Working Paper

Review of Draft Assisted Reproductive Technology Bill, India 2020

March 2021

Sudha Chandrashekar[1], Amoolya C[2],

[1]Health System Transformation Platform, New Delhi
[2]Student intern, O.P. Jindal Global University Law School.

HSTP
Health Systems Transformation Platform

Contact

Sudha Chandrasekhar | Consultant, HSTP (supported by Tata Trusts) | schandrasekhar@hstp.org.in

This working paper titled 'Review of Draft Assisted Reproductive Technology Bill, India 2020' has been developed by Health Systems Transformation Platform (HSTP).

Disclaimer

Health Systems Transformation Platform is a not-for-profit organization registered in the name of Forum for Health Systems Design and Transformation, a company licensed under section 8 of the Indian Companies Act 2013.

Our mission is to enable Indian health systems respond to people's needs. We do this in collaboration with Indian & Global expertise through research for health systems design, enhancing stakeholders' capabilities and fostering policy dialogue.

HSTP activities are funded by Sir Ratan Tata Trusts. HSTP is committed to highest standards of ethics and professional integrity in all its endeavours and declares no conflict of interest on account of its funding arrangements. The funders have no role in planning, design, development, and execution of any HSTP activities including organization of meetings/ workshops/ trainings/ research/ publications/ and any other dissemination material developed for the use of health systems stakeholders in India and elsewhere.

Acknowledgement

The authors acknowledge the inputs of Rajeev Sadanandan, Pallavi Gupta, and Vijayashree Yellappa.

Table of Contents

Abstract

This working paper discusses the context of the Assisted Reproductive Technology (Regulation) Bill India 2020 and the strengths and weaknesses of the same. It also outlines earlier efforts of the Indian Council for Medical Research (ICMR) in attempting to regulate the growing sector of Assisted Reproductive Technology. This paper seeks to ensure that during the discussions of the draft bill the policy makers have the necessary evidence and can take into consideration the challenges of implementation while finalizing the Bill and drafting the rules for the Assisted Reproductive Technology Act once it is passed in Parliament. We have comprehensively reviewed the secondary literature regarding assisted reproductive technology & investigated similar legislation in other countries.

We find that though the current draft bill ART 2020 is well drafted and tries to address the key issues, there are certain areas where further clarity is required, such as in the grievance redressal process, inclusion of certain clauses to strengthen the bill regarding health risks and provision of safeguards to the donors. We also suggest reconsidering the age-limit of the commissioning couples, composition of the registration authority and ensure the timing of introduction of this ART Act is in line with notification of the Surrogacy Act, 2020.

Key words: Assisted Reproduction Technology, Commissioning Couple, Donors

1. Background

India has become a major center of the global fertility industry and for reproductive medical tourism. Among Asian countries, India's Assisted Reproductive Technology (ART) market is at the third position and growing at an annual growth rate of 28%.(Banker,2019) There is a huge demand for ART in India, as fertility problems continue to become more common.(Nadimpally, et.al ,2016) A report in 2015 revealed almost 27.5 million couples were trying to conceive despite issues with infertility, and by 2019, it was estimated that 10-14% of the Indian population is affected by infertility.(Baliga,2018) A recent study valued the Indian In-Vitro Fertilization market which alone stood at USD 478.2 million in 2018, projected at USD 1,453 million by 2026.(Kunsel and Sumant 2019)

ART is used to **treat infertility.** It includes fertility treatments that handle both a woman's egg and a man's sperm, outside the body depending upon the type of ART procedure. (Centre for Disease control and Prevention, 2021) It includes all techniques that attempt to obtain a pregnancy by manipulating the sperm or the oocyte outside the body and transferring the gamete or embryo into the reproductive system of the woman.[1](ART Bill ,2020) Some different types of ART procedures include:

a) In Vitro fertilization (IVF)- IVF works by removing eggs from a woman's body. The eggs are then mixed with sperm to make embryos. The embryos are then transferred back in the woman's body. IVF is the most common and effective type of ART. (Centre for Disease control and Prevention, 2021)
b) Intracytoplasmic sperm injection (ICSI)- It is a type of IVF for male infertility, where a single sperm is injected into a mature egg. (Centre for Disease control and Prevention, 2021)
c) Intrauterine Insemination (IUI)- In an IUI, sperm is collected from the partner and is inserted into the uterine cavity, after being processed in a laboratory. (Society for Assisted Reproductive Technology, 2018)
d) Zygote intrafallopian transfer (ZIFT) - Fertilization happens in the laboratory. A young embryo is transferred to the fallopian tube instead of the uterus. (Centre for Disease control and Prevention, 2021)
e) Gamete intrafallopian transfer (GIFT)- In this procedure, sperm and eggs are transferred into the woman's fallopian tubes. Fertilization takes place inside the woman's body. (Centre for Disease control and Prevention, 2021)

ART procedures sometimes use donor eggs, donor sperm, or previously frozen embryos. It may also involve a **surrogate mother.** A surrogate mother is a woman who bears a child, through surrogacy from the implantation of embryo in her womb. [2](ART Bill, 2020) This child is genetically related to the intending couple who are medically certified infertile and have decided to become parents through the surrogacy.[3] (ART Bill 2020) Thus, the embryo implanted in the surrogate mother's womb is generated from the sperm and the oocyte of the husband and the wife who form the intending couple.

[1] S. 2(c) of the Assisted Reproductive (Regulation) Technology Bill, No. 97 of 2020. (ART Bill)
[2] S. 2 (f) of the ART Bill.
[3] S. 2 (r) of the ART Bill.

1.1 Evolution of ART

The first child born out of Invitro fertilization was Louise Brown on 25th July 1978 in Royton, Oldham England. Robert G Edwards was awarded the noble prize in 2010. The first successful birth by ICSI technique was developed by Gianpiero D. Palermo, on 14th January 1992. From then onwards there has been a rapid growth in children born through ART and about 8 million children worldwide as of 2018. (ESHRE, Bauquis 2018) An ICMR (2015) study found that in India there are 1657 ART clinics of which 385 have the necessary infrastructure and trained manpower and have registered while about 802 are not part of the national registry yet. There is no authenticated data regarding the number of children born through ART in India. (Kalra 2016)

With this immense scientific advancement and rapid rise in demand and utilization, there has arisen a need for a comprehensive legal framework. The Bill seeks to regulate this growing sector, with the aim of providing a legal framework to ensure certain ethical standards in for ART and to prevent misuse. This paper puts forth an analysis of the Assisted Reproductive Technology, Bill, India 2020 and presents certain alterations and comments for the same. It also gives a short overview of experiences of other countries in attempting similar legislations. It outlines certain social and ethical aspects which surround ART, and which may be taken into cognizance by policy makers. It stresses on the need to make ART accessible and affordable & presents a discussion regarding costs & expenses of present ART regimen.

2 Salient Features of the draft Bill

2.1 National Board: The Bill provides that the National and State Boards established under the Surrogacy Act will serve as the respective boards to oversee the use of ART in India. According to the s. 14(2) of the Surrogacy (Regulation) Bill, 2019, the National Board is to consist of

a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, ex officio.
b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, ex officio.
c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, ex officio.
d) three Members of the Ministries of Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, ex officio.
e) the Director General of Health Services of the Central Government, Member, ex officio.
f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—
    1. eminent medical geneticists or embryologists.
    2. eminent gynecologists and obstetricians or experts of sthree-roga or prasuti-tantra;
    3. eminent social scientists.
    4. representatives of women welfare organizations; and
    5. representatives from civil society working on women's health and child issues, possessing such qualifications and experience as may be prescribed.

g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, ex officio; and

h) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, ex officio.

The National Board will advise the government on policy matters, lay down a code of conduct, maintain a National Registry amongst other functions. It will also develop minimum standards and procedures for laboratory and diagnostic equipment and practices that are to be followed by employees to fertility clinics and sperm banks.

2.2 State Boards: State Boards shall have the responsibility of the policies and plans laid down by the National Board for ART clinics and ART banks in the state. The ART Bill provides that the state boards constituted under s. 24 of the Surrogacy Bill, are the State Boards for the ART Bill as well. S. 24 of the Surrogacy (Regulation) Bill, 2019 provides that.

The State Board shall consist of

a. Minister in-charge of Health and Family Welfare in the State, Chairperson, ex officio.
b. Secretary in-charge of Department of Health & Family Welfare, Vice-Chairperson, ex officio.
c. Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, ex officio.
d. Director-General of Health and Family Welfare of the State Government, member, ex officio.
e. Three women members of the State Legislative Assembly or Union territory Legislative Council, members, ex officio.
f. Ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—
    1) eminent medical geneticists or embryologists.
    2) eminent gynecologists and obstetricians or experts of sthree-roga or prasuti-tantra.
    3) eminent social scientists.
    4) representatives of women welfare organizations and
    5) representatives from civil society working on women's health and child issues,
    6) possessing such qualifications and experiences as may be prescribed.

g. An officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, ex officio.

2.3 National Registry: The Centre will, through notification, establish a National Registry of Clinics and Banks serving as a centralized database of all ART clinics and ART banks in the country. The database will also include information on the nature and types of services provided by ART clinics and ART banks, the outcome of the services and other relevant information. S.2 (d) defines an ART bank as an organization which has been set up to supply sperm or semen, oocytes or oocyte donors to the art clinics or the patients. An ART clinic is any premise which is equipped with requisite facilities and appropriate medical practitioners for performing procedures related to ART. [4] (ART Bill, 2020)

[4] S. 2 (e) of the ART Bill.

2.4 Registration Authority: The Bill provides for the appointment of a Registration. authority within 90 days of the commencement of the Act by the Central government for UTs and by state governments for respective states. The Registration Authorities will be composed of three ex officio members, one woman from a women's organization and one eminent medical practitioner. They will grant, suspend, or cancel the license of an ART clinic or ART bank, enforce the standards to be met by the ART clinics or ART banks, investigate complaints of breach of the Act's provisions and supervise the implementation of the Act and the rules and regulations made under it.

2.5 Duties: The Bill lays down duties of ART clinics and banks. These include providing counseling services, testing donors for diseases, making the commissioning couple[5] (ART Bill 2020) or woman aware of the rights of the child, informing them of costs and risks of the procedure involved and maintaining a grievance cell, amongst other functions. As per the Bill, information such as advantages and disadvantages of the procedure, chances of success & rights of the child will be provided to arrive at an informed decision.

2.6 Confidentiality: ART clinics and ART banks will maintain confidentiality regarding the donor, commissioning couple, and woman. The information will be provided only to the database maintained by the National Registry, in a medical emergency at the request of the commissioning couple, or by an order of a court.

2.7 Age: ART treatment services shall be applied to a woman above the legal age of marriage and below the age of fifty, and a man above the legal age of marriage and below the age of fifty-five years. ART banks will obtain semen from males between twenty-one years of age and fifty-five years of age, both inclusive and oocytes from females between 23 and 35 years of age.

2.8 Preimplantation genetic diagnosis: Embryos will be screened for known, pre-existing, heritable, or genetic diseases or for such other purposes as may be laid down by the National Board.

2.9 Consent: ART treatment will be provided only after informed written consent of all the parties.

2.10 Insurance coverage: No ART clinic shall perform treatment unless an insurance cover for the oocyte donor, by the commissioning couple or woman, is provided through an insurance company or agent for guarantee of compensation for specified loss, damage, complication, or death of oocyte donor during the process of oocyte retrieval.

2.11 Research: The gamete of a donor or embryo will be stored for a maximum period of ten years after which it can either be destroyed or donated to a research organization with the consent of the relevant parties. Similarly, an embryo with pre-existing heritable or genetic disease can be donated to a research organization if the commissioning couple or woman gives consent.

2.12 Rights of the Child: Any child born through ART will be considered the biological child of the couple that commissioned the child and shall be entitled to all the rights and privileges available to a natural born child. The donor relinquishes all parental rights over the child born from their gamete.

[5] S. 2 (g) of the ART Bill – "commissioning couple" means an infertile married couple who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorised of the said clinic or bank;"

2.13 Penal Provisions: Trafficking of human embryos, exploitation of the commissioning couple or the donors, providing sex selection services, abandoning, or exploiting the child born through ART, using intermediaries to obtain donors etc., are punishable offences under proposed legislation[6]. (ART Bill 2020) There are penalties prescribed for advertising sex selection by clinics as well.

But it is important to note that, for the same offence of advertisements relating to facilities of pre-natal determination of sex, mentioned in the Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 (PCPNDT Act), the punishment outlined is different. While the ART bill provides for a punishment of a minimum of 5 years imprisonment which may be extended to 10 years, or a fine not less than Rs. 10 lakh which may be enhanced to Rs. 25 lakhs, or both[7],(ART Bill 2020) the PCPNDT Act, outlines a lesser punishment of imprisonment for a term which may extend to three years and with fine which may extend to ten thousand rupees.[8] (PCPNDT Act 1994)

The legislature needs to ensure consistent construction of laws and therefore in furtherance of the same, needs to ensure that there is no difference between the punishment for the similar offences outlined under the ART bill and the PCPNDT Act.

Malpractice by medical geneticists, gynecologists, and registered medical practitioners such as trafficking in embryos will result in punishment of Rs 5 lakh extendable up to Rs 10 lakhs for first contravention. In case of second contravention, a prison term of not less than 8 years and extendable up to 12 years, and a fine of Rs 5 to Rs 25 lakh is prescribed.

3. Review of literature

3.1 ART legal framework of G12 countries

The legal framework for assisted reproduction technology of **G 12 countries**[9] (G12, 1984) were reviewed and is presented in **Table-1**. Though these regulations may not be ideal for all context, it tries to ensure the health and safety of women utilizing ART and the children resulting from these technologies. (Riggan, 2010)

[6] S. 33, ART Bill, 2020
[7] S. 32 (2), ART Bill, 2020
[8] S.22, PCPNDT Act, 1994, pp 15
[9] The Group of Twelve or G12 is a group of industrially advanced countries whose central banks co-operate to regulate international finance. Note that the G12consists of thirteen countries. The twelve refers to the original ten members of the International Monetary Fund who formed the original Group of Ten, plus Spain and Australia. Switzerland when they joined in 1984 the name was not changed.

Table 1: Comparison of ART legislation in G12 countries

Sl. No.	Country	ART Law	Features
1	Australia	*Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*	1. Law prohibits reproductive cloning and allows states to either permit or prohibit research cloning. 2. Prohibits germline modification and the commercial trading of human eggs, sperm, or embryos. 3. Strict recording of the outcomes of ART. 4. The prohibition of non-medical sex selection and commercial surrogacy. 5. Non-commercial or altruistic surrogacy is permitted by some Australian states
2	Belgium	*Law on Research into Embryos In Vitro* 2002 and the *Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes* 2007.	Same as Australia - 1. As of 2003, ART is completely covered by Belgium's national health plan. 2. This insurance provides up to 6 cycles of ART for women ages up to 42 3. Women over the age of 42 are ineligible for ART 4. Limits number of embryos transferred per cycle to 2 for women under the age of 36 and 3 under the age of 40
3	Canada	*Assisted Human Reproduction Act* (2004)	1. In addition to the above the principle of protection of the health and well-being of children born through the application of assisted human reproductive technologies" and that of women are given due importance 2. Discourage discrimination due to sexual orientation and marital status
4	France	*Bioethics Law No. 2004-800* (2004)	1.Same as Australia 2.Surrogacy is also prohibited. 3.National health plan provides complete coverage for ART to heterosexual couples who are of reproductive age and are married or have lived together for two years. 4. Preimplantation genetic diagnosis is permitted only if one of the parents has a serious genetic disorder
5	Germany	*Federal Embryo Protection Law 1990,* the *Adoption Brokerage Law 2006,*	1.Same as Australia 2. Only 3 eggs can be fertilized and transferred in one cycle
6	Italy	*Medically Assisted Procreation Law* (2004)	1.Genetic testing for non-medical purposes is prohibited. 2. The use of ART is restricted to stable heterosexual couples who live together, are of reproductive age, are over the age of 18, have documented infertility, and have been first provided the opportunity for adoption.

7	Japan	*Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* (June 2001).	1.Same as Australia 2. ART activities are regulated by voluntary guidelines produced by the Japan Society of Obstetrics and Gynecology. 3. Research Cloning is permitted
8	Netherlands	*Act Containing Rules Relating to the Use of Gamete and Embryos (Embryos Act)* (July 1, 2002) and the *Commercial Surrogacy Act* (November 1, 1993)	*1.Same as Australia* *2. Act* prohibits commercial and professionally arranged surrogacy
9	Spain	*Assisted Human Reproduction Techniques, No. 14/2006* (May 27, 2006) and the *Biomedicine Law 14/2007* (July 3, 2007)	1.Surrogacy is not recognized in Spain. 2.The commercial donation of gametes is allowed for assisted reproduction and research, although only 6 children can be born from the same donor.
10	Sweden	*Ethics Review of Research Involving Humans, Law No. 460* (2003), and the *Genetic Integrity Act, Law No. 351* (2006)	1.Same as Australia 2.Sweden provides financial coverage for ART to couples who are married or are in a stable relationship. 3. Only one embryo can be transferred per cycle and 2 in older women 4. Embryos can be cryopreserved up to 5 years
11	Switzerland	*Medically Assisted Reproduction* (1998), the *Federal Act on Research Involving Embryonic Stem Cells* (2003), and the *Federal Law on Medically Assisted Reproduction* (2004)	1. Switzerland limits the number of embryos transferred per reproductive cycle to three. 2. requires cryopreserved gametes and embryos to be destroyed after five years.
12	United Kingdom	*Surrogacy Arrangement Act (*1985), the *Human Embryology & Fertilization (HFEA) Act (1990)*, and the *Human Reproductive Cloning Act*	1. Same as Australia 2.The HFEA limits the number of embryos transferred per reproductive cycle to 1-2 embryos for women under the age of 40. A maximum of three embryos can be transferred to women over 40. 3.The HFEA also prohibits commercial egg and sperm donation.
13	United States	*Fertility Clinic Success Rate and Certification Act of 1992*	1.Seven states have legislation that prohibit human cloning for both reproductive and research purposes, while eight states ban reproductive cloning.

			2.Other states prohibit commercial surrogacy or regulate surrogacy agreements. 3.Several states require private insurance coverage of ART and regulate the donation of sperm, eggs, and embryos. Only Pennsylvania extensively regulates and monitors ART clinics and activities.

3.2 ART legislations in the European Union (ESHRE, 2020)

Although in all European country legislation is there regarding ART there are major differences in the details of those legislations. A survey performed by the European IVF Monitoring Consortium of the European Society of Human Reproduction and Embryology (ESHRE) to review the legal and funding framework of 43 European countries has found that almost all of them (with the exceptions of Albania, Bosnia and Herzegovina, Ireland, Romania, and Ukraine) now have specific legislation in place. The key variation found across different countries are:

Access to treatment: In 11 of the 43 countries relationship status permitted for ART are only for heterosexual couples with a diagnosis of infertility. The upper age limit in 34 of the 43 countries was limited to age ranging between 18-51 years. There is evidence that pregnancy at advanced age of parents can cause issues to the children both medical and psychological. (O'Neill and Blackmer 2015)

Third Party donation: All countries permit donor sperm for IVF and intrauterine insemination. Egg donation is banned in **Germany, Norway, Switzerland,** and **Turkey.**

Fertility preservation: The freezing of eggs (and sperm) for the preservation of fertility medical reasons is allowed in all countries, despite an absence of specific legislation in 17 of them. Non-medical ("social") egg freezing is not permitted in **Austria, France, Hungary, Lithuania, Malta, Norway, Serbia,** and **Slovenia**, but is allowed in **Germany** and **Switzerland**.

Public funding: No assistance is provided in 4 countries while limits to funding are defined in all the others based on age of the women, previous children and maximum number of treatments supported. Generous public schemes are found in **Denmark, France, Sweden**, **the Netherlands**, **Belgium**, **Czech Republic**, and **Slovenia**; in the latter three countries funding is linked to a clinical policy, such as the number of embryos transferred (relative to female age) and the rank of the treatment attempt.

3.3 Legislative progress of assisted reproduction techniques in Muslim countries

It is especially useful to understand the legal provisions in predominant Muslim population countries as they may be different due to the restrictions placed on women (Kooli 2020) but these countries have encouraged treatment, and the cure of infertility is permissible. (Al Bar and Hassan 2015)

Table 2: Key features of the legal mechanism in Muslim countries

Sl. No.	Country	ART Law	Features
3.3.1.	**Algeria**	Law No. 18-11 July 2018 dealing with health matters	Art 371- formal request from legally married infertile couples. Donation/sale of gametes, embryos/sperm is strictly prohibited Art 374 prohibits collection of embryos for research Art 375 prohibits sex selection and human cloning
3.3.2.	**Bahrain**	Medical techniques for artificial insemination and fertilization (MTAIF)	1.Only for married couples with formal consent subject to continuity of the relation of marriage. 2. Men's sperm cannot be used to fertilize other than egg of any other women except his wife 3.Human cloning, sex selection, donation of gametes/embryos, research, use of stem cells to treat infertility in others, surrogacy is forbidden 4.Only one embryo in women less than 35 years and up to 3 embryos for women greater than 35 years in one cycle to be placed 5.Storage of sperms, eggs and tissues permitted for 10 years and embryos 5 years 6.Establishment of sperm, and embryo banks, import and export of sperms, eggs and embryo are prohibited
3.3.3.	**Egypt**	Professional Ethics Regulations of the Egyptian Medical Syndicate	1.Third party reproductive assistance disallowed 2. Follow the Islamic rules as stipulated in al-Azhar declaration on IVF and Intra-uterine insemination (IUI) 3. Rest same as Bahrain
3.3.4.	**Jordan**	No specific law. Jordanian government adopted the Law 25 of 2018 regarding medical and health accountability The Jordanian Stem cell bylaw of 2014	1.Similar to Bahrain 2.Stem cell Law sets forth rules for the collection, storage, dispensing, and conduct of research on stem cells, including embryonic stem cells is permitted only in public institutions in accordance with Islam and Sharia's law
3.3.5.	**Lebanon**	No Specific law. A chapter regarding assisted reproduction techniques was introduced in the 1994 law of the medical ethics	1.Similar to Bahrain 2. Permits stems cell research under specific conditions
3.3.6.	**Malaysia**	Malaysian Medical Council (MMC) issued two main regulations. The first one is related to the	1.Similar to Bahrain 2. Permit's stem cell research 3. No penal provisions if deviations found 4. storage and disposal of gametes guidelines are vague

		assisted reproduction, and the second one concerns the stem cell research and therapy	5.Course to surrogacy is not clear and mainly relies on the beliefs of the couples
3.3.7.	**Morocco**	Draft law 47.14 regarding the Medical Assisted Reproductive Techniques adopted in July 2018	1.Similar to Bahrain
3.3.8.	**Pakistan**	No Specific law available. In 2016, the National Bio-ethics committee (NBC) adopted the Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM). In addition, in collaboration with the human organ transplant authority, the NBC adopted the Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan (SCRRP).	1.Health practitioners are not allowed to terminate the pregnancy for obtaining fetus for stem cells research or for transplantation. 2.It is not allowed to create embryos for the sole purpose of obtaining stem cells. 3. Stem cell research is permitted as per the guidelines 4. Commercial use of HBM plausible and stressed the need to conceive suitable forms of compensation or benefit sharing
3.3.9.	**Qatar**	No specific law available regulating the use of medical techniques for artificial insemination and fertilization. Qatar Ministry of Public health issued guidelines for human stem cell research and Qatar supreme council of health adopted the Guidelines, Regulations and Policies for Research Involving Human Subjects.	1.Contain a chapter dedicated for reviewing additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research
3.3.10.	**Saudi Arabia**	Law of Units of Fertilization, Utero-Fetal, and Infertility Treatment 2004.	1.Similar to Bahrain

		Law of Ethics of Research on Living Creatures Regulations:	
3.3.11.	**Sultanate of Oman**	2017, the Omani Ministry of Health issued the Fertility Centre Standards and Regulations for Private Sector As per Sharia'a Law and Islamic rules and regulations	1.Similar to Bahrain
3.3.12.	**Tunisia**	law No. 2001-93 of the 7th of August 2001 on reproductive medicine.	1.Similar to Bahrain 2. Does not cover the issue of the number of embryos that could potentially be placed in the uterus of the female. 3.The ethical question of the security of the pregnant and the fetus is neglected. 4. The issue of sex selection was not also treated.
3.3.13.	**Republic of Turkey**	The first regulatory framework for assisted reproductive treatment was introduced in 1987 and during 3rd of March 2010, they adopted a new regulation	1.Similar to Bahrain
3.3.14.	**United Arab Emirates**	Federal Law 2008 regulates the recourse for the Assisted Reproductive Techniques.	1.Similar to Bahrain 2.Limited the number of embryos or ova to be transferred to a maximum of three, if the wife is aged 35 years or under. In all other cases, a maximum of four embryos was settled.

4. Social Aspects of ART

To prioritize health problems based on quantitative assessment of the disability-adjusted life years (DALYs) lost due to the disability, the World Bank report *Investing in health*, published tables quantifying the burden of disease in females by cause. Seeing that infertility was not included, Fathalla (Fathalla 2002) observed that, had DALYs, been substituted with QALYs (quality- adjusted life years), the ranking would differ. He suggested that if ranking had been based on how the disability is perceived and not just based on productivity loss, infertility would have ranked higher on the list.

"*The physical and psychological burden the infertile couples are willing to go through, and the financial cost couples are willing to pay if they can afford it, attest to the high ranking of infertility as a perceived burden of disease*." (Fathalla 2002, 5)

The failure in making ART and addressing infertility as a social priority, rests in this misguided notion that infertility does not have devastating and material consequences. (Macklin 1995) This is because infertility is not seen as a detriment to health since it does not always manifest as a disease. It should be noted that health is not just defined by the absence of disease. Health revolves around one's mental and social well-being as well.

As we will see below, there are numerous threats to one's social well-being that are engendered by infertility. Many studies have revealed the numerous consequences of childlessness faced by infertile couples. (Gerrits 1999; Mulgaonkar 2001; Unisa 1999; Widge 2001) It is in this context that ART should be looked at to address the demand, understand its accessibility and to ensure informed consent of parties when choosing to undergo this procedure under the intense social pressure.

Understanding gender issues and expectations is the key to decode the social motivations behind the utilization of ART. This is because societal expectations of marriage revolve around women's role as mothers and men's virility as a symbol of masculinity. There is no denying that producing of a 'biological' child remains one of the main expectations of marriage. Given that reproduction and motherhood are central to a woman's identity according to society's expectations, feelings of inadequacy thus develop among the couple. In such an atmosphere, infertility is associated with a lot of stigma which in tun puts tremendous pressure on the couple to produce a biological child.

As Das Gupta, Chen and Krishna have pointed out, even though in today's world there has been an expansion in woman's roles, reproduction continues to be a significant factor that determines the 'socio-economic wellbeing' of most of the women in India. (Das, Chen and Krishnan 1995)

This pressure is exacerbated by the joint family system as evidenced by the study conducted by Jindal and Gupta. (Jindal and Gupta 1989) They also found that social problems increased among couples who were married longer and increased as duration of infertility increased. But these social problems were inversely related to education of the couple, the economic independence of the woman and the income of the husband. The social problems were due to the insistence of producing a male child and occurred among couples facing primary infertility as well as secondary infertility when the first child was female. 34% of infertile women reported having problems with the in-laws and 16% reported having problems with the husband.

A psychological study (Desai, Shrinivasan and Hazra 1992) conducted to understand the emotions of infertile couples found that infertility results in a stressful life and several invisible losses like marital instability and decrease in quality of life, the brunt of which are largely faced by women. 40% of men put the blame on their wives, while 36% of women felt they were responsible even when they were not the ones infertile. This fact of women being blamed for infertility regardless of husband's role in it has also been revealed by several other studies. (Devi YL 1980; Mulgaonkar 2001)

In another study, it was revealed that the "social acceptability of a woman, her legitimate role of a wife, her marital stability, security, bonding and her role in the family and community" (Prakasamma 1999) were all threatened by infertility. In Unisa's study (Unisa 1999) on childlessness in Andhra Pradesh, two-thirds women experienced violence at the hands of their husbands and 13% felt that their childlessness had played a role. Other than physical abuse, threats of second marriages were floated by husbands because of the couple's childlessness. But education as mentioned earlier, did

change women's circumstances. When it was understood that the woman was not solely responsible for the infertility and that infertility was treatable, women's circumstances improved.

Thus, there is a need for a public health campaign that imparts awareness regarding infertility. This is important so that couples know that infertility is treatable and that women are not always the one to blame. They should also be aware of their options if they have interest in having children. This is especially important not only to ensure that they know about ART, but so that they are introduced to other alternative measures as well like adoption or less invasive procedures like intrauterine insemination. (Hodson, Nathan and Bewley 2019)

A regulatory legislation for ART, should thus go hand in hand with a public health campaign about infertility to tackle the consequences to one's social wellbeing that is affected by infertility.

5. Ethical aspects of ART

5.1 Financial Aspect for IVF Treatment: Perhaps one of the most obvious ethical challenges surrounding ART is the inequitable distribution of access to care. The fact that significant economic barriers to IVF exist in many countries results in the preferential availability of these technologies to couples in a position of financial strength.

5.2 Preimplantation Genetic Testing: This is the process by which potentially harmful genetic diseases are identified in the human embryos before they are transferred to a uterus. Pre-implantation genetic diagnosis (PGD) can identify embryos "that have inherited single gene defects in gametes from known carriers or affected individuals when using their own gametes, not donor gametes." (O'Neill and Blackmer 2015) All types of genetic predispositions and conditions can be identified using this process. Thus, PGD has given rise to several ethical concerns regarding its use. (O'Neill and Blackmer 2015)

Soon, with refinements in microarray technology and the defining of genetic sequences associated with certain physical characteristics, it is conceivable that specific physical or mental characteristics may be evaluated to guide the decision as to which embryos to transfer. This possibility raises concerns on both ethical and practical levels. Of utmost concern is also the possibility that in the future, technology will permit the manipulation of genetic material within an embryo. (O'Neill and Blackmer 2015)

This has meant that PGD can potentially be associated with eugenic practices. Concerns regarding use of PGD for convenience rather than for medical purposes has led to recommendations for the banning of this procedure. Countries like Austria, Italy, Luxemburg, Ireland, and Switzerland have carried this out and thus, prohibit PGD. (Duguet, Anne-Marie and Bénédicte 2017) Rigorous public and scientific oversight of these technologies is vital to ensure that scientific advances are tempered with the best interests of society in mind.

5.3 Fertility Preservation: Female fertility is well documented to decrease with age. Recently, several laboratories have demonstrated the ability to successfully cryopreserve oocytes following an IVF cycle. These developments have profound implications. As the birth control pill gave women the

ability to prevent pregnancy, oocyte cryopreservation may give women the flexibility to preserve their fertility potential, starting at a young age, while postponing childbearing. However, as this technology at the present time in many countries is generally only available to those with financial means. This poses ethical and social issues that will certainly need more attention in the future.

5.4 Gamete Donation: The use of donor gametes, either in the form of donor sperm or donor oocytes, is commonplace in ART. Another ethical and legal issue surrounding the use of donated gametes is to what extent the anonymity of the donor should be preserved. The ethical and legal issues surrounding anonymity and gamete donation are sure to be a centrally debated issues within the field of ART for the foreseeable future.

5.5 Embryo Donation: IVF cycles often result in couples transferring several embryos and cryopreserving other embryos produced by the cycle, presumptively for the purpose of a future pregnancy. The ethical and moral issues surrounding how to deal with these surplus embryos have been the source of much debate. In general, four possible fates for these embryos exist:(1) thawing and discarding (2) donating to research (3) indefinite storage (4) donating the embryos to another couple for the purposes of uterine transfer.

5.6 Possible Deleterious Effects of ART: There are questions that remain outstanding regarding the use of ART such as college girls donating eggs for quick money. Since oocyte donation is more complicated than sperm donation, it is a procedure that results in higher financial compensation for women who donate their eggs. Due to this woman in need of money undergo these procedures, with the sole motive of financial incentive without fully understanding specifics and consequences of such processes (Mukherjee, Manjeer and Nadimipally 2006). This is of special concern in India due to the rampant poverty that prevails. It is also seen that women with 'special characteristics' are given high payments. This is concerning because it leads to the notion that oocytes are commercial property and may also objectify children by basing their value on their physical characteristics rather than seeing this value as intrinsic. (ASRM 2000)

5.7 Other questions that come up, relate to egg donors seeking parental rights, excess eggs from IVF patients being used for research with / without consent, Egg donor recruiters ignoring ethical standards and Menopausal recipients above 50 years. Further a recent study (Pinborg 2019) on outcomes of children born out of ART has shown that marked reduction in ART multiple births have improved perinatal outcomes. There is not much difference in neurodevelopmental health and school performance between ART children and spontaneously conceived children. There is no increase in occurrence of cancers either in childhood or adulthood due to conception through ART. Cardiometabolic health risk is still an issue which needs further review.

5.8 Informed decisions: As we have seen before, there are a number of ethical and social issues attached to ARTs. The decision to undergo the procedures, should be based on an informed choice. Given that the progress in ART, has made it very difficult for women to not opt for maternity, they should be able to make their choice independent of society's expectations of them, by basing the decision on their willingness to go through the entire process of ART.

All the parties participating in the procedure should be provided with a full disclosure of all potential medical, emotional outcomes and risks (Shanner 1995). This can be done with the help of supportive

counselling which can also help prepare for disappointing outcomes like medical complications, multiple births, pregnancy loss and inability to attain pregnancy through the process. (Zolbrod 1993)

This is especially important since clinicians and the media create an overly positive and optimistic atmosphere through their choice of words in explaining the results and specifics of the procedure (like 'miracle babies') and by focusing largely on the success rates. This can set the parties up for disappointment if associated risks are downplayed and they are not clearly told the truth of the failure rates. (Shanner and Nisker 2001)

As per the recommendations agreed upon during a meeting on medical, ethical and social aspects of assisted reproduction, held at WHO Headquarters in Geneva, Switzerland, "informed consent provided by the donors of gametes, prior to their donation. should address all possible immediate and future uses of the gametes:

- for gamete or embryo research
- to create embryos that will be used for treatment of the donors.
- to create embryos that will be used to treat others.
- the final disposition of the gametes if not used for treatment or research.
- The gamete providers should state what can, and cannot, be done with the gametes they provide, or the embryos derived therefrom." (Vayena, 2002)

Thus, there are multiple social and ethical aspects of ART that need to be considered while understanding how best to regulate this sector. In furtherance of this pursuit of regulating the ethics of ART, some alterations and additions have been suggested for the proposed bill, below.

6. Observations of the draft bill and recommendations[10]

6.1 Composition & guidelines of the Registration Authority could be re-examined

The Bill mentions that the Authority will consist of an "eminent medical practitioner".[11] (ART Bill, 2020) But, it is essential for the Authority to have a minimum of one eminent Obstetrician and Gynecology (OBG) specialist with ART specialization or at least a MS OBG. The Authority should also consider including Retired judges of Supreme Court or High Court. If this is not possible, law officers with appropriate training should be included after proper assessment of their qualifications.

Including members who have experience in the judiciary would also help make sure that the disciplinary procedures against doctors and clinics, which the Authority has power to undertake for conducting inquiries and searches[12],(ART Bill ,2020) are undertaken in a proper manner as per the provisions in the Code of Criminal Procedure, 1973[13]. (CrPC)

[10] Based on expert feedback and stakeholder consultation
[11] S.12, clause 3(v) of the ART Bill.
[12] S. 20 of the ART Bill
[13] S.93,94,95,97,100,165 of CrPC

It should be ensured that the provisions of this Act are consistent with the provisions of the Clinical Establishment Act, 2010 (CEA). All clinics made to apply for registration under this Act should also be registered under the CEA, when it is promulgated in the states. When brought under the CEA, treatment costs and compliance with standard treatment guidelines of the ART clinics/banks can be regulated better.

Section 16 (5) of the of the bill, which deals with the Grant of Registration, provides that "No registration shall be granted unless the State Board has inspected the premises of the applicant." It would be better to ensure that this inspection is the function of the Registration Authority instead of the State Board.

6.2 More clarity along with specific guidelines for the following points.

It is imperative that minimum standards for ART counselling, clinics, laboratories, personnel, and procedures are explicitly mentioned. To ensure the rights of the parties involved, provisions regarding criteria for approval/rejection of clinics, screening for medical complications and grievance redressal mechanisms should be outlined clearly.

Training for ART centre Coordinators / doctors regarding Standard Treatment Protocols for the procedures should be made mandatory and certification must be given. Standardized Special Insurance Policy for ART related donors should be considered instead of multiple options by different insurance agencies. (At least the minimum extent of coverage must be prescribed.)

Standard prior informed consent form should be devised and adopted across all facilities. Protocols or procedure for winding up or closing Sperm Bank/ Clinic must be clarified in clear words to protect rights of donor and to avoid misuse of samples in the bank. Public notice of approved and rejected clinics for ART services should be put up by the Registration Authority.

The meaning of "woman" as used in the act may be clarified both in the definition and throughout the act. Does the definition of "woman" in section 2(1)(x) include a single woman who may want to conceive using ART or commission to a surrogate or donate oocyte or the surrogate herself? For example, in section (21) it is not clear who does 'woman' refer to.

The section 24(f) and (g) need more clarity (f) the collection of gametes posthumously shall be done only if prior consent of the commissioning couple is available (who is being referred to as 'posthumously').
(g) the clinic shall not use ovum that are derived from a foetus, in any process of in-vitro fertilization (how can ovum be derived from a foetus)

In section 27, how are the donors to be compensated? The Bill does not say anything about how the donor(s) would be decided? Whether the commissioning party would be allowed to choose the "kind" of donors they want i.e., the donors' caste, class, religion, ethnicity etc.? In adoption, the history of biological parents is confidential and not disclosed to the adoptive parents. ART Bill should not be used to reinforce caste/class/religion/ethnicity-based prejudices.

6.3 Age criteria could be reconsidered.

According to the Bill, 55 and 50 are the upper limits for men and women respectively for applying as commissioning couples for ART.[14] (ART Bill 2020) But, in the draft ART bill released by the Indian Council for Medical Research's (ICMR) in 2017, the upper limit had been 50 and 45 for men and women, respectively. The latter version (the 2017 draft bill) should be included along with additional safeguards for persons above the age limit, such they can be considered based on risk assessment and additional counselling. (World Health Rankings 2018) The Central Adoption Resource Authority guidelines could also be referred for composite age of the commissioning couples for ART. (CARA 2016) These couples should be made aware that their rights under this Act are not absolute and that there may be restrictions that can be applied on a case-to-case basis. This may occur when based on the medical evaluation, it is revealed that the procedure may not be in the best interests of the couple. An example of this may be if they have pre-existing conditions that increase the possibility of early death or the possibility of increased liability on the government of a child born to an older couple (in terms of its guardianship).

Thus, the age criteria should be set to balance individual rights, societal needs, safeguard rights of the unborn from conception to attaining majority and to not result in undue burden on the exchequer.

6.4 Grievance redressal process to be revised.

There is a need to re-evaluate the grievance redressal process since the Bill does not provide for the aggrieved party to directly approach the Court, which is antithetical to ensuring their access to justice. Instead, it provides only for the National Board, State Board or officers authorized by the State Board to approach the Courts.

Clarity regarding who can complain to the Registration Authority against a clinic/bank, is required since S.18 of the Bill does not mention this. This is also important since the grievance cell under s. 21(f) may not address the grievances of the commissioning couple if the complaint is considered internal to the clinic or bank. The rules should specify who would be the members of the grievance cell and that it should have appropriate outsiders/neutral parties too, apart from the clinic/bank representatives. Processes for when matters are not resolved in the grievance cell should be outlined along with the subsequent authorities to be approached and when the commissioning parties/donors/surrogates can approach the consumer court.

Renaming Grievance Cell to Counselling, Grievance Redressal and Mediation Cell of the ART clinic involving trained Medical Social Workers as counsellors and trained mediators with purpose to provide alternative dispute redressal mechanisms can resolve issues locally and reduce litigations.

[14] S.21, clause (g) of the ART Bill

6.5 The following clause in the bill needs to be relooked.

Chapter VI, section 41 mentions that "no suit or prosecution or other legal proceedings shall lie against the central or state government or the registration authority or any other officer authorized for anything done in good faith or intended to be done in pursuance of the provision of the act". This clause is vague, especially the mention of good faith which is subject to interpretation. It also takes away many rights of doctors/clinics /establishments to take the legal route in case of harassment or wrongdoing by the officials. Hence, it must be re-examined.

6.6 The following clauses could be considered for inclusion or alteration.

The commissioning couple definition could be broadened to include in stable relationship at least for 2 years[15] ([1] According to the guidelines issued by the Central Adoption Resource Authority and for whom opportunity for adoption has been provided.

The terminology of commissioning couples needs to be used consistently, since in most places it says, "commissioning couple or woman" and in a couple of places it says, "commissioning couple or individual". There needs to be consistency in the terminology used. Section 28(2) uses the term "commissioning couple or individual" which may be used throughout the Bill instead of "commissioning couple or woman".

The Bill is silent on the health risks to donors and does not provide adequate safeguards. Therefore, it is suggested that guidelines for these safeguards are included in the bill.

The Bill requires an egg donor's written consent but does not provide for her counselling or the ability to withdraw her consent before or during the procedure (unlike for commissioning parties). She receives no compensation or reimbursement of expenses for loss of salary, time and effort. Failing to pay for bodily services constitutes free labour, which is prohibited by Article 23 of the constitution.

Section 24(1) of the bill should provide for adequate compensation to the "woman" (surrogate) if the commissioning party withdraws consent mid-way or make a reference to the Surrogacy Bill for it. The commissioning parties, according to the bill, only need to obtain an insurance policy in her name for medical complications or death; no amount or duration is specified. The egg donor's interests are subordinated in the Bill and needs to be re-assessed. There are possibilities of abuse due to unscientific treatment, including injection of hormones and steroids, which has long term consequences. So, it is further suggested that a provision that requires abiding by the clinical parameters prescribed by the National Board, be inserted.

Unlike the Surrogacy Bill 2020, there is no prohibition on foreign citizens accessing ARTs. Hence, clarity on marital status of foreign couples also needs to be provided and whether they need to provide a marriage registration certificate should be clarified.

[15] According to the guidelines issued by the Central Adoption Resource Authority, married couples may adopt however both spouses must consent to the adoption. Also, no child shall be given in adoption to a couple unless they have at least two years of stable marital relationship.

6.7 Timing of introduction to be in line with notification of Surrogacy Act 2020.

As per the Provisions of the proposed Bill, the National and State Boards established under the Surrogacy (Regulation) Bill, 2019 are to function as boards overseeing ART. The Surrogacy Bill, 2019 has only been passed in the Lok Sabha and is not yet an Act of law. Thus, certain provisions of the ART bill are incumbent on another pending legislation and this needs to be taken into consideration while making this bill into law. Consistency between the two bills and its timing of coming to effect must be ensured as there is dependency.

7. Costs

Utilization of ART is linked to the financial burden that it imposes on the couple. Affordability is one of the main obstacles that many couples can face. Compared to costs around the world, the cost of ART in India is substantially lower. The cost of ART in India varies from city to city. The cost of ICSI ranges from Rs. 20,000 to Rs. 45,000. (Dailyhunt 2021) The following table shows the approximate cost of IVF among different cities in India.

Table 3: Average cost of infertility treatment (Dailyhunt 2021)

City	Average Cost per IVF Treatment Cycle (not inclusive of Medicines and Blood Tests) *
Mumbai	2,00,000- 3,00,000
Bangalore	1,60,000- 1,75,000
Chennai	1,45,000- 1,60,000
Delhi	90,000- 1, 25,000
Nagpur	75,000- 90,000
Hyderabad	70,000- 90,000
Pune	65,000-85,000
Kolkata	65,000-80,000

There are a lot of differences among countries regarding the direct costs of the treatments and USA tops that chart, with the highest direct costs. This difference is because these costs are reflective of the costs of the healthcare system prevalent in the respective country. It has been found that the extent to which treatments are subsidized for different situations and patient groups, has a lot of bearing on the utilization of ART, clinical practice, and infant outcomes. (Connelly et.al 2010) In a study (Chambers, et.al ,2009) that compared the economic aspects of ART in developed countries, it was concluded that

ART is only expensive from the patient's perspective, but not from a societal perspective. It was also revealed that *"only countries with funding arrangements that minimize out-of-pocket expenses met expected demand. Funding mechanisms should maximize efficiency and equity of access while minimizing the potential harm from multiple births."*

A wonderful example of a successful implementation of ART in a developing country is the Colombian Profamilia Programme. This improved accessibility and affordability of ART by increased support of non-profit organizations by the government. (Reproductive Health Outlook) Thus, public-private partnerships can go a long way in making infertility care more equitable. Given that it is the private sector in a few metropolitan cities, that houses most of the state-of-the-art facilities for infertility management and ART services, (Chander, Indira and Kusum 2000) a public-private partnership is very much needed. This could be done through "exchange of expertise or technologies (Chander, Indira and Kusum 2000) between the government and the private sector. For example, a private ART centre can go ahead and perform an IVF for free for a patient unable to afford the treatment, while the government can contribute PGD services to the centre. (Chander, Indira and Kusum 2000) Sharing of equipment can also so help in reducing costs and ensuring "optimum utilization". (Chander, Indira and Kusum 2000)
It should also be noticed that the more the couple is to spend on conceiving the child, more is the probability that the child may not receive the best start in life. This may be exacerbated by unexpected multiple births. Therefore, ensuring affordability is not just in the interest of justice and equity in access, but also to ensure that the result of the entire process- the child, can get a good start in life with parents who are able to meet the demands and costs of raising it.

8. Conclusion

Given the massive expansion in ART facilities and utilization, not just around the world, but in India as well, there is an urgent need for a legal framework to regulate this industry. There are numerous social, ethical, economic, and cultural aspects that need to be taken into consideration while drafting legislation pertaining to ART. The women though are free to make an informed choice they are still limited in their capability due to asymmetry of information, technical nature of the procedure, costs, and pressure to go through the procedure from families. Hence regulation should provide some level of support for the women and ensure she has access to good quality services and providers and redressal in case issues. ART represents a confluence between the social norms, reproductive health, scientific research, and the law.

Therefore, it is imperative that policy makers consider each of these aspects while forming legislation and also ensure appropriate congruence between existing laws and new legislations for similar issues.

Laws:

1. Assisted Reproductive (Regulation) Technology Bill, No. 97 of 2020. https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/BillFile/Bill/14/142/97%20of%202020_2020_10_11.pdf.
2. The Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994. https://www.indiacode.nic.in/bitstream/123456789/8399/1/pre-conception-pre-natal-diagnostic-techniques-act-1994.pdf.
3. Code of Criminal Procedure, Act No. 2 of 1974. https://legislative.gov.in/sites/default/files/A1974-02.pdf.
4. Surrogacy (Regulation) Bill, No. 156-C of 2019.

9. References

1. Banker, Manish. 2019. "41 Years of IVF – the Revolution of Assisted Reproductive Technology!" *ET Health World*, July 25, 2019. https://health.economictimes.indiatimes.com/news/industry/41-years-of-ivf-the-revolution-of-assisted-reproductive-technology/70380646.
2. Nadimpally, Sarojini, and Deepa Venkatachalam. "Marketing reproduction: assisted reproductive technologies and commercial surrogacy in India." *Indian Journal of Gender Studies* 23, no. 1 (2016): 87-104.
3. Baliga, Vivek. 2018. "Infertility in India: The Silent Truth Behind the Booming Population." *Medlife* (blog). September 28, 2018. https://www.medlife.com/blog/infertility-india-silent-truth-behind-booming-population/.
4. Tenzin Kunsel, and Onkar Sumant. 2019. "India In Vitro Fertilization (IVF) Services Market by Gender, Procedure, Cycle Type, End User and Offerings: Opportunity Analysis and Industry Forecast, 2019-2026." A01842. https://www.alliedmarketresearch.com/india-ivf-services-market.
5. Centre for Disease control and Prevention, 2021 "Infertility". https://www.cdc.gov/reproductivehealth/infertility/index.htm.
6. Society for Assisted Reproductive Technology. "The Difference between IUI and IVF - a Patient Education Micro-Video." Sart.org, 2018. https://www.sart.org/patients/fyi-videos/the-difference-between-iui-and-ivf/.
7. European Society of Human Reproduction and Embryology (ESHRE), Christine Bauquis,. "More than 8 million babies born from IVF since the world's first in 1978", ESHRE, 3 July 2018, https://www.eshre.eu/Annual-Meeting/Barcelona-2018/ESHRE-2018-Press-releases/De-Geyter.
8. Aparna Kalra. 2016. "Without Knowing Its Test-Tube Babies, India Seeks to Control Their Lives." IndiaSpend. Indiaspend. October 6, 2016. https://www.indiaspend.com/without-knowing-its-test-tube-babies-india-seeks-to-control-their-lives-95672/.
9. Riggan, Kirsten. "G12 country regulations of assisted reproductive technologies." *Dignitas* 16, no. 4 (2010): 6-7.

10. European Society of Human Reproduction and Embryology (ESHRE). 2020. “Europe Moves towards Complete Statutory Regulation of Assisted Reproduction.” Eshre.eu. 2020. https://www.eshre.eu/Press-Room/Press-releases-2020/ART-in-Europe.
11. O’Neill, S., and J. Blackmer. "A Canadian Medical Association white paper: Assisted reproduction in Canada (An overview of ethical and legal issues and recommendations for the development of national standards)." *Canadian Medical Association, Ottawa* (2015).
12. Kooli, Chokri. "Review of assisted reproduction techniques, laws, and regulations in Muslim countries." *Middle East Fertility Society Journal* 24, no. 1 (2020): 1-15.
13. Al-Bar, Mohammed Ali, and Hassan Chamsi-Pasha. "Assisted reproductive technology: Islamic perspective." In *Contemporary bioethics*, pp. 173-186. Springer, Cham, 2015.
14. Fathalla, Mahmoud F. 2002. "Current Challenges in Assisted Reproduction." In *Current practices and controversies in assisted reproduction: report of a meeting on medical, ethical and social aspects of assisted reproduction, held at WHO Headquarters in Geneva, Switzerland.*, by Effy Vayena, Patrick J. Rowe and P. David Griffin., 3-14. World Health Organization.
15. Macklin, Ruth. "Reproductive technologies in developing countries." *Bioethics* 9, no. 3 (1995): 276-282.
16. Unisa, Sayeed. "Childlessness in Andhra Pradesh, India: treatment-seeking and consequences." *Reproductive health matters* 7, no. 13 (1999): 54-64.
17. Widge, Anjali. "Beyond natural conception: a sociological investigation of assisted reproduction with special reference to India." (2001). [Thesis] Jawaharlal Nehru University, 2000. https://shodhganga.inflibnet.ac.in/handle/10603/15157.
18. Mulgaonkar, Veena B. “A research and an intervention programme on women’s reproductive health in slums of Mumbai.” *Mumbai: Sujeevan Trust* (2001).
19. Gerrits, Trudy. *Involuntary, infertility and Childlessness in resource-poor countriesan exploration of the problem and an agenda for action*. No. F/616.692 I5. 1999.
20. Das Gupta M, Chen LC, Krishnan TN. “Women’s health in India: risk and vulnerability.”*, Oxford University Press*. (1995).
21. Jindal UN, Gupta AN. “Social problems of infertile women in India.” *International Journal of Fertility* 34, no. 1 (1989):30-33.
22. Desai, P., V. Shrinivasan, and M. Hazra. "Understanding the emotions of infertile couples." *Journal of Obstetrics and Gynaecology of India* 42 (1992): 498-503.
23. Devi YL et al. “Social factors contributing to sterility.” *Asian Medical Journal* 23 (1980): 896–900.
24. Prakasamma, M. "Infertility: A social and gender perspective. National consultation on infertility prevention and management." (1999).
25. Hodson, Nathan, and Susan Bewley. "Abuse in assisted reproductive technology: A systematic qualitative review and typology." *European Journal of Obstetrics & Gynecology and Reproductive Biology* 238 (2019): 170-177.
26. O’Neill, S., and J. Blackmer. "A Canadian Medical Association white paper: Assisted reproduction in Canada (An overview of ethical and legal issues and recommendations for the development of national standards)." *Canadian Medical Association, Ottawa* (2015).

27. Duguet, Anne-Marie, Bénédicte Boyer-Beviere. "Preimplantation genetic diagnosis: the situation in France and in other European countries." *European journal of health law* 24, no. 2 (2017): 160-174.
28. Mukherjee, Manjeer, and Sarojini B. Nadimipally. "Assisted reproductive technologies in India." *Development* 49, no. 4 (2006): 128-134.
29. ASRM. 2000. *Financial Incentives in Recruitment of Oocyte Donors.* Committee Report, Fertility and Sterility. As cited in Mukherjee, Manjeer, and Sarojini B. Nadimipally. "Assisted reproductive technologies in India." *Development* 49, no. 4 (2006): 128-134.
30. Pinborg, Anja. "Short-and long-term outcomes in children born after assisted reproductive technology." *BJOG: An International Journal of Obstetrics & Gynaecology* 126, no. 2 (2019): 145-148.
31. Shanner, Laura. "Informed consent and inadequate medical information." *The Lancet* 346, no. 8969 (1995): 251.
32. Zolbrod A. *Men, women and infertility: intervention and treatment strategies*. Lexington Books, 1993. *See also*, Leiblum SR, editor. *Infertility: psychological issues and counseling strategies*. John Wiley & Sons, 1997.
33. Shanner, Laura and Nisker Jeffrey (2001) "Bioethics for Clinicians Series: Reproductive Medicine" *CMAJ* 164, no.11 (2001) http://www.cmaj.ca/cgi/content/full/164/11/1589.
34. Vayena, Effy, Patrick J. Rowe, and P. David Griffin. *Current practices and controversies in assisted reproduction: report of a meeting on medical, ethical and social aspects of assisted reproduction, held at WHO Headquarters in Geneva, Switzerland*. World Health Organization, 2002.
35. World Health Rankings. "Life Expectancy in India." 2018. World Life Expectancy. 2018. https://www.worldlifeexpectancy.com/india-life-expectancy.
36. Central Adoption Resource Authority (CARA). "Eligibility criteria for prospective adoptive parents" 2016. Cara.nic.in. 2016. http://cara.nic.in/Parents/eg_ri.html.
37. "What Is the Cost of IVF in India: Is It Really Affordable?" Dailyhunt, 2021. https://m.dailyhunt.in/news/india/english/the+health+orange-epaper-orange/what+is+the+cost+of+ivf+in+india+is+it+really+affordable-newsid-80848919#:~:text=IVF%20costs%20in%20India%20are,lakhs%20on%20their%20IVF%20treatments.
38. Connolly, Mark P., Stijn Hoorens, and Georgina M. Chambers. "The costs and consequences of assisted reproductive technology: an economic perspective." *Human reproduction update* 16, no. 6 (2010): 603-613.
39. Chambers, Georgina M., Elizabeth A. Sullivan, Osamu Ishihara, Michael G. Chapman, and G. David Adamson. "The economic impact of assisted reproductive technology: a review of selected developed countries." *Fertility and sterility* 91, no. 6 (2009): 2281-2294.
40. Reproductive Health Outlook. "Overview and lessons learned." *Infertility*. http://www.rho.org/html/infertility-overview.html
41. Chander, P. P., H. Indira, and Z. Kusum. "Need and feasibility of providing assisted technologies for infertility management in resource poor settings." *ICMR bulletin* 30, no. 6-7 (2000): 55-62.