THE ASSISTED REPRODUCTIVE TECHNOLOGIES (REGULATION) BILL & RULES (Draft) – 2010

Issues and Concerns

Sama – Resource Group for Women and Health

Introduction

The Draft Assisted Reproductive Technology Bill and Rules 2010, is the latest draft of following the incorporation of additions and modifications to the Draft of 2008. While the previous Draft was an effort to include issues concerning Assisted Reproductive Technologies (ARTs), it had several limitations, and it was expected that the new Draft would address these gaps. We acknowledge and appreciate that the Indian Council of Medical Research and the Ministry of Health and Family Welfare have taken into consideration some of the concerns raised by Sama- Resource Group for Women and Health with regard to the previous Draft. Nonetheless, the present Draft is not as yet comprehensive and falls short of addressing many concerns vis-à-vis women's health and rights.

While changes have been made in different clauses, significant modifications have been introduced in clauses specific to Surrogacy. This is a welcome step, considering the complexities of issues such as citizenship (of the children born out of surrogacy arrangements). Some earlier concerns regarding the nature of operationalization of the provisions of the Bill, the functional relationship between the ART Bank (replaced by the earlier nomenclature of Semen Bank) and the ART clinics still remain.

The Preamble

The Draft Bill 2010 has incorporated a Preamble, which was expected to explain the significance and rationale of the proposed legislation. However, the Preamble in its present form represents infertility as one of the most highly prevalent medical problems, mandating technological intervention. In fact, ARTs and medical technologies have been made to sound like the miracle solution to every kind of infertility problem. The Draft states… "With the enormous advances in medicines and medical technologies, today 85 per cent of the cases of infertility can be taken care of through medicines, surgery and/or the new medical technologies….." To have a biological child seems imperative with the availability of technologies. This narrow perspective is also reflected in statements in the Draft suggesting that children are a kind of old age insurance in India. Not only do such statements reinforce the notion of biological parenthood, but they are also based on certain simplistic and generalized assumptions (such as the assumption that every biological child will take care of his/her parents in their old age).

The Preamble of a national regulatory framework must contain a more nuanced, comprehensive and inclusive understanding of infertility, including inter-linkages with other relevant issues and policies such as health, population etc., as it puts forth the 'need for regulation, ethical practice and the rights of all concerned'.

The Other Players & Provision In The Public Health

As in the previous Draft (2008), the present document restricts itself to regulating only ART clinics and Banks, without recognizing the role that other players like travel agents, surrogacy agents, surrogacy law firms, etc. play. A Draft legislation must take cognizance of the diverse players of the ART industry to be able to effectively regulate it. The legislation must contain concrete and stringent provisions for regulating the functioning of these varied agencies.

Further, the Draft Bill still does not adequately dwell on the regulation and monitoring mechanisms for public hospitals offering these technologies, although it has been observed that some public hospitals have started providing ARTs since the last few years.

Eligibility

The Draft Bill states that "Assisted Reproductive Technology shall be available to all persons including single persons, married couples and unmarried couples". While seeming liberal, the present Draft is still restricted to a heterosexual framework. While the words man and woman are not used in defining 'married couple' and 'unmarried couple', the Bill by its very definition of couple prohibits same sex couples from accessing ARTs in India. The Draft Bill defines Couple as two persons living together and having a sexual relationship that is legal in India.

> "married couple", means two persons whose marriage is legal in the country / countries of which they are citizens;
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> "unmarried couple", means two persons, both of marriageable age, living together with mutual consent but without getting married, in a relationship that is legal in the country / countries of which they are citizens;
>
> "couple", means two persons living together and having a sexual relationship that is legal in India;

Health Risks and Side effects

The present Draft of the Bill has done away with the word 'small' in describing risks associated with ARTs. This is an

acknowledgement of the adverse health implications of these technologies. The present Draft lists complications such as Multiple Gestation, Ectopic Pregnancy (5 per cent), Spontaneous abortion and Ovarian Hyperstimulation Syndrome (0.2 to 8 per cent) to the same degree as mentioned in the previous Draft. (Rule 6.13). It does not, however, elaborate on other complications arising from the use of these procedures, which have been established by medical research. Further, though the present Draft does mention that ART procedures carry risks both to the mother and the child, there is no listing of the risks and adverse outcomes of these technologies for children. Recent media reports have also clearly highlighted the side-effects of ARTs for children born using these technologies.

Adoption

The present Draft, as was previously the case, does not adequately emphasize adoption as a credible alternative to ARTs. Rule 2.4 mentions that, "The counselor must invariably apprise the couple of the advantages of adoption as against resorting to ART involving a donor". In addition Rule 5.4 states, "Further treatment for the unresponsive couple will then consist of counseling and an in-depth investigation, leading to the use of ART- failing which, adoption may be the only alternative". The Bill therefore regards adoption as an option only in the case of donor gametes, or failure of ARTs. Considering the low success rates and health risks associated with ARTs, the legislation should present adoption as an equally, if not more, valid course of action.

Oocyte retrieval

With regard to Oocyte retrieval the draft bill 2010 [(Clause 26(8)] mentions that a woman may donate oocytes up to 6 times in her lifetime with not less than 3 months interval between the cycles. However, there is no specification regarding the maximum number of cycles that a woman can undergo, which may be 6 or more, as not every cycle may result in oocytes viable for donation. Also, there is no system stipulated in the present Draft to monitor and record the number of times a woman donates oocytes. Further, the three-month interval between the donations, as stipulated by the Draft Bill, is extremely inadequate as oocyte retrieval requires the stimulation of ovaries using hormonal drugs, which adversely affect women's health.

Further, the specification regarding number of oocytes to be retrieved is only in case of donors. It is also important for the Draft Bill to specify the number of oocytes that can be retrieved from women undergoing IVF or women in egg-sharing programmes, where there is a possibility of retrieval of a large number of eggs. Moreover, Rule 6.13.1 of the Draft Bill allows for more oocytes to be retrieved and more embryos to be implanted in the case of older women, putting them under considerable risk.

> "…not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, except ing under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality)."

Pre-implantation Genetic Diagnosis (PGD) and Sex Selection

The use of technologies like PGD has raised many social and ethical issues, including concerns around eugenic implications and sex- selection.

The present Bill (like the previous one) does not detail any Consent Form for the procedure of PGD. In the Agreement for Surrogacy (Form J) there is a mention that the surrogate will not be asked to undergo a sex determination test for the child, however, this does not include PGD, which is conducted on the embryo before it is transferred into the surrogate's uterus. Further, the Consent Form for IVF and ICSI (Form D, Pg 41) does not mention the prohibition of sex-selection during these procedures. Given the growing use of PGD, it should be strictly monitored and made available only in cases where there is significant risk of a serious genetic condition in the embryo.

Role of the ART Bank

The nomenclature of 'Semen Bank' used in the previous Draft Bill 2008, has been replaced with 'ART Bank' in the current Draft. However, there is an absence of clarity about what or who comprises an ART Bank, as well as its role, registration, functions, etc. As a substantial part of the management of ART 'treatment' is expected to be carried out by the ART Bank, merely changing the nomenclature without detailing its various aspects is problematic.

> "ART bank", means an organisation that is set up to supply sperm /semen, oocytes / oocyte donors and surrogate mothers to assisted reproductive technology clinics or their patients

Surrogacy

> "surrogacy", means an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belong to her or her husband, with the intention to carry it and hand over the child to the person or persons for whom she is acting as a surrogate;
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> "surrogate mother", means a woman who is a citizen of India and is resident in India, who agrees to have an embryo generated from the sperm of a man who is not her husband and the oocyte of another woman, implanted in her to carry the pregnancy to viability and deliver the child to the couple / individual that had asked for surrogacy;
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> "surrogacy agreement", means a contract between the person(s) availing of assisted reproductive technology and the surrogate mother;

Age and number of cycles

As per the Draft Bill 2010 the maximum age at which a woman can become a surrogate has been reduced from forty-five

years (Draft Bill 2008) to thirty five years. However, the Draft has also increased the number of successful live births that a surrogate is permitted, from three (in the previous Draft) to five. Although this number includes the surrogate's earlier pregnancies, the reasons for this increase are not clear. The previous Draft (2008) did not include earlier pregnancies that the surrogate may have undergone. The increase to five successful births for a surrogate seems to emerge from the need / pressure to retain the number of permitted live births to at least three, after factoring in the surrogate's own children, assumed to be two. However, the Draft does not limit the maximum number of cycles that the surrogate is permitted to undergo. This is extremely important because the number of live births is not equivalent to the number of ART cycles. A major concern is that ARTs, given their low success rates, often imply multiple cycles for successful outcome, thus posing serious risks to the surrogate's health.

Eligibility

While it explicitly permits single women to access ARTs, this Draft Bill (like the previous one) neither prohibits nor explicitly permits single women to be surrogates. It also states:

"In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate" [Clause 34(16)].

Whether single women are permitted to be surrogates or not has been left open to interpretation. Such ambiguities should be avoided and the provisions of the Draft Bill should be explicitly clear.

The present Draft has also an added clause prohibiting the ART Bank/ ART clinic from receiving or sending an Indian for surrogacy abroad. Clause [34(22)] states that Only Indian citizens shall have a right to act as surrogate, and no ART bank/ART clinics shall receive or send an Indian for surrogacy abroad.

Insurance for the Surrogate

The present Bill also states that the commissioning parent(s) shall ensure that the surrogate mother and the child she delivers are 'appropriately' insured till the child is handed over to the commissioning parent(s)..... till the surrogate mother is free of all health complications arising out of surrogacy :Clause 34(24). Although a welcome addition, the Bill does not elaborate on the nature and the kind of insurance; nor does it state the factors which determine the 'appropriateness' of the insurance. Also, it does not clearly lay down the responsibilities of the commissioning parent(s) with regard to post-delivery and follow up care of the surrogate mother. The surrogate might need assistance even after the child has been handed over to the commissioning parent(s). Further, there is no provision for legal aid or assistance to the surrogate. Given that a surrogacy arrangement entails considerable legal complexities, the Draft Bill should take steps to address the legal needs of the surrogate. Therefore, detailed information with regard to health insurance and legal aid for the surrogate is required in the Draft.

Guardianship

Clause 34 (19) of the present Draft mentions that in case the intended parents are from outside India and refuse to take custody of the child born out of the surrogacy arrangement, following a period of one month, the 'local guardian' shall be legally responsible for either bringing up the child or handing over the child to an adoption agency. It has also been stated that in either instance, the child will be given Indian citizenship. Such additions to the earlier Draft appear to have been done keeping in mind recent legal tussles about the citizenship of the children born out of surrogacy. However, the welfare of the child / children cannot be the sole discretion of an individual - the local guardian - in such a situation. There is need for a system to be put in place that can objectively discern the course of action to be taken, and follow-up and monitor the same, keeping the child/ children's best interests in mind. Such concerns should be addressed and the role of the local guardian should be clearly explained.

Further, the appointment of a local guardian to keep a close watch on the surrogate is an impingement on the autonomy, freedom and rights of the surrogate, and as such, is completely unacceptable.

Payment to the Surrogate

The present draft's provisions with regard to payment to the surrogate raise serious concerns about the undermining of her rights. According to this draft, payment to the surrogate is to be made in five installments instead of three (previous Draft) with the majority, i.e. 75 per cent, to be paid as the fifth and final installment, following the delivery of the child. This is in complete contrast to the previous Draft, wherein the majority of the payment, i.e. 75 per cent, was to be paid as the first installment. This shift reflects that the priority accorded to the intended parent(s) is much higher than that of the surrogate. The health risks that the surrogate might face (as a result of undergoing IVF) are not taken into account, and her 'worth' is wholly contingent on a measurable reproductive 'output', i.e. the baby. It is clear that a more balanced mode of payment to the surrogate is required.

Requirement of legal documents from foreign couples

A positive addition in the present Draft is the requirement of legal documents from foreign couples declaring that their respective countries permit surrogacy and that the child born out of such an arrangement will be the legal citizen of their country. This provision will be useful in addressing legal complications that have been known to arise regarding the citizenship status of children born of surrogacy arrangements.

The party seeking the surrogacy must ensure and establish to the assisted reproductive technology clinic through proper documentation (a letter from either the embassy of the Country in India or from the foreign ministry of the Country, clearly and unambiguously

stating that (a) the country permits surrogacy, and (b) the child born through surrogacy in India, will be permitted entry in the Country as a biological child of the commissioning couple/individual…

The present Draft with additions and modifications has tried to take into consideration some of the concerns with the previous document. While some of these are welcome changes, the Draft is its present form is far from being an inclusive document. If the proposed legislation is expected to effectively regulate the proliferating ART and surrogacy industry in India, these lacunae will have to be addressed.

Policy Recommendations

- There needs to be systematic regulation of the other players offering ART and Surrogacy services like the law firms, medical tourism agencies, surrogacy agencies. The Bill should make provision for a centralized registry mechanism and database for such institutions towards better and effective monitoring.
- The 2010 draft permits multiple embryo implantation (up to three), which increases the chances of achieving pregnancy, but also has additional health risks. Further, in case of 'exceptional circumstances' such as elderly women, poor embryo quality etc, this upper limit does not hold. This raises concerns about exposing women already more vulnerable due to their age etc to even greater health risks. World over, there is a move towards single embryo implantation in view of health risks to mother and child due to fetal reduction and multiple pregnancy. Thus, in India too, the Bill should stipulate single embryo implantation, including under 'exceptional circumstances'.
- Many serious health risks (procedural and drug-related, for both the woman and the child) need to be acknowledged and clearly mentioned in the consent form. The consent form should also mention, where relevant, that long term effects of drugs and procedures are under-researched.
- The revision in the present Draft vis-a-vis payment to the surrogate (as mentioned above) is highly imbalanced and unfavourable to the surrogate. Not only has the number of installments being increased, but the maximum payment is also to be paid as the last (5th) installment. This therefore necessitates a more equitable distribution of payment in the form of equal installments.
- The Bill mentions that the commissioning parent(s) shall ensure that the surrogate mother and the child she delivers are 'appropriately' insured; while this is indeed necessary, more elaboration is required on the nature and extent of insurance that will be provided, particularly with regard to post-delivery follow-up and care, failing which the commissioning parent(s) and the overseeing clinic should be held legally responsible.
- While the Bill mentions the availability and accessibility of ARTs to all single persons, married couples and unmarried couples, the reading together of all the definitions (as mentioned above) is not clear. Further, there is no clarity if ARTs will be available for gay couples, particularly Indian gay couples. This needs to be clarified and ascertained from a rights perspective, without any discrimination, since homosexuality has been decriminalized (but not legalized) in India.
- The maximum number of cycles that a woman can undergo for the oocyte retrieval has not been specified in the Bill. This is significant, as every cycle may not result in oocytes viable for donation. The maximum number of oocytes to be retrieved per cycle also needs to be prescribed in case of donors, as well as for women undergoing IVF or in egg-sharing programmes; the hyperstimulation of ovaries may prove fatal. Also, a comprehensive system for monitoring and recording the number of times a woman gives oocytes needs to be clearly stipulated in the Bill.
- The Bill mandates the appointment of a local guardian in case of intended couples staying outside India, who will be legally obliged to take delivery of the child born of the surrogacy arrangement if the intended couple does not do so. It appears that the local guardian may hand over such a child to an adoption agency, or bring him/her up. This is a significant responsibility. In such a context the role of the local guardian needs to be clearly demarcated and overseen to prevent abuse.
- According to the Bill, only gestational surrogacy, i.e. through IVF and ET (Embryo Transfer), will be permitted and genetic surrogacy, i.e. through IUI/ Artificial Insemination is not allowed. By ruling out genetic surrogacy, the Bill seeks to foreclose the possibility of any contesting claims over the baby by the surrogate mother, thus preserving the contract. Yet, genetic surrogacy through IUI where possible remains a less commercial and less invasive option, and avoids the excessive use of IVF for obtaining donor eggs. Thus, genetic surrogacy should be an option.
- Independent and long term counseling should be available for the surrogate and the intended parents.
- In view of her vulnerable position, the provision of a state sponsored legal counsel for the surrogate should be mandatory in all surrogacy arrangements, to oversee the contract, its preservation and any legal contests on behalf of the surrogate.

This document is an attempt to bring forth some of the important concerns in the Draft Bill 2010, there by also drawing linkages with the concerns with the previous Draft of 2008, so that they can be rectified towards a pro-people and pro-women legislation. We do hope that these concerns will be taken into account in the process of finalising the document.

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