

Critical Analysis of the Current Assisted Reproductive Technology Guidelines

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ABSTRACT

Aim: To present an overview of the current Artificial Reproductive Techniques (ART) guidelines focussing on grey zones

Introduction: Infertility is a major health and social concern in modern day India. Due to the great diversity in management protocols and absence of standard operating procedures, there is a necessity to develop country-specific guidelines for assisted reproduction. Also, there is need to curb unethical practices. Guidelines in this regard have undergone several changes over the years. It is important that adequate care is taken before the bill becomes a law so that both patients and health workers mutually benefit from ART

Overview: The present article gives an insight into the development of guidelines over the years with elaboration of the salient features of the current ART Bill under specific chapter headings, ten chapters in total. Also discussed is the recent Surrogacy Bill. In each context, critical analysis is provided that underscores the grey areas that need to be addressed. At the end of the article, certain recommendations have been put forward to aid the successful implementation of current guidelines

Clinical significance: It is imperative that all ART practitioners be well versed with the current ART guidelines as ignorance cannot be cited as an excuse under any circumstance. Also, practitioners can give valuable inputs before the bill finally becomes a law. The law must ensure that physicians are not unnecessarily persecuted in the name of patient rights, as this will lead to fearful practice, which in turn will hamper patient management.

Keywords: Artificial Reproduction, Assisted reproductive technology, Bank, Bill, Donor, Guidelines, Law, Surrogacy, Third party.

How to cite this article: Sharma PJ, Mittal M. Critical Analysis of the Current Assisted Reproductive Technology Guidelines. *Int J Infertil Fetal Med* 2017;8(3):113-119.

Source of support: Nil

Conflict of interest: None

Date of received: 06/09/2017

Date of acceptance: 01/10/2017

Date of publication: November 2017

INTRODUCTION

Infertility is emerging as a major health and social concern in modern day India. According to the World Health Organization, overall prevalence of primary infertility in India has been estimated to be between 3.9 and 16.8%.¹ Consequently, there has been a mushrooming of centers providing assisted reproduction throughout the country. Due to the great diversity in management protocols and absence of standard operating procedures, there is a necessity to develop country-specific guidelines for assisted reproduction. There is also a need to curb unethical practices. An attempt has been made by the Indian Council of Medical Research (ICMR) in this regard and a draft of assisted reproductive technology (ART) bill was introduced for consideration in 2014. However, it is important that adequate care is taken so that both patients and health workers mutually benefit from ART.

VARIOUS GUIDELINES OVER THE YEARS

Development of Guidelines

- The ICMR proposed “National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India” in 2002. This draft document then underwent extensive public debate (seven cities were chosen—New Delhi, Jodhpur, Mumbai, Bangalore, Chennai, Hyderabad, and Kolkata). The participants were given a prescribed pro forma to enter their opinion (85% general public, 13% Indian doctors, and 2% international doctors).
- Based on this survey, along with comments and suggestions from the National Commission for Women and National Human Rights Commission, the National Guidelines were finalized.
- The Ministry of Health and Family Welfare examined these guidelines and after slight modifications published the National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India as National Guidelines of Government of India in 2005.²
- Since these National Guidelines were not being appropriately followed, the ICMR formulated the draft ART (Regulation) Bill in 2008,³ which was again subjected to extensive public debate.
- Thereafter, the ART (Regulation) Bill was revised and finalized in 2010.⁴ The 2010 bill has now been revised by the Ministry of Law & Justice as ART (Regulation)

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Table 1: Salient features of guidelines and bills over the years

Year	Salient features
2005	First time guidelines were formulated Sperm donor 21–45 years; Oocyte donor 18–35 years Allows both commercial and altruistic surrogacy
2008	Legally enforceable surrogacy agreement Oocyte donor—up to six times Surrogacy—maximum thrice Semen donor—maximum 75 times
2014	Age to avail ART services—women: 23–50 years; men: 23–55 years Only married infertile couples Oocyte donor—Only once in a lifetime. Age 23–35 years Surrogate—Only once in a lifetime Semen donor—maximum 25 times Ban on commercial surrogacy for foreigners
2016	Complete ban on commercial surrogacy Infertile couple married for at least 5 years

Bill—2014.⁵ The salient features of various guidelines and bills over the years have been summarized in Table 1

- Surrogacy (Regulation) Bill was passed in 2016.⁶ This bill prohibits all forms of commercial surrogacy.

CURRENT ART (REGULATION) BILL, 2014

Chapter 1—Preliminary

Definitions

- Important terms as defined in the Bill with relevant critical analysis comments have been tabulated in Table 2. The ART Bill says no ART procedure shall be

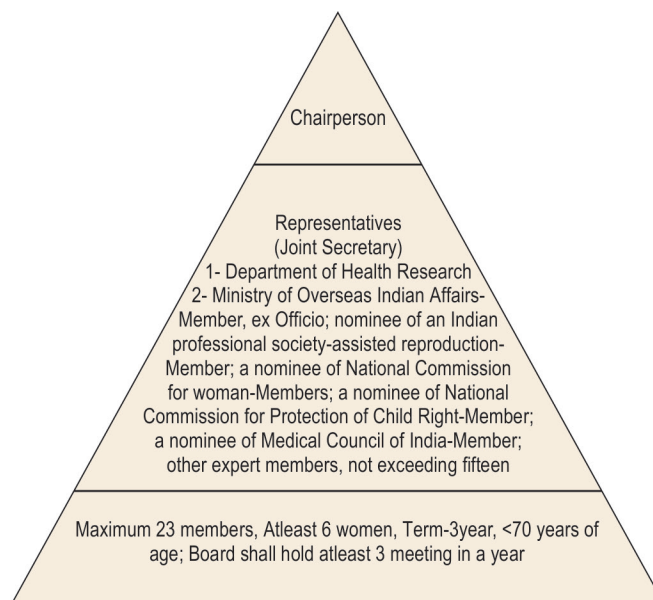


Fig. 1: Structure of national board

performed below the age of 23 years. This needs to be modified in case individuals are diagnosed to have conditions like azoospermia, cancers, etc.

Chapter 2—Authorities to Regulate ART

National Board: (Fig. 1: Structure of National Board)

- Functions of the National Board:
 - To develop new policies in the area of ART

Table 2: Important definitions and comments

Term	Definition	Critical analysis
Infertility	Inability to conceive after at least 1 year of unprotected coitus or an anatomical or physiological condition that would prevent a couple from having a child	Fixing a time limit of 1 year is not appropriate for all cases. The American Society for Reproductive Medicine (ASRM) recommends earlier evaluation in older women ⁷ (after 6 months if age >35 years or immediate if age >40 years)
ART	All techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive tract of a woman	Intrauterine insemination (IUI) would also involve manipulation of gametes outside the human body. Clinics performing IUI should also be registered as ART clinics
ART Bank	Organization, i.e., set up to supply sperm or semen, oocytes or oocyte donors, and surrogate mothers to the ART clinics or their patients	ART clinic cannot be ART Bank. Clinics previously recruiting semen donors have to depend on ART Banks for donor semen
ART Clinic	Premises, other than the clinics of AYUSH System of Medicine, equipped with the requisite facilities for carrying out the procedures related to the ART	No clear directions on minimum requirements, especially of lab Differences between centers carrying out IUI and centers with IVF facilities not mentioned
Couple	Relationship between a male and female person who live together in a shared household through a relationship in the nature of marriage which is legal in India	No ART services for single parents, homosexuals Single foreign individuals can adopt an Indian child, but single Indian parent cannot avail ART
National registry	An institution shall be established under Section 18 at the Indian Council of Medical Research, New Delhi and shall act as the central database of all the ART Clinics and Banks in India and helping the State Boards and National Board in accreditation, supervision, and regulation of the ART Clinics and Banks in country and help in policymaking	National Registry should be set up immediately to curb the malpractices with respect to multiple oocyte and semen donations at various centers Why should the National Registry be under ICMR as ART procedures are no longer research?

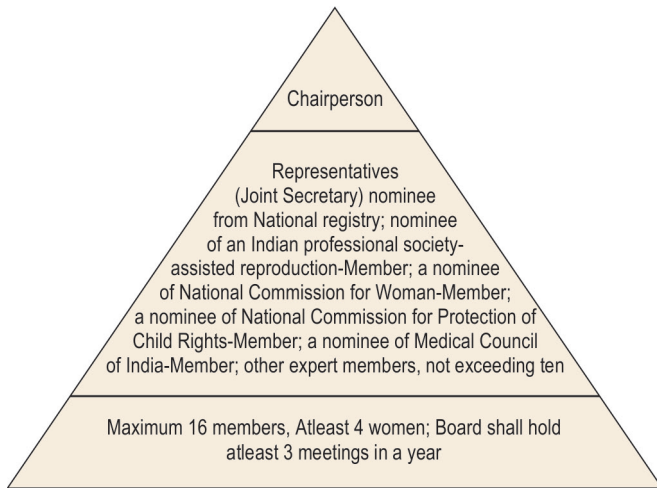


Fig. 2: Structure of state board

- To assist the State Boards in accreditation and regulation of services, staff and physical infrastructure of ART Clinics and Banks
- To make regulations regarding permissible ART procedures and selection of patients
- Encouragement and promotion of training and research in the field
- Regulation of third-party reproduction, including counseling of potential surrogate mother and oocyte donor (possible long-term effects, psychological risks, and vulnerabilities and possible effects on their existing relationship and children)
- Regulation of dissemination of information related to infertility and ART to the society
- Regulation of consents and records to be kept by the clinics and banks

State Board: (Fig 2: Structure of State Board)

Chapter 3—Procedure for Registration and Complaints

- Within a period of 90 days from the date of constitution of the Registration Authority under this Act, make an application for registration as an ART Clinic or ART Bank under this Act.
- Apply to the state board.
- Registration can be issued or rejected within 90 days.
- Valid for 3 years.
- Need to submit the copies of certificates of all the persons employed.

Critical Analysis

No specific mention of qualifications of treating doctors and embryologists.

Chapter 4—Duties of ART Clinic and Bank

- Should not disclose the identity of oocyte donor to recipient couple or anyone else except in case of medical emergency or order of a competent court.
- Ensure that patients, donors, and surrogates are free from viral infections.

Critical Analysis I

The ART bill does not mention anything about human immunodeficiency virus (HIV) discordant couples who want to become parents. This is an important aspect of legislation as patients with HIV or hepatitis B cannot be denied the benefit of assisted reproduction, which will help prevention of transmission of the virus from husband to wife or *vice versa* while providing the joy of parenthood.

- The European Society of Human Reproduction and Embryology (ESHRE) has specific guidelines for embryology labs to prevent viral transmission.⁸
- The ASRM has specific guidelines for serodiscordant couples.⁹ Such guidelines are lacking in the current ART bill.
- All ART banks shall cryopreserve semen sample for a quarantine period of at least 6 months before being used.

Critical Analysis II

No mention of quarantine for oocyte donors. Ideally even oocyte donors should be tested twice to avoid seroconversion of the recipient in case the donor is in window period.

- Specific instructions and written consent with regard to death or incapacity of any of the parties is mandatory before freezing human gametes and embryos.
- All consents and agreements should be in local language.
- All information regarding biochemical and clinical pregnancy should be uploaded online within 7 days of receiving the information, withholding identity of the patient.

Critical Analysis III

While uploading the results would help us know the outcomes at each individual clinic and also the number of positive outcomes from a particular donor, especially semen donors, it is unclear as to where should the details be uploaded.

- All records, charts, forms, reports, consent letters, and all other documents required to be maintained under this Act and the rules made under shall be preserved for a period of 10 years and after which the records shall be transferred to the National Registry of Assisted Reproductive Technology Clinics and Banks in India of the ICMR.

- If the ART Bank closes before 10 years, the records shall be immediately transferred to the National Registry.
- The number of oocytes or embryos to be placed in a woman in a single treatment cycle would be specified by the National Board or the concerned State Board.

Critical Analysis IV

- Till such a board is constituted, there is no limit to number of embryos transferred, leading to more high-order multiple pregnancies and related complications. There is an urgent need to curb this problem.
- On the contrary, strict limitation on the number, as required by law in few countries, prevents individualization of cases.
- It is recommended that each center must monitor its own data and develop protocols depending on patients’ clinical features, to decrease adverse events like multiple pregnancy and maintain good success rate.¹⁰
- Furthermore, since only embryos and not oocytes are artificially transferred into a woman’s uterus, the term “oocyte” should be removed from the statement in the bill.
 - Cannot mix semen from husband and donor
 - No transfer of gametes of more than one individual at a time
 - No self and surrogate embryo transfer simultaneously
 - In case the spouse has imminent death, his/her gametes can be procured for use by surviving spouse
 - Ova from fetus cannot be used under any circumstances
 - The destruction or donation, with the approval of the patient, to an approved research laboratory for research purposes of an embryo after preimplantation genetic diagnosis; shall be done only when the embryo suffers from preexisting, heritable, life-threatening, or genetic diseases

Critical Analysis V

Research should be allowed on any embryo donated for such purposes and not only on embryos with known diseases.

Chapter 5—Sourcing, Storage, Handling, and Record Keeping for Gametes, Embryos, and Surrogates

Oocyte Donor

- Criteria for oocyte donor and critical analysis are presented in Table 3. Not more than seven eggs should be retrieved from one donor

Table 3: Criteria for oocyte donor

<i>Criteria</i>	<i>Critical analysis</i>
Ever married	Ever married—Even legal experts are unable to explain the meaning of the term ever married
23 to 35 years of age	Lower age limit for semen donor is 21 years, but for oocyte donor it is 23 years. Women can get married at 18 years of age, but cannot be an oocyte donor until 23 years
One live child 3 years of age	Previous ART guidelines and present ASRM have suggested maximum six cycles of oocyte donation in a woman’s lifetime, ¹¹ but present bill restricts this to only once
Once in lifetime	Consent of spouse cannot be obtained if the woman is separated or is a widow
Requires consent of spouse	

- Oocytes from one donor can be shared between two recipients only, but each recipient should get minimum of seven oocytes

Critical Analysis I

The provision of obtaining just seven oocytes from the donor is controversial, as on the one hand, the Act allows for sharing of oocytes with seven eggs to be given to each party, on the contrary, how is that possible if only seven eggs can be obtained from one donor.

- Aadhaar card is to be used as proof of identity.

Critical Analysis II

Aadhaar card has been made voluntary. Hence, other proof of identification is to be used.

- In case of death or disability of the oocyte donor, it shall be presumed to be caused by the negligence of the ART clinic unless proven otherwise.

Critical Analysis III

Chances of critical ovarian hyperstimulation syndrome (OHSS) are low as there is no conception (low human chorionic gonadotropin levels) and gonadotropin-releasing hormone agonist trigger can be used, which is well known to prevent OHSS.

- The risk of other serious acute complications like infection, hemorrhage, and torsion is <0.5%.¹¹
- Also the responsibility of the ART Bank that recruits the donors must be clarified upon.
- Oocyte donated by a relative or known friend of either of the couple should not be used.

Critical Analysis IV

Many couples requiring oocyte donation request to obtain oocytes from their relatives or friends. The present



guidelines prevent this but it should be given a second look as social complications arising from such a situation are less because ultimately birth mother is the recipient.

On the one hand, the ART Bill does not allow altruistic oocyte donation; on the contrary, the Surrogacy Bill, 2016 recommends only altruistic surrogacy.

Regulations with Respect to Surrogacy

Issues with Commercial Surrogacy

Exploitative: Rural background, poor, illiterate women

- Agents and brokers get the bulk of money

Health issues: Forced to deliver by C-section

- Repeated pregnancies can affect cardiovascular health
- Psychological stress

Unbalanced act: Leave home for the duration of the pregnancy

- Rights of their own children compromised.

Issues with Altruistic Surrogacy

- Family members may be forced to become surrogates
- Develop bonding with the unborn child
- No form of monetary compensation
- Women in need may not find an appropriate surrogate at all!

SURROGACY (REGULATION) BILL, 2016

- Complete ban on commercial surrogacy.
- For the intending couple: Age of female partner should be between 23 and 50 years and male partner between 26 and 55 years.
- The intending couple should not have a living child born biologically or through adoption or through surrogacy earlier.
- Couple should be married for 5 years
 - Women suffering from disorders like Müllerian agenesis need not wait for 5 years to avail surrogacy.
- Certificate of proven infertility
 - Rather than a certificate of proven infertility, more appropriate would be a certificate to declare inability to carry the pregnancy to viability.
- All records shall be preserved for a period of 25 years.
- Any offence shall be cognizable, nonbailable, and noncompoundable.

Critical Analysis

No specific numbers of abortions or implantation failures to qualify for surrogacy.

Adoption of unborn child; no legal procedure described.

Legal implications to the surrogate if she terminates the pregnancy.

Semen Donors

Criteria

- Age: 21 to 45 years
- Screened for infectious diseases
- Consent of spouse if married
- Maximum of 25 times.

Research has shown that in a population of 80,000, there should not be more than 25 pregnancies from single semen donor in order to prevent inadvertent consanguinity.¹² However, instead of keeping a limit on the number of semen samples from a donor, it is more important to document the number of pregnancies.

Cryopreservation

- A human embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of 5 years and at the end of such period such embryo shall be allowed to perish or donated to a research organization.
- No donor gamete shall be stored for a period of more than 5 years.

Critical Analysis

There cannot be an arbitrary limit of 5 years for cryo-preservation. If the couple are willing for birth spacing then this time period can be extended. Also it is important to increase this time limit in case of cancer survivors.

Chapter 6—Regulation of Research on Human Embryos

- The transfer of any gametes and embryos to any country outside India for research is prohibited.
- Research only on gametes and embryos donated for such purpose.
- For research, permission of the Department of Health Research to be obtained.
- No human embryo created *in vitro* is maintained for a period exceeding 14 days or such other period as recommended by the National Board.

Chapter 7—Rights and Duties of Patients, Donors, Surrogates, and Children

Child Rights

- A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.
- A child or children may, upon reaching the age of 18 years, ask for any information, excluding personal identification, relating to the donor or surrogate.

Donor and Surrogates

Salient features of Rights and Duties are as follows:

- Appropriate formula and mechanism needs to be developed under rules for payment of compensation to the gamete donor and to transfer the funds to the bank account of the gamete donor
- Specific guidelines regarding monetary compensation for gamete donors are required
- If there are any complications that have arisen during pregnancy (i.e., gestational diabetes, chronic hypertension, etc.) which are likely to continue for the rest of her life, then it shall be covered appropriately under insurance
- Insurance companies may not come forward to provide insurance for a lifetime
- A surrogate shall relinquish all parental rights over the child or children
- Appropriate adoption guidelines are required.

Chapter 8—Offences and Penalties

- No ART Clinic shall offer a couple to provide a child of predetermined sex.
- Offenders shall be punishable with imprisonment for a term which may extend to 5 years or with fine which may extend to rupees 10 lakhs or with both.
- The transfer of a human embryo into a male person or into an animal, i.e., not of the human species shall be an offence.

Chapter 9—Finance, Accounts, Audits, and Reports

- This chapter in the bill deals with the regulations regarding salaries of members of national and state boards.
- Regulations regarding the maintenance of accounts and audits by the national and state boards.

Chapter 10—Miscellaneous

Miscellaneous chapter deals with the dispute and their settlement between national and state boards and/or government.

Critical Analysis

There are large areas where specific guidelines are yet to come.

Example—Medical tests for gamete donors, amount of monetary compensation, manner of harvesting oocytes, manner of storage of embryos, etc.

RECOMMENDATIONS

- Immediate setup of national registry.
- Fingerprints can be used as proof of identity instead of Aadhaar card.
- Nongovernment organizations or government organizations should be made in charge of third-party banks to curb malpractices.
- Promote oocyte banking similar to semen banking with proper quarantine.
- More debate on altruistic surrogacy is needed.

CONCLUSION

Assisted reproductive technology is a technology that has opened new frontiers. Along with bringing new hope to infertile couples across the globe, it has brought in its wake a slew of unethical practices promoted by unscrupulous businessmen seeking to exploit the emotions of such couples. Hence, there is a need to bring this technological revolution under the rule of law. However, the law has to keep pace with the fast developing science. The Indian Bill is already 15 years in the making with still no established laws or accreditation bodies. At this rate, the law will already be obsolete by the time it is passed.

Society viewpoint about newer technologies will always differ depending on moral, religious, and scientific opinions. Hence, it is difficult to please all. The responsibility of ethical practice lies with the ART practitioners. Simultaneously, the law must ensure that physicians are not harried and unnecessarily persecuted in the name of patient rights as this will lead to fearful practice, which in turn will hamper patient management.

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