Aims & Objectives of TCB

1. To be a Christian voice on ethical issues based on Biblical values



2. To analyze, interpret and engage with the existing and emerging bioethical issues pertaining to health care and research





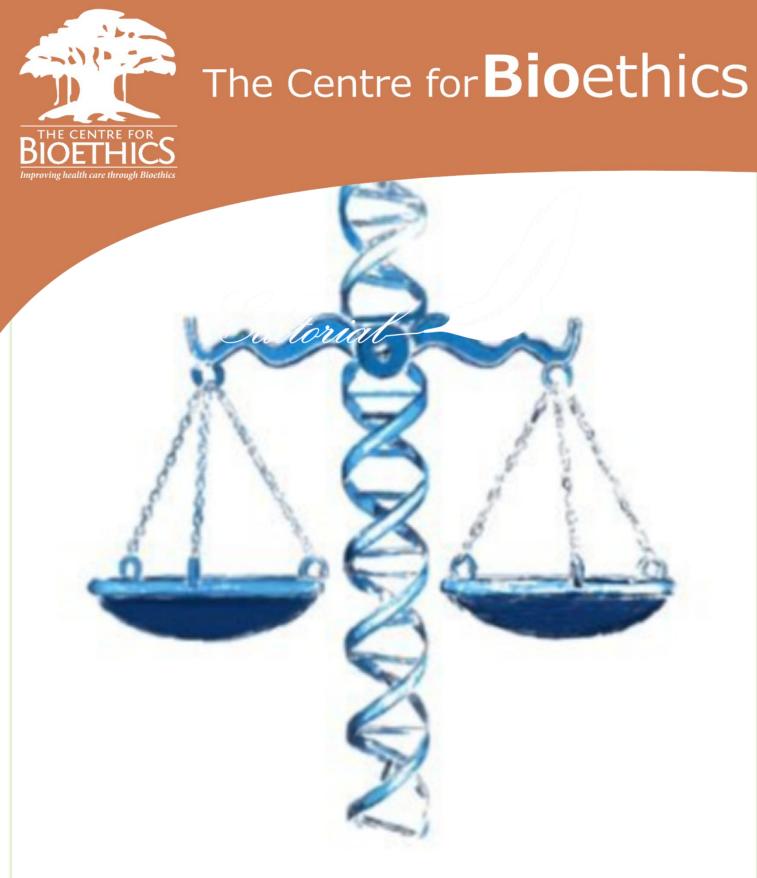
3.To facilitate upholding the sanctity of life and dignity of humans in medical practice and research



4. To promote ethical medical practice



5.To build leadership in the field of Bioethics, in the areas of Medical education, Medical practice and Medical research



Bioethics Bulletin Vol - 4, 2023

Editorial

<u>Artifical Reproductive Techiniques – the artist's intention or</u> <u>the buyer's desire?</u>

Dr. Satish Thomas

Greetings everyone!

Welcome to another issue of Bioethics Bulletin. In this issue, we focus on artificial reproductive technology (ART). As is obvious, our primary concern is the ethical aspects revolving around this topic. However, as this is a relatively new domain, we also need a technical understanding of all that ART involves. It is only as we understand the technical aspects, we can then begin to reflect on its ethical legitimacy and permissibility. So we have a few articles that would serve this purpose.

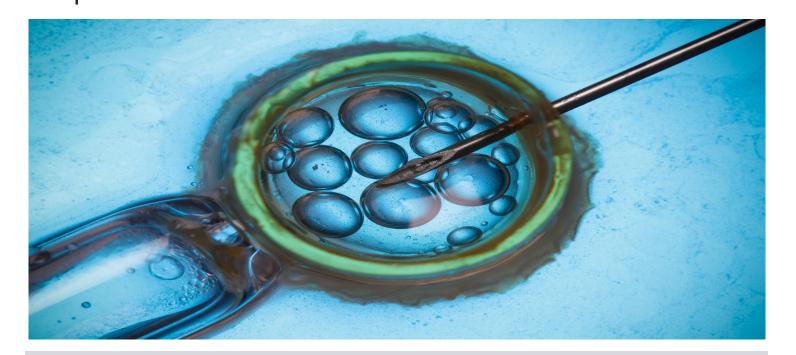
As with any new technological introduction, society gets divided on the ethical aspects. There are likely to be people who see this as humanity's attempt to play God, or as the devil's instrument for destruction of society. At the other end, there will be people who do not even entertain such questions of ethical permissibility, and think that if something can be done, then that's all that matters. Yet, as we have considered previously, it is theological reflection based on the Bible that equips a Christian to wrap his or her head around these ethical considerations. Even in the issue of ART, it is helpful to view it through our analogy of the role of medicine as art restoration. Can ART be justified biblically? Of course, as an idea and a human endeavour. If infertility, and all its causes and effects can be seen as a tragic result of the Fall, we do not need to accept the status quo. Instead, as agents and image bearers of God the creator and sustainer, we take up our mandate to rule and subdue, tend and care for all of creation. Using all our God given abilities and resources, we try to redeem and restore the bad effects of the Fall as much as we can. However, this ought not to be without qualification or limits.

We are standing at a time in human history where a transwoman, a transman, or even a cisgender man might all demand a uterine transplantation because they desire to gestate a baby. It can be done, but does raw desire justify the act?

This is where we need to ask the question, what was the original artist's intention? We as restorers have no license to try and improve upon the original artist's intention. This creation is His work, and He only employs us as co-workers. And this is where for a Christian boundaries need to be clearly drawn where ART transgresses the sanctity of life, the sacredness of marriage, or gender limits.

Yet another concern is the abuse of technology for financial gains. Especially for developing countries like India, in the rural population, there is a huge knowledge gap between the physician and the patient. The patient is entirely dependent on the doctor to guide her and even choose the treatment for her. Therefore, the ethical status of the doctor become a big determining factor in the society. Dr Gigi's examples from counselling only underline this hugely important area which we need to address. The medical professionals more than anyone need to be made ethically competent and morally excellent.

Artificial Reproductive Technology (ART) and Ethics- they go hand-in-hand! Dr. SHINY VARGHESE



In today's day-and-age where technology and the rapid improvement in Science is taking control over every sector, the medical sector is not left far behind. With the advancement in scientific instruments, techniques and measures, the concept of Artificial Reproductive Technology (ART) is merely growing by large amounts on a daily basis. Right from Artificial Insemination in the

18th century, which is recorded to be the first form of ART to varied forms of In-vitro Fertilisation that exists today, ART and Reproductive Medicine has surely come a long way in aiding lives of so many who dream of a successful conception.

The simple and the most straightforward reason to why ART is developing at a rapid rate is due to the increased evidence of infertility among couples today. In 2023, most women are on the

road to becoming independent- whether that's financial independence or independence in the other domains, and in this process which may take years, they often tend to forget, a woman's egg HER age! Infact, each ovary has 600,000-800,000 eggs in the embryological stage which only decreases with time as the female embryo develops and grows. Thus, physiological reasons pertaining to the eggs of a woman is one major cause for the boom of the industry over the last couple of decades.

The right practice while carrying out our responsibilities,keeping in mind and upholding the right morals and ethics is of utmost importance and holds true even while conducting the various processes linked with ART. A couple enters a chilled cubicle of an infertility specialist with hopes of a safe conception, submitting their full and complete trust to the doctor, longing to hold a new life in their hands sooner or later! It is thus, the duty of the expert personnels to ensure every possible ethical measure is taken and kept in mind at all times.

Transparency at every step of the way is something which must be guaranteed. Donor centres where eggs, sperm and embryos are frozen and dealt with must have protocols which allow the parents to track progress at any given point, because, an ART centre without transparency is nothing but cheating patients!

While Science and technology lead us on, let's not forget to ensure Ethics and the right morals are what actually steer the boat of a healthy, normal and safe conception for every seeking couple in our country!

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Today's perspective on Artificial Reproduction

Dr. JENNI GEORGE



. The first chapter of the first book in the bible, Genesis, voices God's command to man – 'Be fruitful and multiply and fill the Earth and subdue it...'.But what can man do when after years of marriage the soil is still barren and dry? Hope, Pray and knock on multiple doors for help. One such door is that of the gynecologist/infertility specialist. By definition(WHO), 'Infertility is a condition of the male or the female reproductive system defined by the failure to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse.'* As a gynecologist situated in a secondary hospital setting in rural India, it is not too common to see a couple seek advice or treatment for infertility.

The patient is always the anxious, stressed out woman at the brink of tears accompanied by her mother-in-law or mother more often than her husband. She waits with a bated breath for our diagnosis as to the cause of infertility as though we are pronouncing a verdict for her future. The male partner is often declared problem-free as long as he can ejaculate or perform and often denies getting tested or treated. This highlights the real social stigma that it is socially, mentally and physically damaging for a childless woman than a man. Womanhood is often defined through motherhood or rather the reproductive capability of women by society. So much against the will of the female patient, at times married for just 3-6 months, she undergoes unnecessary, expensive and invasive testing. This trend is observed more in the population who has delayed child bearing, educated till graduation or post-graduation or in those who are constantly exposed to media. The other side of the spectrum are couples who have been married for more than 7 to 10 years and have exhausted all their resources consulting indigenous practitioners, quacks, brokers or even their local village head. The low cost and easy availability of AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy) medicine attracts more couples in rural areas than seeking advice of a specialist which is perceived to be more expensive and unaffordable in contrast. So the many years of wait are spent in false information and practices rather than timely diagnosis and accurate treatment or information. Simple lifestyle changes, stress reduction, treatment of STI's or just basic counselling might be all it takes for a couple trying to conceive in the early years of marriage. The first few months to years of the gynecologist appointments cover multiple cycles of ovulation inductions, IUI and often surgical procedures like diagnostic hysterolaparoscopy and tubal tests. When all fails, the option of assisted reproductive technology(ART) is placed at the table. By then the couple is often exhausted financially, psychologically and mentally.

ART or more commonly known as 'test tube' baby is a novel concept in rural India even if it has been in practice for the past three decades. For a common man, ART seems like an impossible solution due to the lack of easy availability, duration of treatment, reduced chances of success on first attempt, stringent national policies and ART laws with the looming costs.

ART also raises multiple ethical questions when we see God as the sole creator of life. How can man accept a child created in an artificial setting? Isn't it a form of adultery to have a third person intervene in a holy covenant of marriage and procreation even indirectly? And what has to be done with the unutilized embryos? Would it be morally acceptable to discard them? As life begins at conception. The church holds their independent views to these ethical issues raised. The catholic church stringently accepts only children born through natural means however other congregations allow availing ART unless they are same sex couples. The Methodist church allow discarding 'spare' embryos upto 14 days after fertilization (UK law) When it comes to insemination also, most churches are liberal to artificial insemination by husband's sperm rather than donor sperm.

The cultural context of religious literature also accepted more than one spouse when the woman was barren. However, today it would definitely be bizarre to remarry or divorce just for the sake of completing one's family. With the changing times, advent and progress in technology one has all rights to access the best of medical services. When the personal suffering exacerbates it slowly leads to an unstable marriage, stigmatization or even domestic violence and ostracism which amount to more social issues. Hence, it should be the fundamental right of every couple to have accurate information, diagnosis and a treatment plan disseminated early on along with appropriate spiritual counseling.

This would help them make healthy and correct choices and alleviate much of their prolonged suffering. In India, one way this can be facilitated is through community programs such as RCH where married couples are identified and counseled through the reproductive period and further onto antenatal and postnatal period also. There is also a need for male reproductive health specialists along with facilities for diagnosis and testing at affordable costs. The poor man we often see fall prey to marketing and business agendas of unwarranted ART initiation. The concept of unexplained infertility or now better known as subfertility also needs more awareness.

Adoption should also always be a viable option for couples who have no means for affording ART. It sure is near suicidal and thoughtless to sell off one's land and house or even circle a drain of debts that are incurred from loans taken to pay for ART treatment. After all, a child needs no more than a loving family and a secure environment. Just like every fundamental right in India, ART should be one other reproductive right of a couple. When we have moved forward in other aspects of day to day living and technology with Alexa controlled smart homes, AI powered cars, robotic surgeries, 5G phones – embracing ART should be free from bias.

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However, to make it more accessible it has to be offered at an affordable cost and protected with laws that protect its potential misuse and economic burden. The right to a child is a need not just for a family but also for a society to grow.

World Health Organization(WHO) International Classification of Diseases, 11th Revision(ICD 11) Geneva: WHO (2018).



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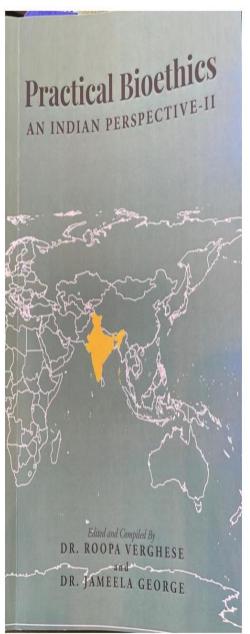
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DREAMS OF FORMING A FAMILY - A DIFFERENT PERSPECTIVE

Dr.GIGI CHANDY

A young couple approaches the doctor in the department of Reproductive Medicine . Having been married for over two years and being in the profession of medicine they had just started thinking of planning a family. To their pleasant surprise the specialist said , " I am going to take you through three months of counselling before starting investigations." When the couple met the specialist for the second counselling session, the wife had already missed her periods. They were overjoyed when the pregnancy test came positive. Husband had been really anxious about giving the semen test.

This is the case of several couples especially those in very busy professional fields.

Awareness of a healthy husband wife relationship and planning a family sometimes does not happen the way the couple plans. This is the experience even for those in the medical field. So when they approach the Reproductive Medicine Specialist a friendly chat during the first visit will put the couple at ease. It also helps to establish a healthy doctor – couple wrapport.

It is good to consider the couple as one unit and also as a client. The friendly chat helps to identify the issue the couple is struggling with and hence inability to start a family is a situation of concern not an illness or disease. This awareness itself helps the couple to relax and start sharing all their problems with the specialist.

Few problems identified during the course of the counselling sessions. After marriage the husband has left the country as he is working abroad . Hopes of taking the spouse is time consuming. This is the situation if the partners are in two different places even if it is within the country.

The expectations of the parents and grandparents to have a child within one year of marriage puts the couple under stress. They like to have a control over the life of the couple.

Limited or no knowledge of the fertile period and how to observe that. Sexual dysfunction for one of the partners.

The various research that they have done has given them partly wrong information that treatment is extremely expensive.

Considering all the above factors, the Reproductive Medicine Specialist needs to spend few sessions of counselling with the couple. The problem may be sorted out during the counselling sessions itself. The Specialist has to decide when to start active investigations or should refer to the Psychologist.

Every Reproductive Medicine Centre should have a Psychologist as part of the faculty. Couples going through Reproductive Medicine Technology like IVF should have counselling sessions with the Psychologist with whom they can share their concerns and clear their doubts.

A couple in their mid thirties came from Kerala for infertility treatment. They have been married for ten years and undergoing treatment for infertility for the past seven years. The wife has been diagnosed with Endometriosis and has already undergone one IVF cycle in Trivandrum. Having gone through her reports and treatment history the Doctor planned some investigations and registered them for an IVF cycle nine months later as that was the nearest date available. As the doctor also was from Trivandrum the couple had a pleasant time chatting with her as she incorporated counselling also into the conversation. The counselling experience was a totally different one for the couple as they never had so much time talking and sharing with the Doctor in all the centres they had visited previously. The lady intermittently broke down through the conversation but soon was cheerful. She found a lot of happiness and joy just talking to the Doctor. They left a very happy couple having planned their stay when they come for IVF.

A month later the Doctor gets a call from the couple. Her joy knew no bounds as they told her that the pregnancy test was positive.

This is a clear example of a relief of anxiety developed by just sharing the experiences and feeling relieved that they have been booked for IVF and waiting for the best.

Counselling is an area which gives very good results in certain circumstances. Psychologists are essential in every department of a hospital. They must be part and parcel of corporate centres also. When a couple comes to the Reproductive Medicine department, the specialist should access the necessity for a counselling session with the Psychologist. Those couples planned for Reproductive Technology like IVF, should definitely have counselling session with the Psychologist.

The counselling sessions should be for the couple, avoiding the parents and members of the extended family. The couple should be able to support each other and that will create a stronger bond between them. Occasionally the husband needs examination and counselling by a male specialist. This saves the husband from embarrassment. If male infertility is the problem it takes longer periods of counselling for the husband to accept it . The wife provides a strong support system to the husband in this case. This is the Indian culture. Hence counselling sessions yield very good results especially for those who are totally against donor programmes.

Counselling sessions

A)Advice regarding fertile period – explanation about physiology of menstruation and ovulation. The contact between husband and wife to be planned during the time of the dominant follicle formation. This to be repeated two to three months before starting investigations.

B)The couple to take some time off from work to go on a holiday and relax. This is particularly for those software engineers working for American companies. While one partner sleeps the other partner will be having meetings. Problem of different time lines in different continents !!!

C)Relaxing exercises for women with mild Vaginismus.

D)Provide space for the couple to talk to each other regarding their expectations. Be a silent observer.

E)Explain to the couple when Intervention Technology is necessary promising to be available whenever they would want to see the Counsellor.

When the Reproductive Medicine Specialist is also the counsellor, there is a huge advantage as all the medical doubts and concerns of the couple can be answered to a certain extent. The Specialist / Counsellor should also know when it is beyond the scope of counselling and investigations and treatment should be commenced.

Country	India	United Kingdom	South Africa	Canada	Australia (Victoria)
Payment to the donor	 Medical expenses and insurance coverage. 	 Reasonable medical expenses. 	 Reasonable expenses 	 Reimbursements include for travel and counselling. 	 Reasonable expenses
Age of commissioning party	 Male between 21-55 Female between 21- 50 	 Not specified 	 At least 18 years of age 	 Not specified. 	 Not specified.
Marriage needed to commission ART	 Marriage required, but single women allowed. 	 No requirement. 	 No requirement. 	 No requirement. 	 No requirement.
Medical reason to commission ART	 Couples must prove infertility. 	 Not specified. 	 Not specified. 	 Not specified. 	 If woman cannot conceive/carry child to term without treatment, or the woman/her partner risks transmitting a genetic abnormality.
Age of donor	 Male between 21-55 Female between 23- 35, with at least one child (minimum 3 years old). 	 Male between 18-45 years. Female between 18-35 years (except in certain cases) 	 At least 18 years old. Exception made in case of a medical indication. 	 At least 18 years old Exception made for preservation of own gamete. 	 At least 18 years old Exception made if there is a risk of the child becoming infertile before adulthood.
Restrictions on donors	 Only one donation for an egg donor (with up to 7 eggs retrieved). 	 Not more than 10 families per donor. 	 Not more than six births using donor gametes. 	 Not specified. 	 Donated gametes cannot be used to produce more than 10 families.

Sources: India: The Assisted Reproductive Technology (Regulation) Bill, 2020; United Kingdom: The Human Fertilisation and Embryology Act, 2008; Code of Practice, 2019; South Africa: National Health Act, 2003; Regulations Relating to Artificial Fertilisation of Persons, 2012; Canada: Assisted Human Reproduction Act, 2004; Reimbursement Related to Assisted Human Reproduction Regulations; Consent for Use of Human Reproductive Material and In Vitro Embryo Regulations; Australia (Victoria): The Assisted Reproductive Treatment Act, 2008; The Prohibition of Human Cloning for Reproduction Act, 2008; PRS.

Fertility Related Issues ---WHAT SHOULD A COUPLE PLANNING PREGNANCY KNOW INFERTILITY - AN OVERVIEW WHAT IS INFERTILITY ?

Dr. T K CHERIAN

Infertility is a term used to denote a medical condition when a couple desiring to have a child fails to achieve a pregnancy after not less than a period of 12 months of regular unprotected coitus in the fertile phase of wife's menstrual cycle. However older couples in late thirties or forties should consider consulting a RELIABLE fertility centre without much delay.

Infertility can either be primary or secondary. It is termed primary when the female partner has never been able to conceive and secondary when a conception was achieved atleast once before the period of infertility.

Approximately 15 to 20 million(25%) of affected couples are from India alone out of the 60 -80 million(8to 10%) affected couples worldover.

INFERTILITY FACTORS (IDENTIFIABLE) CAN BE IN EITHER OF THE PARTNERS IN BOTH OR IN NONE

- Male factor infertility when the reason can be purely of male origin
- · Female factor infertility if cause is in the female partner
- · Combined when both have causative factors.

· Unexplained when both are found to be normal after a complete infertility work up. The couples under this group are probably "subfertile" when both the partners have a fertility potential below the optimum. If a partner with a sub optimal fertility potential marries a person with a higher potential, the difficulty may be overcome by compensating the deficiency in one of the partners by the higher potential in the other. A good percentage of this group conceives though after a longer cohabitation.

CAUSES OF INFERTILITY

• It is a medical situation which is on the rise worldwide due to various life style changes such as changing food habits, consumption of junk food, excessive consumption of alcohol, smoking, drug abuse, sedentary work, lack of adequate exercise, change in the echo system and pollution, social situations and family responsibilities leading to postponement of marriage and pregnancies and inadequate regular cohabitation once married . This is a very relevant factor in Kerala state where the young people work outside the state or the country which make the partners meet together and cohabit for hardly 1 to 2 months in a year or two.

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Add A Footer

· Electromagnetic radiation has been identified as a causative factor of low sperm count

and abnormal sperms, especially in those men who carry the mobile phone in their trouser pockets. Prolonged use of anabolic steroids to increase muscle mass is also another causative factor for azoospermia by affecting the functions of hypothalamus(the part of the brain controlling the pituitary gland) and pituitary gland(the gland situated at the base of the brain monitoring the function of endocrine system).

THE COMMON CAUSES OF INFERTILITY are grouped into three main categories.

- MALE FACTORS
- FEMALE FACTORS
- PSYCHOSEXUAL FACTORS

MALE FACTORS

Ejaculatory dysfunction ,absence or blockage in the sperm passage duct from the testis to the urethra , abnormalities of the reproductive system ,absence or low levels of spermatogenesis(sperm production in the testis),or abnormal shape (morphology) and movement (motility) of the sperm.

Male infertility results from a failure in the production of sperms or , in its transportation to the penile urethra or as a result of en a difficulty in its deposition into the vagina .The following are certain medical terms used to denote the abnormalities in semen. Male infertility results from a failure in the production of sperms or , in its transportation to the penile urethra or as a result of a difficulty in its deposition into the vagina .The following are certain medical terms used to denote the abnormalities in semen

• Azoospermia-- absence of sperm in the seminal fluid can be due to testicular defects or due to a block in the reproductive tract carrying the sperm from the testis to the penile urethra This can result from an abnormal reproductive system from birth, such as cryptorchidism (undescended testis)or due to genetic disorders .It can also result from trauma or infection of the reproductive gland or genital tract. Azoospermia can also result from radiation or chemotherapy affecting the testicular tissue producing the sperm.Azoospermia can also be caused by endocrinological disorders . Pituitary gland and hypothalamic dysfunction can be a cause for either azoospermia or low sperm count.

• Oligospermia-- a low sperm count in the seminal fluid can be a result of a suboptimal stimulation of the sperm producing cells in the testis due to certain medical conditions mainly related to the endocrinological system or damage to the testis from a temperature change such as varicocele. Infection of the prostate gland also can lead to semen abnormalities. • Asthenospermia-- reduced motility of the sperm

• **Pyospermia** --when there is significant number of pus in the semen due to infection in the genitourinary tract.

• Teratospermia--when the sperm morphology (shape) is abnormal

• Aspermia-- absence of semen. It can be caused by congenital disorders certain medications, or in a condition called retrograde ejaculation when the semen gets discharged into the urinary bladder and not into the penile urethra during the sexual act resulting in the failure of semen discharge into the vagina.

Disorders in spermatogenesis can be caused by genetic ,chromosomal, congenital disorders or it can be acquired after birth due to injuries, infections, tumours, medicines such as cancer drugs or radiation damaging the testicular tissues.Hydrocele, varicocele and scrotal hernia are other causes

Conditions such as ejaculatory dysfunction, loss of libido(sexual desire) can result from uncontrolled diabetes in people who are otherwise normal. Vascular disorders causing decreased blood supply to the external genitalia or reproductive organs can be another causative factor. Endocrinological diseases ,neurological diseases, chronic liver and kidney diseases genetic /chromosomal abnormalities , alcoholism and drug abuse can also cause sexual

FEMALE FACTORS

Female factors can be either related to ovarian function(Ovulatory) or to abnormalities of the vagina, uterus and Fallopian tubes

Anovulation – absence of egg production in the ovary

Anovulation(absence of egg formation in the ovaries) or inadequate ovulation can be primarily due to ovarian dysfunction or abnormalities.This can be secondary to other medical conditions such as endocrinological diseases rather than a primary defect in the ovary itself.

Main causes of anovulation are endocrine gland disorders especially secondary to hypothalamic pituitary dysfunction, obesity. Poly cystic ovarian syndrome or disease(PCOS or PCOD) is one of the common clinical conditions seen in young women now a days. This is a clinical situation of transvaginal ultraosund scan finding of 20 or more ovarian follicles of usually 2 to 9 mm in size along the periphery of the ovary with increased echoic central part of the ovary, associated with other clinical features such as delayed or scanty menstrual cycles or amenorrhoea(absence of menstruation), increased weight gain,abnormal hair growth on the face neck and the body and also laboratory findings of increased male hormone in the blood. This condition can occur also without any weight gain(lean PCOD).

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Women with a family history of diabetes have a higher chance of developing PCOD.

Ultrasound findings of multiple cysts alone in the ovary within the period of 8 years from the menarche(age at which menstruation commences in girls) or in those young women below the age of 20 years should not be grouped as PCOD on the basis of an ultrasound finding of multiple ovarian cysts alone.During this period of adolescence ovaries may show multilpe cysts in the ovary which are not to be confused with "PCODs". The present tendency to do an ultrasound scan or to depend on laboratory investigations or any other modalities of

investigations without checking the medical history and doing a physical examination of a patient is highly deplorable. What I experienced in my limited period in "God's Own Country" (where stray "dogs" can exercise unlimited "freedom of bite"), is patients walking into the doctor's consultation chamber with the common slogan of "doctor I have PCOD" even before I could ask her ,her name, leave alone the medical history.

Endocrinological diseases such as thyroid dysfunction, pituitary hypothalamic dysfunction genetic /chromosomal disorders can also interfere with ovarian function. Radiation and chemotherapy are other causes.

Abnormalities in the reproductive system

Congenital abnormalities (abnormalities present from birth) of the vagina, uterus and the uterine opening into the vagina(Cervix) septum in the vagina or uterus Fallopian tubes* (passages from either side of the uterus to the corresponding ovary) or abnormalities of the ovary. These abnormalities can be a part of the genetic disorders as well. This can present as abnormal shape and size or absence of the entire or part of the reproductive tract.

* Fallopian tubes -----

• The mature ovum (egg) released from the ovary to the tubal fimria(tubal opening of the Fallopian tube near the ovary) gets fertilised in the Fallopian tube by the sperm. The fertilised egg reaches the uterine cavity around 48 hours after the fertilisation.Meanwhile uterine lining gets prepared to receive the embryo(fertilised egg)for implantation

• Pelvic disorders

These can be secondary to infection or inflammation such as endometriosis causing damage to the tubes ovaries and to the endometrial lining of the uterine cavity. Infections may follow a previous Delivery, abortion or it can be due to sexually transmitted disease(STD).

Tumours such as fibroids may distort the uterine cavity, interfere with the Fallopian tube opening or make the endometrium not suitable for the implantation of the embryo

PSYCHOSEXUAL DYSFUNCTION AND INFERTILITY

Ignorance of human reproductive system and sexual function and lack of education are the common reasons for psychosexual dysfunction leading to inadequate or loss of normal sexual relations between the couple.In India the relatives and neighbours are more concerned about a couple's delay in having a child. In Kerala, ,the man walks hundred yards ahead of his wife in public places as though the wife has to respect him by walking behind him. But when it is a visit to a fertility consultant not only this practice is reversed, but the man is totally absent from the scene. .The young girl is usually brought by her mother or other immediate relatives to prepare her for the grand arrival of her husband from abroad as though a land is prepared for the seasonal crop...Many a time the girl is brought by her husband's parents as if they are very confident of their son's reproductive prowess and function. This practice itself is disparaging to the girl. Even when both the partners cohabit, there is a reluctance on the male partner to c

THE COUPLE DESIRING TO HAVE A CHILD SHOULD CONSULT THE DOCTOR TOGETHER AND SEEK

A woman gets incomparable solace and courage by the presence of her husband which alleviates her unnecessary tension forced upon her by the attitude of the people around who appear to be more concerned than the couple themselves.

THE COUPLE DESIRING TO HAVE A CHILD SHOULD CONSULT THE DOCTOR TOGETHER AND SEEK HELP. A woman gets incomparable solace and courage by the presence of her husband which alleviates her unnecessary tension forced upon her by the attitude of the people around who appear to be more concerned than the couple themselves. Most commonly, in Kerala the parents of one of the partners bring the wife first to a gynaecology department where she is usually seen by a lady gynaecologist. Husband is either working abroad or reluctant to come for a consultation. The husband consults a urologist only if he has some obvious sexual dysfunction. The husbands with no such issues shy away from accompanying his wife, partly because the first consultation is usually with a lady gynaecologist and there is a reluctance on the part of the husband to be examined by a lady doctor and also hesitance on the part of the lady doctor to interrogate and examine the male partner.

Sooner or later we can expect an "avatar "of a new association in Kerala under the banner named the "Downcast Young Fellows of Infertility" calling for a lightening bandh(strike) paralysing the life in Kerala for their right to have fountain of life.

WHAT SHOULD A COUPLE KNOW ABOUT INVESTIGATIONS AND TREATMENT

• Investigations - The first and the foremost step is for the couple to consult a good reliable fertility centre. A recording of medical history and a full systemwise physical examination by the doctor is essential before laboratory tests. The decision to choose the investigation is based on the history and the examination findings .In a normal couple with no obvious cause detected on clinical examination husband 's semen analysis and a trans vaginal ultrasound scanning of the wife are the investigations to start with, followed by testing of the lining of the uterine cavity around the 21st day of the menstrual cycle(Pre menstrual endometrial biopsy)with abstinence as advised by the doctor to avoid pregnancy in the month of test. Usually this is from the 8th or 9th day of the menstrual cycle till the day of the test. This is a very minor procedure .The endometrium thus tested confirms ovulation if occurred and also excludes infection such as pelvic tuberculosis which may exist without any symptoms though rare now. A small percentage of women with no tubal block and with a normal semen report of her husband conceives within a couple of months without any further treatment. This is followed by the checking of abnormalities of the uterine cavity and patency of the Fallopian tubes by ultrasound or by x-ray.

The ultrasound procedure called sonosalingogram can detect the abnormalities without any radiation exposure to the patient. If further test is required an endoscopy procedure called hysterolaparoscopy should be done to exclude any abnormalities of the uterus Fallopian tubes and ovaries.

Hormonal tests and other endocrinological studies are done if abnormalities in ovum(egg) and sperm production are suspected. Chromosomal studies and related tests are indicated if abnormalities of the secondary sex characters or reproductive organs are suspected. Ultrasound scanning and Doppler study of the male reproductive glands and tract may also be done when indicated. Tests should be done to not complete the available list of tests but to detect the cause as suspected from the medical history and the physical examination .

A very significant number of married couples need proper counselling, as they are ignorant of the reproductive system, fertile period in a menstrual cycle and timing of coitus. They may conceive without much delay once they follow the advice of their doctor as they are relieved of their ignorance and stres.

If there is a further delay in conception, the couple should undergo investigations starting with husband's semenanalysis, wife's ultrasound scan and thyroid gland function. Premenstrual endometrial biopsy may be done after these initial tests. Some may conceive within a month or two following an endometrial biopsy as it may increase the endometrial receptivity, So further tests should be deferred for two months.

Sonosalpingogram to detect any uterine or Fallopian tube pathology should be the next step. This protocol for infertility investigation is relevant to women who are in their twenties or early thirties if the duration of infertility is not very long . However , the investigations and treatment should not be unduly delayed if the duration of infertility is more than two to three years or wife's age is more than 35 years , The fertility function decreases with age in men also. Hysterolaparoscopy can then be planned if necessary and should never be the first step to investigations unless there are definite reasons. The couple should consult a reliable hospital and should not "hop" from hospitals to hospitals seeing road side flex boards .

Treatment Modalities

Recanalisation of the blocked Fallopian tubes in women and blocked Vas deferens(passage for sperms) in men may be helpful in a very small percentage of patients. Uterine fibroids interfering with the uterine cavity space and endometrial lining should be removed .Endometriosis in its early stages can be medically treated or dealt with laparoscopically (key hole surgery).

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Men with poor spermatogenesis can be helped with medicines if the cause is secondary to poor stimulation from hypothalamus or pituitary gland .Surgery for varicocele may improve the sperm count in selected cases.

Treatment such as ovulation drugs , IUI (intrauterine insemination with husband's prepared semen-IUI-H)may help if no obvious cause is detected and are not very expensive . Treatment with ovulation drug should always be monitored by a transvaginal ultrasound scanning . One can consider assisted reproductive techniques (ART)if there was no success with these treatment measures .

IUI-H is a procedure to help the sperm meet the egg ,as it is released into the Fallopian tube during ovulation, by placing the prepared semen with a higher and better motile sperms in uterine cavity near its fundus. Normally the sperms travel from the upper part of the vagina through the uterine opening (cervix) and the uterine cavity to reach the Fallopian tube . This procedure is successful approximately in 25% of cases with atleast one normal Fallopian tube . The female partners of men with low count or low motility or with abnormal penis who cannot discharge semen into the vagina will benefit from this procedure. Semen can be obtained by using certain equipment such as vibrators in men with erectile dysfunction .

. IUI-D

This is carried out by using donor semen from a sperm bank when husband's gonads fail to produce sperm. This has ethical issues and may not be acceptable to the couple.

ART.

The techniques used to fertilise the male and female gametes outside the human body in the laboratory and to transfer the resulting embryo into the wife's uterus(Embryo Transfer-ET)are collectively called ART. The two main techniques used are:-

• Conventional IVF(In Vitro Fertilisation) .The aspirated ovum(egg) is placed in a Petri dish and the required number of prepared sperms are added in the dish . These dishes are then incubated in a special incubator

• ICSI(Intra Cytoplasmic Sperm Injection) . This technique uses a special microscope to inject each sperm into each ovum separately and then incubated This technique is mainly used in male factor infertility with low count or low motility .

There are some variants of these main techniques also.

Hormone injections are given to the wife under control to obtain adequate number of eggs and at the same time to avoid overproduction of eggs which can create complications to the wife. Ten to twelve eggs is a good number showing good ovarian response and a number less than 5 is a very poor response. A high response of 18 eggs or more can lead to a complication called Hyper Stimulation Syndrome (OHSS) which ,occasionally be a life threatening situation. However , with better medicines and monitoring techniques, it is not very common . When the number of eggs are high .the quality of eggs tend to be unsatisfactory which affects the pregnancy outcome. Success of ART in an unstimulated natural ovulation cycle when only one mature egg is formed is very remote ,hence the need to stimulate ovaries to produce more eggs

FROZEN EMBRYO TRANSFER(FET)

In an ART procedure normally not more than two good quality embryos are transferred into the uterus to prevent multiple pregnancies and also to increase the chances of atleast one embryo developing to a foetus. Young women with good ovarian response and with a good quality of sperm from her husband can have more than two good embryos . These embryos can be frozen and preserved usually for about 5 to 10 years for future use if the first attempt fails or if the couple wishes to have more children. This avoids further ovarian stimulation in the wife and its probable complications The cost of another cycle is also avoided.

No technique can offer a hundred percent success . **"Take Home Baby Rate"** is in the tune of 25%-roughly speaking 25 live births can be expected in hundred ART cycles. This is not a very depressing figure for those who had no success with other measures. ART is not the first choice of treatment unless there are specific indications such as male factor where sperm can be obtained in the semen or retrieved from the testis . It is the first choice when the both the Fallopian tubes are. damaged or blocked. This can also be considered without much delay in women in late thirties or in forties after a short trial of other treatment. The cryopreservation of the egg or ovarian tissue in women and sperm in men is a treartment modality to preserve the fertility for those who undergo chemotherapy or radiation for ovarian or testicular tumours. This should be done prior to chemotherapy or radiation

The rest of the couples should opt for ART only if others method fail.

The couple undergoing ART should have proper counselling with the treating doctor and the team prior to their final decision. Most of the ART centres have counsellers to educate the couples on ART procedures, its benefits, success rate , complications and other related matters. In case of a male factor such as azoospermia or a semen with doubtful and occasional dead or live sperm, the availability of useful and satisfactory number of sperms should be confirmed prior to starting the ovulation induction drugs on the wife. This is of paramount importance if the husband's sperm abnormality is associated with a raised blood FSH level and the couple has no intention to use donor sperm.

There appears to be no direct association between ART treatment and an increased risk of invasive cancer in infertile women, but there may be a small increased risk of borderline ovarian tumours. This may be the after effect of multiple ovulation and ovarian epithelial damage in hyperstimulation. The couple should seek proper medical counselling with an ART specialist before deciding on repeated ART treatment . There is suggestive, yet unconvincing, evidence that ART treatment may increase several risks, including childhood cancer risk to children.

There is a human instinct to misuse any scientific invention meant for a good cause and even ART is not devoid of this negative effect .

The Indian parliament passed "The Assisted Reproductive Technology (Regulation) Bill, 2021" in December 2021 This is to stop the misuse of this technology especially its use in third party ART which employs surrogacy (Womb renting) or donor ovum(egg) or sperm .It also provides the guidelines for the ART practice

As far as the procedures do not involve a third person the ethical issues are limited mainly to the utilisation of the usable good quality frozen embryos if the couple does not wish to have more children.

The viable embryos are in the early development stage of a human being .Each adult individual once was an embryo in the early stage of development, just as being a foetus, infant, adolescent through various stage of growth.So an embryo has the right to live and cannot be "killed". This raises the issue of the disposal of the viable unused embryos.

It is very difficult to come to a consensus as opinions differ on moral and religious convictions .I strongly believe that we have no right to destroy a viable embryo. One suggestion is to transfer the embryos to the biological owner of the embryo in the luteal phase of the menstrual period(third week of a normal menstrual cycle which is the usual time the embryo reaches the uterine cavity in the reproductive phase of a woman. Not more than two embryos are transferred at a time without the supporting medication given for the implantation of the embryo in an embryo transfer intended for a successful pregnancy. There is only a very remote possibility for an embryo of such a transfer to develop into a foetus, though it cannot be absolutely ruled out. Such non implantation of embryos do occur even in natural reproductive phase of a women.

The other probability is altruistic embryo donation to needy couples chosen by the biological couple of the embryo with the prior approval of the concerned authority such as National /State ART Board. It is very doubtful whether any biological owners of the embryo would ever agree for such a procedure.

Main ethical concerns are with the third party ART when a third person comes in the picture., either in the form of surrogacy or donor eggs and sperms.

Gestational Surrogacy

This involves a lady other than the wife willing to implant the infertile couple"s embryo created in an ART clinic through one of the ART procedures for medical reasons difficult for the wife to go through pregnancy It may be due to uterine causes or some life threatening medical conditions in the wife. The surrogate and the biological parents of the embryo are governed by the guidelines of the country .

The rules governing surrogacy in India/Eligibility criteria for intending couple:

The intending couple should have a 'certificate of essentiality' and a 'certificate of eligibility' issued by the appropriate authority.

A certificate of essentiality will be issued upon fulfillment of the following conditions: (i) a certificate of proven infertility of one or both members of the intending couple from a District Medical Board; (ii) an order of parentage and custody of the surrogate child passed by a Magistrate's court; and (iii) insurance coverage for a period of 16 months covering postpartum delivery complications for the surrogate.

The certificate of eligibility to the intending couple is issued upon fulfillment of the following conditions: (i) the couple being Indian citizens and married for at least five years; (ii) between 23 to 50 years old (wife) and 26 to 55 years old (husband); (iii) they do not have any surviving child (biological, adopted or surrogate); this would not include a child who is mentally or physically challenged or suffers from life threatening disorder or fatal illness; and (iv) other conditions that may be specified by regulations.

Eligibility criteria for surrogate mother:

To obtain a certificate of eligibility from the appropriate authority, the surrogate mother has to be: (i) a close relative of the intending couple; (ii) a married woman having a child of her own; (iii) 25 to 35 years old; (iv) a surrogate only once in her lifetime; and (v) possess a certificate of medical and psychological fitness for surrogacy. Further, the surrogate mother cannot provide her own gametes for surrogacy.

Should a surrogate get the consent from her husband and also from her own children who are old enough to understand the procedure? This may not pose an issue in India as an Indian wife may not dare to do such an act even for altruistic reasons

HFEA(Human Ferilisation and Embryology Authority) has laid down guidelines for surrogacy and also for the use of donor gametes.

Traditional(Natural) Surrogacy(Not allowed in India)

In traditional surrogacy the surrogate mother consents to fertilise her own ovum by IUI using the sperm of the intended biological father of the child for medical reasons preventing his wife to go through a pregnancy.

Here the surrogate mother is the biological mother of the child and raises more ethical issues and differs from the gestational surrogacy practised in third party ART

WHAT ARE THE ETHICAL CONCERNS

Questions that arise from the use of gametes(Ovum/Sperm) from an unknown donor :-

The possibility of the children born from donor gametes are genetically and biologically related to the donor. There is a possibility of these children born of donor gametes marrying donor's own children born of wedlock ,leading to incest and consanguinity as they are half brother or sister

· Can a relative be a donor ?. If permitted the donor should not be a blood relative to the recipient - ovum should be from a blood relative of the wife and not of the husband and vice versa. There are possible emotional and psychological repercussions attached to such a practice.

· Can transgenders/homosexuals /single woman be allowed to have children through donor gametes or surrogacy? We who practise ART should ask ourselves--

1. Are we not denying the right of a child to be breast fed(except in a relation where one of the partners is the biological mother) and also a normal parenthood ?

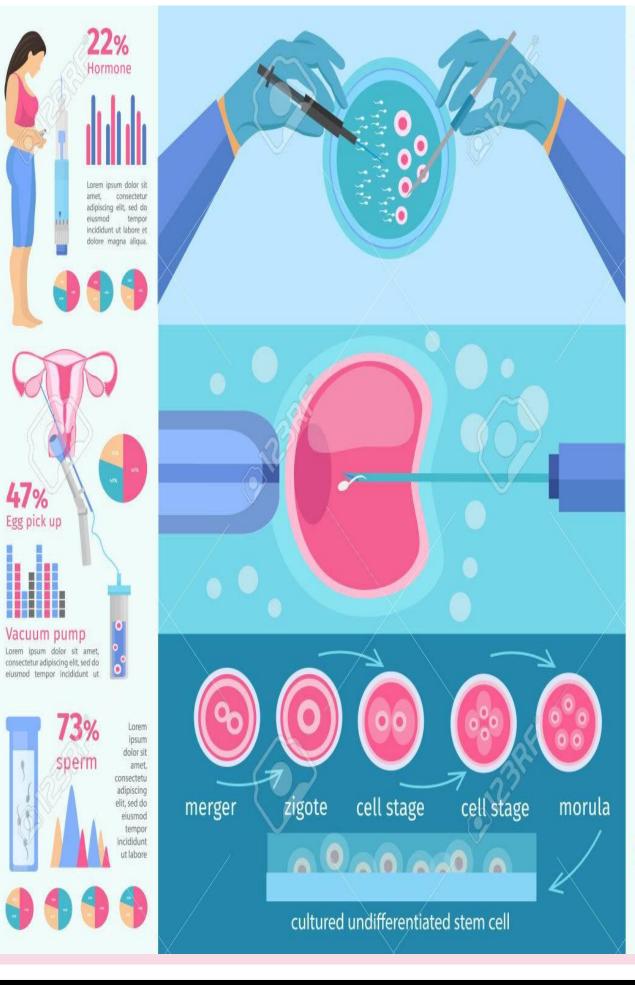
2. Are we not responsible for their emotional and psychological repercussions as they grow ?.

3. Can medical procedures be used for a purpose which is against nature merely to satisfy the fantasies or some abnormal psychiatric personal behaviour which are not in accordance with the normal human reproductive function designed by our Creator ?.

4. Doesn't it amount to violation of the very basics of medical practice – a denial and disrespect to the very declaration we doctors take as we graduate –the "Hippocratic oath"-- "the Sanctum Sanctorum" of medical profession

5. Is it socially and morally acceptable to offer ART to elderly couple who are old enough to be the child's grandparents ? What would be the emotional and psychological status of those children to introduce their "ART parents " to the society ?

"ART" is a medical technology to be used in indicated situations to help humanity and not meant to be practised as an "art" to destroy the very basics of humanity and the basic structure of a healthy society

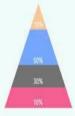




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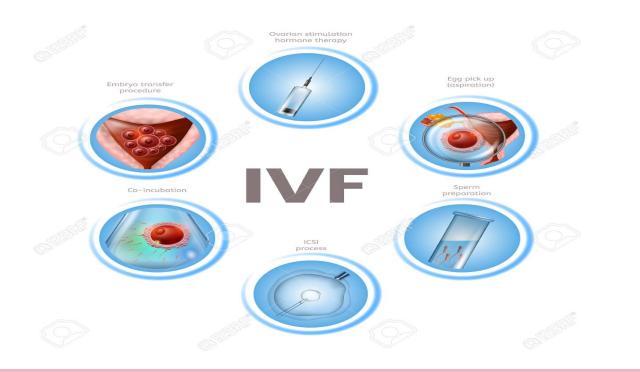
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Today's Understanding of Artificial Reproductive Techniques In the Indian Senario

Dr. ROOPA VERGHESE



Artificial reproductive techniques (ART) have indeed undergone significant changes in recent years. These techniques, which include in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), and various other assisted reproductive technologies, have revolutionized the field of reproductive medicine. **Increased Acceptance:** There has been a greater societal acceptance of ART, as more people are embracing these techniques to overcome infertility or to have children without a partner. In the past, infertility was often stigmatized, but now there is a growing recognition of the importance of reproductive autonomy.

Advancements in Technology: Technological advancements have greatly improved success rates and expanded the possibilities of ART. Innovations, such as preimplantation genetic testing (PGT), time-lapse embryo imaging, and vitrification (rapid freezing) of embryos and eggs have enhanced the efficiency and outcomes of ART procedures.

Expansion of Indications: ART is no longer limited to treating infertility caused by biological factors. It is increasingly being used for social or lifestyle reasons, such as elective egg freezing for career planning or fertility preservation before medical treatments like chemotherapy. Additionally, same-sex couples and single individuals can also benefit from ART to achieve their desired parenthood.

Accessibility and Affordability: The accessibility and affordability of ART have improved in many parts of the world. More countries have established legislation and regulations to govern ART practices, making it accessible to a larger population. Additionally, advancements in technology have also contributed to cost reductions, although ART can still be expensive for many individuals.

Third-Party Reproduction: There has been a rise in the use of third-party reproduction, including donor sperm, donor eggs, and surrogacy. These options allow individuals or couples with specific needs or circumstances to achieve parenthood.

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Ethical and Legal Considerations in all these situations: The use of ART has raised new ethical and legal questions. Issues such as the ownership of embryos, the regulation of surrogacy, the use of donor gametes, and the implications of genetic testing have prompted ongoing debates and discussions.

Focus on Health and Safety: There is an increased emphasis on the health and safety of individuals undergoing ART procedures. Clinics and regulatory bodies have implemented guidelines and protocols to ensure the well-being of patients, including the screening of donors, monitoring of treatment cycles, and addressing the potential risks associated with multiple pregnancies.

Stigma and Judgment: In some religious communities, there may be social stigma or judgment associated with infertility or the use of ART. This stigma can create additional emotional burdens for individuals or couples seeking reproductive assistance, potentially leading to feelings of shame or guilt.

Access to artificial reproductive techniques (ART) in rural areas of India can still be challenging, although efforts have been made to improve accessibility and awareness. Some factors that contribute to the perception of ART as a dream in rural areas:

Limited Infrastructure: Rural areas in India often lack the necessary infrastructure, including specialized fertility clinics and medical facilities, that are required to provide ART services.

The concentration of such facilities is predominantly in urban areas, making it difficult for individuals in rural areas to access these services.

Lack of Awareness and Education: Awareness about ART and its availability may be limited in rural communities. Due to lower literacy rates and limited access to information, many people in rural areas may not be aware of the existence and benefits of ART, making it seem like a distant dream.

Financial Constraints: The cost associated with ART can be a significant barrier for individuals in rural areas. The expenses involved in fertility treatments, including consultations, medications, laboratory tests, and multiple cycles of treatment, can be prohibitive for those with limited financial resources.

Cultural and Social Factors: Cultural norms and societal attitudes can influence the perception of ART in rural areas. Traditional beliefs and taboos surrounding infertility and reproductive health may discourage individuals from seeking or discussing fertility treatments openly.

Limited Availability of Specialists: Rural areas often have a scarcity of specialized reproductive health experts and fertility specialists. The shortage of trained professionals in these areas contributes to the perception that ART services are inaccessible or unavailable.

While ART may still be considered a dream for many in rural areas of India, ongoing efforts are being made to address the challenges and ensure that individuals in all regions have access to appropriate reproductive healthcare options. Access to ART in rural areas of India is indeed a significant concern, and it is essential to acknowledge the barriers and work towards improving the situation. The disparities in healthcare infrastructure, awareness, affordability, and cultural factors create challenges for individuals in rural areas to access and benefit from ART services.

Yet in all these situations the use of ART has increased significantly too in these sectors without proper understanding of the reasons. These are mainly due to the cusp of individuals who have been living in the rural settings by have had an exposure of the urban areas due to job opportunities.

Addressing the misuse of ART requires a comprehensive approach involving legal frameworks, ethical guidelines, and responsible medical practices. Striking a balance between promoting access to ART for those who need it and preventing potential abuses is crucial to ensuring that these techniques are used ethically and responsibly.

		Surrogacy (Regulation) Bill, 2019 (as passed by Lok Sabha)	ART Bill, 2021 (as passed by Lok Sabha)
•	Infertility	 Infertility is defined as inability to conceive after five years of unprotected sex. Married couples must prove infertility to access surrogacy. 	 Infertility is defined as the inability to conceive after one year of unprotected sex. Married couples must be infertile to access ART.
	Regulation	 Framework: The central and the state governments will constitute National and State Surrogacy Boards. The functions of the National Board include advising the central government on policy matters and supervising the functioning of State Boards. Registration: Appropriate Authorities at the national and state level will regulate registration of clinics. Registration must be granted within 90 days and will be valid for a period of three years. 	 Framework: National and State Surrogacy Boards under the 2019 Surrogacy Bill will act as the Boards under the ART Bill. These will be called National Assisted Reproductive Technology Surrogacy Board and State Assisted Reproductive Technology Surrogacy Board. Registration: The central government will appoint Appropriate Authorities (called the Appropriate Assisted Reproductive Technology and Surrogacy Authority) which will regulate the registration of clinics for both surrogacy and ART services (includes banks). The Authorities will be constituted at national and state level.
			 The Appropriate Authority must report all registrations to the State Board. Registration will be granted only after the State Board inspects the premises.
			 Registration must be granted within 30 days (or will be deemed granted) and will be valid for five years.
	Eligibility to commission	 Indian couples: (i) where the woman is 23-50 years old and the man is 26-55 years old, (ii) married for at least five years, and (iii) with no surviving biological, adopted or surrogate children. 	 Commissioning couples woman is between 21-50 years and the man is between 21-55 years. Single women may avail ART services. Foreigners are not prohibited from availing ART services.
2	Offences	 Punishes acts (e.g. selling gametes) with imprisonment of up to 10 years and fine of up to Rs 10 lakh. Any other violation by a surrogacy practitioner or clinic owner attracts imprisonment of up to 5 years with fine, with higher penalties for subsequent offences. Imprisonment up to 3 years with fine, if no penalty set out. Any person may directly file a complaint (with notice of at least 15 days to the appropriate authority). 	 Prohibits similar acts with fine of Rs 5-10 lakhs. Subsequent violations attract imprisonment of 3-8 years, along with fine of Rs 10-20 lakh. Similar punishment (as above) applies to those offences where no penalty is specified. Complaint to court may only be made by the National Board, the State Board or its authorised officer. Offences are bailable.
	Seizure	 Offences are non-bailable. Only the registration authority may enter premises, search clinics and seize documents. 	 The National/State Board and the National Registry have the powers to search premises and seize documents.
	Storage	 25 years or such other prescribed period. 	 At least 10 years; then records transferred to the Registry.

Sources: The Surrogacy (Regulation) Bill, 2019; ART Bill, 2021 (as passed by Lok Sabha); Reports of the Standing Committee and Select Committee; PRS.

Our Contributors



Dr. Shiny Varghese has over 19 years of experience as a Gynecologist in India. Has a postgraduate degree in OBG with a special interest in Endoscopy. Worked and taught as a professor in CMC, Ludhiana. Has attended many national and international conferences and presented papers. Has several publications.



Dr Achamma Chandy is an MBBS and DGO graduate from CMC, Vellore. She worked as a faculty of the Reproductive Medicine Department at CMC Vellore for 25 years. She has done her MA in Bioethics from Trinity International University, Chicago. She has been a faculty in the department of Bioethics in CMC Vellore for 5 years now.

Dr T. Koshy Cherian is a Senior Consultant with decades of experience. In addition to his compassionate care, he has a strong ethical conscience that is very much appreciated by his patients. Before joining our family, he worked as the Head of the Departments of Reproductive Medicine, and Obstetrics and Gynaecology at St. Stephen's Hospital Delhi.

He completed both his graduate and postgraduate studies at CMC Ludhiana.

Dr Jenni George is a consultant Obstetrician and Gynaecologist trained at CMC, Ludhiana and Vellore. She is presently working as the Medical Surinderndent at Jiwan Jyoti Hospital. Robertsganj. UP. An avid reader and a person with an infectious smile.







Dr. Roopa Verghese MD (ObGyn), MA(Bioethics). Executive Director and Senior Consultant. The Center for Bioethics, New Delhi. Chatarpur Christian Hospital. Chatarpur.MP

ed.tcbi@gmail.com



Dr. Satish Thomas, MD(AIIMS), DNB, FICO(Sydney) MA Bioethics (Chicago), MA OLM (Allahabad) Fellowship in Pediatric Ophthalmology & Strabismus (Sankara Nethralaya) Professor & Head of Ophthalmology BCMCH, Kerala 689103



Dr. Roopa Verghese is a Senior Consultant Obstetrician and Gynaecologist trained at CMC, Ludhiana and went on to do her Masters' in Bioethics from Trinity International University, Chicago. She has worked in varying capacities for 20 years in remote locations of Northern India as a part of the Emmanuel Hospital Association.Presently she is the Executive Director for The Centre for Bioethics and Senior Consultant at Christian Hospital Chatterpur.