of newer enterprises that may undertake such advertising. Further, the contents of the advertisements should be monitored and regulated and the Draft Bill should have specific provisions for this.

Rights and Welfare of the Child

The Draft Bill states that,

> *"A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having been born in wedlock, with the consent of both the spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse"* [Clause 35 (1)]

It is unclear as to why there is a separate listing of the legitimacy of a child born through ARTs 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. This essentially violates the right of a child to live a life of dignity and respect.

The document also falls short of the measures to ensure the well-being as well as the welfare of children born through ARTs.

Adoption not suitably emphasized or endorsed

The Draft Bill does not adequately emphasize on adoption. Rather, it mentions adoption as the only option if and when ARTs fail for a particular couple, further demonstrating the endorsement of the desire for a 'biological' child or 'genetic make' in an official document. This shows the medical-technical bias of the Bill to the issue of infertility as also the fact that it presents ARTs as a perfect solution to the problem of infertility which actually they are not at all. The making of informed choice by the user is compromised in the process.

> *"...Further treatment for the unresponsive couples will then consist of counseling and an in-depth investigation, leading to the use of ART failing which, adoption may be the only alternative..."*
> (Rules 5 .4)

Conclusion:

Apart from these inconsistencies in the document, a larger concern emerges from the outlook with which different issues have been approached. The medical approach to address a problem rooted in the social context creates a narrow and limited perspective of the issue. The Draft Bill is retrograde in its intent because it reiterates

patriarchal values, and it reinforces eugenics. The Draft Bill seems to have been prepared mostly by individuals from medical fraternity who are practicing ARTs. It tends to promote the interest of the private sector providers of these technologies rather than regulate them and compromises on women's health and the rights of women and children in many ways.

Policy Recommendations

- The Draft Bill in its present form is completely unacceptable, and there is an urgent need for regulation of present practices of ARTs, NOT regularization and promotion, which seem to be its main thrust in the current form.
- There is a need to locate the current legislation on ARTs within the framework of the country's health policy, population policy and other relevant policies. This is important in order to understand the perspective and the motivation with which these technologies are being regulated.
- A clear preamble outlining the purpose and fundamental approach to the Bill emerging from the government's own perspective within the context of pre-existing policies on population and health is seriously lacking in the Bill.
- There should be clearer articulation in dealing with health risks borne by the users, especially women and surrogates mothers, and the children born through ARTs.
- In case of surrogacy arrangements, the Draft Bill should make an effort to safeguard the rights and health of the surrogate and of the child born thereby, especially in the case where the commissioning couple is out of the country. There has to be some sort of follow up or reporting back by the couple/individual regarding the child.
- The Draft Bill must ensure that the commissioning parents understand and agree to the fact that the surrogate has a right to physical integrity and bodily autonomy, i.e. she cannot be forced to abort the foetus, go through foetal reduction or made to follow a certain diet.
- When a surrogate gives birth to a child, the birth must be officially documented and she must be the natural parent of the child born to her.
- Considering the fact that these technologies do not 'treat' or cure infertility, and keeping the potential risks for the mother and child in mind, a responsible legislation regarding infertility and ARTs must encourage adoption and present it as a course of action as significant as ARTs.
- The various procedures and the steps involved, including the drugs being used, standard dosage, appropriate monitoring need to be laid down in detail.
- A clear demarcation between mandatory information to be provided to the users and counseling is necessary, and the two should not be clubbed as one.
- The central database as mentioned in the Draft Bill should also keep a record of live birth rate/take home baby rate, number of implantation rate, number of still births, number of health IVF children born etc.
- The requirements of a semen bank in terms of the facilities needed, kind of personnel employed and their qualification to run a semen bank must be clearly spelt out. It should make adequate provision for the inspection, monitoring and regulation of semen banks.
- The Draft Bill must ensure that the act of taking 'informed consent' should be a continuous process of explanation and interaction over a period of time and not merely restricted to taking a signature of the concerned person.
- The Draft Bill should deal with the issue of sex- selection more stringently. Further, the use of techniques such as Preimplantation Genetic Diagnosis (PGD) should be strictly monitored and should be available only in cases of significant risk of serious genetic conditions present in the embryo.
- The MOHFW and ICMR should not rush into finalizing the Bill until a wider debate across the country, at various levels and regions has been conducted and their responses incorporated.
- Public hearings in different parts of the country with active involvement of women's and health movements, and other sections of the civil society should be organised.
- The ICMR as a premiere medical research body should undertake research on the health of the women and children born through ARTs to understand all the implications of these technologies in the long run, especially for women and children.

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*** SAMA Resource Group for Women and Health is a Delhi based organisation working on issues of women's rights and health by placing them in the larger context of their socio-historical, economic and political realities.**

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