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**Ethical, Logistic And Legal Aspects
Of Fertility Preservation**

**ONCOFERTILITY
COMMUNICATIONS**

An academic initiative by IFS

Supported by AstraZeneca Pharma Ltd

Ethical, Logistic and Legal Aspects of Fertility Preservation



Dr Puneet Rana Arora

Executive Editor

It's my pleasure to set the release of **volume 3** of “**Oncofertility Communications**”.

I am very glad to share that we have had very positive and reassuring response with the releases of Oncofertility Communications so far. Our doctor fraternity completely accepts the need for awareness in this sub-specialised field of Reproductive medicine.

I would like to pay my gratitude to Dr Gouri Devi and Dr Pankaj Talwar to understand this need and initiate series of bulletin on this important topic.

My special thanks to Dr Rajapriya Ayyappan for her contribution in this edition .

Here we present our 3rd edition.

Happy Reading !



Dr Rajapriya Ayyappan

Guest Editor

Oncofertility awareness is the need of the hour with improved survival. The first step is to give patient the opportunity to comfortably discuss. Multidisciplinary efforts and convenience of facilitating the fertility preservation will go a long way in making it fruitful.

Happy Reading !

PUBLISHED TOPICS

1.	Fertility Preservation : An Overview	January-2019
2.	International And National Review Of Uptake Of Oncofertility	March-2019

UPCOMING TOPICS

1.	Breast diseases and Fertility Preservation	June-2019
2.	Fertility preservation in Males	August-2019
3.	Fertility preservation in Gynaecological Malignancies	October-2019
4.	Non-malignant conditions and role of fertility preservation	November-2019
5.	Childhood cancers and fertility preservation	December-2019

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Ethical, Logistic and Legal Aspects of Fertility Preservation

I. INTRODUCTION

The advancements in oncology including new techniques and technology, allows patients to not just survive disease, but to potentially live long, and attain healthy lives. In order to seek a better outcome, aggressive treatments are pursued, but they also bring serious side effects including the risk for infertility or sterility. Precautions are taken, but not all risk for infertility or sterility can be eliminated. Many patients turn to fertility preservation to prevent this. Oncofertility is a term coined in 2006.

ESHRE in 2017 created fertility preservation as a special interest group. 1 in 250 female cancer survivors belong to reproductive age group.

Proactive fertility preservation helps cancer patients to reproduce. Although many embryos are created, only few get the chance to grow into a child. UK (**HFEA, 1990**) introduced strict guidelines on the requirements for informed consent in respect of the storage of gametes and embryos and their use. During counseling, its essential for patient to understand procedural risk, long term freezing and surviving thaw.

Semen Cryostorage is not itself a treatment but a process which concerns two parts: the storage and the subsequent use. For most cancer patients the latter is the reason for storing spermatozoa but the choice of option at that stage by the patient and his future partner will be determined by a number of other factors which are unknown at the time of freezing. These include their prevailing semen quality, post-thaw sperm quality, whether further information on the genetic damaging effect of treatment is available, who the partner may be, her age and whether she is prepared for a more intrusive form of assisted conception technique. Fully informed consent is therefore not realistically possible.

II. THE PATIENT'S DILEMMA: BALANCING CANCER AND FERTILITY

A diagnosis of cancer is a life crisis for any person. During the stressful period of receiving a diagnosis and treatment plan, patients (and their parents, in the case of a minor) must also consider possible choices to preserve fertility. They may be given the option of more conservative treatment for the cancer or the chance to preserve gametes or gonadal tissue. Each choice carries risks and uncertainties. If treatment brings cure or remission, cancer survivors may consider having children. If they are unable to reproduce through natural physiologic methods, they may seek reproductive assistance, including the use of stored gametes or tissue. They may also consider donor gametes, gestational surrogacy, or adoption.

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III. THE ONCOLOGIST'S ROLE IN PRESERVING FERTILITY

Oncologists have traditionally focused more on providing the most effective treatments available, and less on the patient's post treatment quality of life. All oncologists may not be as attentive to issues of fertility. Oncologists may also be unaware of the options available for women and men or to whom to refer their patients for further advice. It is important to make sure that information is appropriately conveyed and options explained to younger patients faced with cancer.

IV. THE ROLE OF FERTILITY SPECIALISTS

Variations in type of cancer, time available to onset of treatment, age, partner status, and recommended treatments (i.e., chemotherapy, radiation, bio immunotherapy, surgery) require that each case have its own treatment strategy. Fertility preservation is available for males and females, and from young children through adults. It is critical not to categorize all fertility preservation into a singular discussion because of the myriad of factors and possible scenarios and decisions that have to be made. While prepubescent children have access to a few research protocols, adults have standard of care options available.

V. CONSENTING - LEGAL ASPECTS

The key concerns are **age, partner status, inheritance, posthumous use of gametes and experimental nature of certain methods.**

- **Age** less than 18 is seen as minor in India. Adolescent age group is someone between 12-17 years age. In England and Wales, patients over the age of 16 years can give consent to treatment according to the Family Law Reform Act 1969. 1989 Children Act, and similar acts for Scotland and Northern Ireland, state that children under 16 deemed to be competent and can refuse medical or psychiatric examination. The United Nations Convention on the rights of the child emphasizes the best interests and welfare of the child, which includes adults listening respectfully to the child's views on all matters affecting the child (**United Nations, 1989, Article 12**).
- In the case of adolescents, there is more than likely, no **partner** to consider in the cryopreservation process. In the case of embryo cryopreservation, an egg or sperm donor needs to be identified. This can be done through either a known or anonymous donor, but this needs to be a serious conversation to have between the parents and adolescent. Since sperm and oocyte cryopreservation is a viable, safe, and effective option, healthcare professionals should recommend that over embryo cryopreservation for adolescents. Adolescents may be legal adults (over eighteen), but are still live

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at home with their parents or are in college and on their parents insurance. While legally, they may be adults, their decision making ability may still need to include parents in the process.

- If a patient is unable to produce semen by masturbation, the possibility of preserving testicular tissue arises (**Bahadur and Ralph, 1999**). In the case where the patient is **pre-pubertal**, and the **testicular tissue** does not contain 'gametes' as defined by the Human Fertilisation and Embryology Authority (HFEA), the legal, practical and ethical considerations are covered by the Children's Act 1989 and the Tissues Act 1961. Under these circumstances **parental consent** is essential (Bahadur et al., 2000). Secondly, where in the opinion of the medical practitioner, 'gametes' are present and the patient has reached Tanner grade 2 maturity, then under the provisions of the UK (HFEA) consent must come from the patient (**Tanner, 1989; Deech, 1998**).
- Challenges may arise with respect to legal parentage of the children resulting from cryopreserved tissues. The need to determine **legal paternity** arises in context of inheritance and federal benefits. Most courts recognize that if a spouse dies before placement of his/her gametes or embryos, the deceased spouse is not a parent of the child resulting from posthumous assisted reproduction unless he or she consented otherwise. Hence, it is important to include in the informed consent the patient's intended legal relationship to any resulting child. In addition to paternity, legal complications may arise to establish legal maternity for those women who want their frozen gametes or embryos to be transferred to a gestational carrier. Legal uncertainties may arise even with the established technique of embryo cryopreservation in situations such as when a couple divorces, one partner dies or if the couple was never married.
- **Posthumous** use of stored tissue. The legal system has recognized that the person's prior wishes about disposition of reproductive material are generally controlling after death. The position statement directs that programs storing gametes, embryos, or gonadal tissue for cancer patients should request clear instructions about what should be done with stored materials in the event of the patient's death, unavailability, nonpayment of storage fees, or other contingency.

In case of a formal written directive or declaration given by the deceased, the rightful legal owner of the gametes is the spouse or lawful partner. If there is no dying declaration available, the mere act of getting sperm cryopreserved (after marriage) can be seen as a sign of willingness to reproduce and bear children in the future.

Furthermore, jurisdictions vary on the status of children arising out of such a coalition; of their legal recognition as rightful heir of the deceased and also whether they are entitled to any property or social rights based on their legal status. The ICMR has no formal guidelines on posthumous sperm retrieval. Canada, France, Germany, and Sweden have legislation forbidding posthumous reproduction

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VI. ETHICAL CONCERNS

The concerns include trying experimental methods without taking appropriate ethical approval, using frozen embryos of cancer survivors in wombs of surrogates, rights and risks of unborn offspring, poor prognosis of cancer survivors, handling minors.

Bioethics should be present to ensure patients rights, and to critically examine the hope that patients have towards fertility preservation prior to any cryopreservation procedures. While patients may benefit from the research, it is not a guarantee or to be expected. Additionally, it is also important for patients to understand the difference between current research studies and the potential future research studies.

While, sperm, oocyte and embryo cryopreservation have been accepted as established techniques, both cryopreservation of ovarian and testicular tissue be offered only as a part of an institutional review board-approved protocol. It is advisable not to advertise or offer these techniques as established procedures. Prepubertal girls or women who cannot delay cancer treatment to undergo ovarian stimulation have no currently effective way to preserve their fertility. Experimental protocols do exist, however, for removing and freezing ovarian cortical tissue. The hope is that ovarian tissue can be thawed and implanted after cancer treatment as an auto graft, either back into to the pelvic cavity or to a heterotopic site, so that mature oocytes could be fertilized naturally or harvested for in vitro fertilization. Likewise, young women need to agree to undergo a cycle of ovarian stimulation and an invasive procedure to collect the ovarian tissue. If a young teenager objects to any of the above procedures, they should not be done, despite parental wishes.

Particular difficulties of information and consent arise in those who have reached an age where sperm storage is physically possible (puberty) but are not yet deemed legally competent. The transition through puberty includes significant biological developmental, emotional and cognitive changes. Combining these with the prospect of a serious disease such as cancer and the need to grasp the legal formalities can be daunting for those at any age but particularly the early adolescent patient. Teenagers may be embarrassed to discuss the option of masturbation in front of their parents. A mental health expert, oncology nurse or a social worker can minimize the embarrassment by discussing it outside the presence of their parents. For boys who cannot ejaculate, invasive procedures as described earlier can be done with their assent and parental consent (**Schover et al., 1998**).

A cause of concern for both fertility specialists and cancer survivors seeking fertility preservation is whether their offspring are at higher risk for physical defects and cancer because of the effects of their disease, anti-cancer therapy and cryopreservation techniques.

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Children born with disabilities may allege medical negligence in connection with their parent's fertility preservation during cancer treatment that preserved their life (**Crockin, 2005**). Some experts have also questioned if it is ethical to enable cancer patients to reproduce, as they face a greatly lowered life span and thus their leaving a minor child bereft of one parent (**Robertson, 2004**). Furthermore, providers who store human genetic material for future use may face liability for damages in the event of loss or destruction of the cryopreserved tissue (**Crockin, 2005**)

Post pubertal males will ordinarily be capable of ejaculation and can provide sperm for storage. Sensitivity and tact should be taken in discussing this option with them, including discussion outside the presence of their parents. If they cannot ejaculate, in some cases a testicular sperm extraction or epididymal sperm aspiration could be done with their **assent and parental consent**. As a special case, Prepubertal boys may be candidates for the harvesting of spermatogonial cells via testicular biopsy, an experimental procedure. The mindset of parents is often riddled with fear, apprehension, concern, survival, treatment, not to mention the risk of infertility in the future. Parents are still expected to make decisions in the best interests of the child no matter their personal feelings or emotions.

Of ethical concern is healthy women opting for oocyte banking just on grounds of delaying motherhood or lack of suitable partner, this new age marketed so called social freezing is a debatable issue. In Europe and USA, this has raised many social and moral questions. In search of biologic parenthood is it right to undertake risks to mother and baby by embarking on pregnancy, late in life. In Netherlands, 45 is age limit to allow donor eggs and in USA, the age limit to offer donor eggs is 50.

VII. POSTHUMOUS SPERM RETRIEVAL-AN ETHICAL DILEMMA

Posthumous sperm retrieval is a delicate and controversial aspect of fertility preservation. The time of sperm harvest from the time of death varied from 7.5 to 36 hours. Complicated issues may still arise in situations, such as when the patient dies without banking his semen and the surviving partner requests the healthcare provider for posthumous extraction of spermatozoa.

In case the request is made by the parents or family members, the ethics committee opinion by ASRM clearly states that in the absence of written instructions from the decedent, programs that are open to considering requests for posthumous gamete procurement or reproduction from surviving spouses or life partners should decline requests for such services from other individuals.

VIII. LOGISTIC CONCERNS

This includes the appropriate trained **committed team** who get networked at an appropriate time frame to suit the specific needs of the affected client. The **funding** through self or insurance company

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and to be able to predict the actual long term costing is the biggest challenge. The whole exercise is at the end of the day only a hope and not a guarantee. These dismal words on success rate makes decision making a challenges. Usually elder, wealthier, early stage cancer patients get better access to fertility preservation.

Oncofertility being a new field, there is an urgent need for all oncologists to be sensitive to a referral attitude, and an available easy way for patients to enjoy the parenthood. Training the reproductive medical clinicians to the special complex needs of cancer afflicted patients is strongly recommended.

To date, management strategies for oncofertility in the world are still fragile and unequal. To structure the oncofertility sector, a multidisciplinary project enabling teams to work together should be implemented, particularly in low and middle-income countries.

Semen banking should ideally be done before the start of cancer treatment. Theoretically semen collection and storage is feasible after the initiation of chemotherapy and radiation therapy, at least until azoospermia ensues. However, it is advisable to wait for 12–18 months because of the time taken for the recovery of spermatogenesis and significant increase in the frequency of sperm aneuploidy persisting for 18 months or more after initiation of anti-cancer treatment. There is no proven method for fertility preservation in prepubescent boys. Testicular tissue freezing is considered highly experiment, and no lives births have resulted from this research as of yet.

There is the possibility that the treatment will not affect fertility or puberty, and the child can go back to living a normal healthy life. In those cases, parents should think about what to do with the cryopreserved tissue. There should also be a discussion of the maintenance and financial expectations with the cryopreservation bank. More than likely these cryopreserved material will be in storage long term. Patients and parents need to be aware of the arrangements of who is paying for how long and when does that financial burden change from the parents to the patients.

Several recent reports from sperm-banking facilities concur that less than 20% of men who store sperm before cancer treatment end up using it to try to conceive. Given that insurance rarely covers the costs of cryopreservation, patients should be made aware of the financial costs as well as the benefits of sperm banking.

IX. CONCLUSION

Ethical and logistic discussions including defining the beginning and intrinsic value of life, moral status of embryos, the right to reproduce, issues of access to reproductive technology, funding of research, the cost for long term cryopreservation and the discussion of insurance coverage for reproductive technology. The discussion must consider the specifics of the context including gender, age, and socioeconomics of the patients as well as the availability of standard of care and research protocols.

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Patients also need to be made aware of the financial costs involved as the insurance companies will not always cover the costs of cryopreservation. The informed consent process for minors needs the involvement of patient's parents or legal guardians. Assent (permission less than full consent) is required in case of minors who are able to understand the issue, such as post-pubertal boys and girls, together with the parental consent. However, for children too young to give an assent, parents may consent to experimental procedures only if the expected benefits are sufficient to justify the risks involved.

Uncertainty of treatment outcomes and experimental nature of therapy is of logistic concerns. Reproductive autonomy is getting compromised when it comes to fertility preservation as men get the more easier option of time tested sperm banking. Gender discrepancies are also strikingly against women. Inequalities in access to healthcare due to absence of good networking of multidisciplinary team leads to non comparable outcomes in fertility preservation. Its complicated because of the paucity of meaningful options and very little time available to most of the patients for taking any decision!

X. RECOMMENDED READING

1. **G. Bahadur J. Whelan D. Ralph P. Hindmarsh.** Gaining consent to freeze spermatozoa from adolescents with cancer: legal, ethical and practical aspects. Human Reproduction, Volume 16, Issue 1, 1 January 2001
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3. Technical and ethical challenges of fertility preservation in young cancer patients. Reproductive Bio Medicine Online; www.rbmonline.com/Article/3292 on web 18 April 2008, **Dr Ashok Agarwal**
4. **Dr Aditya P Sharma.** Fertility preservation in men: Perspective -Indian journal of urology Oct 2018

Dr M Gouri Devi
President - IFS

Prof (Dr) Pankaj Talwar
Secretary - IFS

Dr Puneet Arora
Executive Editor

Dr Jayesh Amin
SIG Committee

Dr Papa Dasari
SIG Committee

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Theme: Beyond Tomorrow

15th Annual Congress of
Indian Fertility Society
FERTIVISION
2019 6-8 December
The Leela Ambience Hotel, Gurugram
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Invitation

Dear Friends, Welcome to *FERTIVISION 2019*

On behalf of the Indian Fertility Society (IFS), we are extremely pleased to announce and cordially invite you to the much awaited academic event – the **15th National Annual Conference - Fertilvision 2019**, to be held on **6th, 7th & 8th December 2019** at Hotel The Leela Ambience, Gurugram, New Delhi / NCR, India.

This conference is aimed to provide the most comprehensive academic platform in the field of Infertility and Assisted Reproductive Technology (ART) befitting the theme of the meeting “**Beyond Tomorrow**”

Renowned and leading expert faculty from around the world would gather and deliver talks in our cutting edge scientific program which will not only enrich your current knowledge and clear all doubts faced in day-to-day clinical practice, but will also enlighten you about the latest innovations and ongoing research.

A large number of renowned international faculties have already confirmed their participations till date. The pre-congress workshops on 6th December are specially designed for informal in-depth training with hands on sessions on simulators and live, where ever feasible. There will be 4 simultaneous running streams on 7th & 8th December covering a wide variety of topics, enabling you to choose the deliberations specific to your area of interest and clinical practice. We are having a dedicated hall for the esteemed embryologist friends.

The best oral and poster presenters under various categories and the quiz winners will be honoured with special awards and prizes. Do join us in large numbers and update your knowledge with most updated current standards in clinical practice, as well as get inspired to innovate further to overcome remaining enigmatic issues!

The three days of scientific program will encompass didactic lectures, keynote presentations, panel discussions and orations. There will be 9 Preconference workshops based on Ovulation Induction, Ultrasound, Andrology, Embryology, Hands on Embryo Transfer, Ovum Pickup and more. These workshops will be in addition to the special state of the art workshops by the faculty from IFFS and ESHRE. We expect delegates across India, Sri Lanka, Bangladesh, Nepal, Middle - East Countries and African Nations and the arrangements are being made to accommodate more than 2500 delegates.

The exhibition area will be one of the highlights of the conference. Exhibiting provides tremendous benefits to both participating industry and the society. Tea, coffee and lunch will be served confluent with the trade area to allow optimal interaction between the trade companies and delegates during beverage and lunch breaks.

We invite you to participate in the Fertilvision 2019 and exchange your expertise with more than 2500 specialists in the field of Assisted Reproduction.

We look forward to your active participation and suggestions for successful conduct of the conference.

With Our Best Regards



Dr. M Gouri Devi
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Pregnancy and Lactation. **PRECAUTIONS:** Children: Zoladex is not indicated for use in children, as safety and efficacy have not been established in this group of patients. Males: Use in patients at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and patients monitored during first month of therapy. Females: Exclude pregnancy before treatment. Non-hormonal contraception should be employed during therapy. Loss of bone mineral density, which may recover on cessation of therapy. Caution in women with known metabolic bone disease. Increase in cervical resistance, requiring care of dilating the cervix. Currently, there are no clinical data on the effects of treating benign endometriosis conditions with Zoladex for periods in excess of six months. An increase in benign pituitary tumours has been observed in male rats following long-term repeated dosing. (Relevance to man not established). Pancreatic islet cell hyperplasia and a benign proliferative condition in the pyloric region of the stomach observed in mice following long-term repeated dosing with human dose (relevance to man is unknown). There is no evidence that Zoladex results in impairment of ability to drive or operate machinery. **PREGNANCY AND LACTATION:** Although reproductive toxicology in animals gave no evidence of teratogenic potential, Zoladex should not be used in pregnancy, as there is a theoretical risk of abortion or foetal abnormality if LHRH agonists are used during pregnancy. Potentially fertile women should be examined carefully before treatment to exclude pregnancy. Non-hormonal methods of contraception should be employed during therapy. The use of Zoladex during breast-feeding is not recommended. **SIDE EFFECTS:** Rarely, hypersensitivity, skin rashes, generally mild. Arthralgia. Changes in blood pressure. Occasional mild bruising at injection site. 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AstraZeneca Pharma India Limited
Block N1, 12th Floor, Maratha Embassy Business Park
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AstraZeneca Pharma India Limited

IFS SECRETARIAT

302, 3rd Floor, Kailash Building, 26 Kasturba Gandhi Marg, CP, New Delhi-110001

Mobile : +91 9667742015+91 9899308083 | Landline : +91 11 40018184

Email: indianfertilitysocietydelhi@gmail.com | Web: www.indianfertilitysociety.org



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