



## Preservation of Fertility Considering the Masculine Factor, Opinion of a Group of Specialists in Reproductive Biology

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### Abstract

**Objective:** The goals of this group of reproductive biology specialists were to create guidelines for non-subspecialist physicians so they can provide well-informed advice to people who decide to Preserve Fertility ("Fertility Preservation", FP) and that they make an informed decision. The different techniques for FP in men, children and adolescents, people with HIV, people with different sexual perceptions, as well as the legal and ethical foundations that FP entails were reviewed.

**Material and Methods:** Prior to meeting, updated bibliography on topics to be discussed was distributed, and experienced FP professionals were selected. Ten round tables were held, with a representative from each of them presenting the conclusions and enriching them with the rest of the attendees, achieving the final recommendations.

**Results:** 1. Methods proposed as an alternative for FP for men of childbearing age include: semen recovery, epididymal sample and/or testicular biopsy. 2. Men living with HIV must have multidisciplinary management and sample washing required for FP. 3. In men

who wish to undergo sex reassignment, if they have gender dysphoria, assisted ejaculation can be performed. 4. Before vasectomy, patients should be counselled about FP and the chances of success. 5. In girls and adolescents, the oncological or non-oncological diagnosis should be identified as soon as possible in order to be able to offer the patient all options for FP in a complete and appropriate manner. 6. In the case of prepubescent children and young people, FP methods are limited to testicular biopsy. 7. It is considered that the ideal for a good reproductive prognosis (at least one child) is to have between 8 and 12 metaphase-II eggs to cryopreserve. The prognosis of each case largely depends on this. 8. During counselling of FP for males, regardless the origin is oncological or not, it is of utmost importance to provide counselling in a complete, precise and detailed manner before FP and it should be provided by a specialist in the area. 9. There are no laws that support physicians, their only protection is the complete informed consent reviewed by lawyers; also, collection of posthumous reproductive cells is not legislated. 10. The Mexican Association of Reproductive Medicine (AMMR) is the generator of knowledge and information for non-subspecialist physicians in the area and support for professionals dedicated to FP.

**Keywords:** Fertility Preservation; Male Fertility Preservation; Prenatal; Adolescents; Cancer; Longterm Survivors; Ethics; Legal

## Introduction

In 2020, the first Mexican consensus on FP was held. The consensus was discussed and approved by a group of specialists in the area [1]. In this consensus, guidelines for the care of cancer patients requesting FP were proposed and voted on, as well as for the community with different sexual preferences who desire FP. In both areas, ethical and legal aspects were covered. The first consensus focused mainly on women and men with cancer, because it is the first reason that motivates preserving fertility [1]. In the case of women, survival from uterine, ovarian, and cervical cancer under the age of 45 ranges from 6.5%, 12%, and 36% respectively [2]. There are age groups that are also of interest to preserve fertility, such as children and adolescents, either because they survive cancer or other types of diseases such as autoimmune diseases or genetic syndromes, such as Turner syndrome [3].

On the other hand, since men have better survival rates in the oncological area, seminal preservation has been sought, either because the cancer is located in the reproductive area, the treatment causes damage to gametogenesis [4], the damage is at the level of the hypothalamic axis or at the level of the spine and the reproduction process in men is affected [5]. Likewise, in men, the desire to preserve their sperm must be considered in non-oncological diseases, for example, systemic diseases that require some gonadotoxic treatment, people living with HIV or when they want a sex reassignment.

Every day more information is published about fertility preservation techniques, partly because more people are requesting it. For example: women who delay pregnancy due to professional development, men who want to preserve their gametes before

vasectomy, the transgender community that wants biological children, better management of autoimmune diseases that prolongs survival, etc. All of this means that, in addition to advances from a technical and technological approach, there is a greater need for legal and ethical support that accompanies these procedures.

In this 2022 meeting of specialists on FP, we cover diseases, events and particular situations, in which the desire for FP is not only because of the cancer and its treatment. We integrate the topics of management in men who do not have cancer, FP in children and adolescents, preservation in people living with HIV, in sex reassignment, all this from the technical, scientific, legal, ethical and psychological perspective.

As goals of this meeting, we proposed that Mexican specialists in the area issue guidelines to help the primary care physicians to provide well-informed advice and then the person who wants FP makes the decision with knowledge. The specialists in this consensus were selected for their experience in FP from the scientific community of our country.

## Methodology

The invited specialists, gynaecologists, oncologists, urologists, reproductive biologists, psychiatrists and embryologists, received the bibliography of the topics to be discussed, in addition to the bibliographical consultation that they could make. In a closed place, 10 round tables were held by knowledge of the area. The topics of the round tables involved: 1. Men of childbearing age without oncological medical conditions; 2. Men of childbearing age living with HIV; 3. Men of childbearing age, prior to sex reassignment; 4. Prevasectomy Fertility Preservation; 5. Fertility Preservation in girls and

adolescents; 6. Fertility Preservation in boys and adolescents (update); 7. Technical aspects (update); 8. Importance of counselling in male Fertility Preservation; 9. Ethical aspects in Fertility Preservation; and 10. Legal aspects of posthumous reproduction. At the end of the 10 round tables, a representative of each team exposed the conclusions of the topic to all the participants of the group; comments were made and each topic discussed was concluded. In order to strictly adhere to the conclusions, presentations were audio-visually recorded.

The recommendations of the Mexican Fertility Preservation specialists' panel are below.

### Men in childbearing age without oncological medical conditions

Although more emphasis has been placed on cancer as a factor for FP, 10% of patients who consult for FP do not have any pathology. Although proportionally, patients with oncological diseases are those who most frequently request FP, non-oncological diseases have higher prevalence; for example, in 2003 it was reported that the prevalence of Systemic Lupus Erythematosus (SLE) was 24 per 100,000 inhabitants and that of testicular cancer at that time was 7 per 100,000 inhabitants [6]. Requests for FP in men without oncological conditions include: First, social perpetuation, which is the man who wants FP of his own free will. Second, there are patients who want FP prior to vasectomy, generally men under 45 years of age. Third, patients with inflammatory diseases such as psoriasis, SLE and other immunological diseases, almost all of which include treatment with gonadotoxic drugs [7]. Fourth, people with a different sexual perception. Fifth, patients in critical condition, in intensive care units, and at risk of death; and Sixth, men who will participate in acts of war.

The method for FP in fertile men is the preservation of semen collected by masturbation. If this is not possible, other methods are used such as vibratory stimulation, electroejaculation, epididymal aspiration or testicular biopsy.

From an ethical perspective, it is important to consider an informed consent. The patient is warned that if FP is not performed before treatment with gonadotoxic drugs, it may have a teratogenic or mutagenic effect. In cases of critical illnesses, which involve imminent risk of death, posthumous recovery must be considered. In this case, it is important to consider the ethical aspect of who must sign the consent: the patient before death and/or a family member or the legal partner afterwards.

### Recommendation

In men who wish to undergo FP due to systemic diseases, the preservation method should be through semen recovery, as long as possible. A complete semen study should be performed (spermiogram and sperm DNA fragmentation) ruling out any abnormality, since sometimes the same disease that led to the desire for FP can lead to alterations in seminal parameters. It is then necessary to warn the patient of the need for alternative measures such as cryopreserving several samples or even performing a testicular biopsy. In the case of infectious diseases, these should be treated before FP or the sample should be cryopreserved in separate containers (cases of HIV, hepatitis B, etc.).

### Men in childbearing age living with HIV/AIDS

Whether due to the infection itself, over-aggregated pathologies or treatments for some of these situations due to the disease, there may be consequences at reproductive level. These patients may require FP. In these cases, an assessment by a Virologist or Infectologist shall be required to specify the real status of the patient regarding the infection, the viral load and the scope of the medications used. In addition, an assessment by a Psychiatrist or Psychologist shall be required to specify the mental and emotional state of the patient; it is known that, not only the disease can change the mental state of the patient, but also some of the treatments used. The appropriate infrastructure must be available: specific storage tanks for this type of samples, which must follow a specific washing protocol, regardless of the viral load detected. From a legal perspective, it is essential to have the necessary documentation specified by the Federal and State Health Authorities in order to preserve these samples.

### Recommendation

People living with HIV/AIDS who want FP should have an additional medical assessment by an Infectologist or Virologist and a Psychiatrist or Psychologist with experience in FP.

Samples must be washed, even if the viral load is not detectable [8].

People living with HIV/AIDS should be treated in accordance with the four principles of bioethics: 1<sup>st</sup>, Code of autonomy where the patient has the ability to decide whether or not to preserve their fertility; 2<sup>nd</sup>, Code of beneficence, that is, the benefit that will be given to this patient by doing so; 3<sup>rd</sup>, Non-maleficence, which is not causing harm to the patient with FP; and 4<sup>th</sup>, Code of justice, both for the patient and for society.

### Men in childbearing age, prior to sex reassignment

Gender dysphoria is dysphoria in relation to incongruence between an individual's gender and sex assigned at birth [9]. The prevalence of transgender women in the United States is 531 per 100,000 inhabitants with a tendency to increase [10]. Unfortunately, in our environment, this is an issue that still generates confusion; there is not enough information. Physicians who are the first line of contact with the patient must have the appropriate information to advise them and/or refer them to a reproduction centre for multidisciplinary management while respecting the basic bioethical principles.

In this group there are two subgroups of patients: the post-pubertal patient and the prepubertal patient.

Post-pubertal patient: these patients must be under psychiatric-psychological, endocrinological, andrological evaluation and legal assistance for at least one year; and once this period has concluded, if they wish to continue with FP prior to sex change, they may do so. The ideal patient is one who, although he has received all the necessary advice, has not received hormonal treatment and his hypothalamus-pituitary-testicular axis is intact.

The patient should undergo two spermatobioscopies and sperm DNA fragmentation. The sample should be collected by masturbation, but if this causes dysphoria and issues, there are techniques assisted by electrical or vibratory stimulation [10] or ejaculation under sedation. The sample can also be collected by Percutaneous Epididymal Sperm Aspiration (PESA) or by Testicular Sperm Extraction (TESE), although the results in terms of live birth rate decrease with PESA compared to masturbation and even more so with TESE.

Usually 3 – 6 semen samples are frozen. This can relieve the patient and assure that, in the future, if the conditions of their life change, they will have support to promote their fertility.

On the other hand, if the patient has already started hormone replacement therapy, it must be explained clearly and precisely that for FP, the patient must stop hormone replacement therapy, that he or she must undergo complete serial hormonal-metabolic studies and ultrasounds on a regular basis, that the restart of spermatogenesis will take three to six months and that during this time a "re-virilization" will occur, which will partially recover masculine physical features that may cause certain moral burden or anxiety.

If FP is carried out, this implies the cost of annual maintenance of the cryopreserved samples. The patient must be informed in detail to avoid the risk of "abandoned samples" and it must be explained to him/her that after a certain clearly specified time, if he/she does not cover these costs, the samples will be discarded.

In the case of prepubertal patients, it must be clear that in our country FP is not yet legal until the patient has reached the legal age. A multidisciplinary approach should be initiated that includes psychiatry-psychology, andrology and endocrinology.

### Recommendation

In the case of FP in post-pubertal stage patients, the sample should ideally be collected by masturbation or by assisted stimulation in the case of genital dysphoria, although it is not ideal, it is also possible by PESA or TESE.

Transgender women should be informed that by stopping hormone replacement they may acquire masculine traits.

In the case of patients in pre-pubertal stage, they should have family counselling by a multidisciplinary team that includes a psychiatrist-psychologist with experience in reproduction, endocrinology, andrology, reproductive biology and also from the legal perspective. In our country, this type of procedure is not yet legal in healthy patients in the pre-pubertal stage.

### Pre-vasectomy FP

Vasectomy is one of the most common methods of sterilization. Nowadays, it is no longer a definitive method because microsurgical techniques and highly complex assisted reproduction techniques can reverse the effect of vasectomy. Approximately 6% of men with vasectomies request a reversal due to changes in their life [11]. The effect that paternal age has on sperm quality should not be forgotten, especially after 40 years.

Surgical techniques to reverse vasectomy offer results that depend on multiple variables [11]: age, evolution time (time with vasectomy is inversely proportional to the pregnancy rate achieved with reversal due to the formation of reactive oxygen species, formation of anti-sperm antibodies, etc.), dependent operator and age of the partner. Therefore, ideally, pre-vasectomy counselling should be considered by both the andrologist and the reproductive biologist, to assess the preservation of semen before vasectomy.

Unfortunately, the vast majority of patients did not have the opportunity for FP due to lack of information or they did not consider it appropriate at that time, so PESA or TESE must be used.

With the current assisted reproduction techniques, a new pregnancy is possible with cryopreserved semen, whether collected by masturbation, PESA or TESE.

### Recommendation

Any man who desires a vasectomy should receive clear, precise and sufficient information about FP from an andrologist and/or a reproductive biologist.

The ideal method to collect the sample is by masturbation, but also by PESA or TESE.

The ideal method for cryopreserving the sample will be slow freezing when dealing with normal or slightly variable samples. Samples with severe variations should be vitrified, but this is a more laborious and expensive method.

### Girls and adolescents (update from the prior consensus in 2020)

FP in girls and adolescents should always be treated by a multidisciplinary team. It is extremely important to identify this group of patients opportunely. In the group of oncological patients, sometimes biologists receive patients who have already been treated, when and adequate management for FP is no longer possible.

It is very important to inform patients about the strategy and all the possible options, including advantages, disadvantages and scope of each one, before starting any treatment.

### Recommendation

The oncological or non-oncological diagnosis should be identified as soon as possible in order to be able to offer the patient all FP options completely and appropriately before starting any medical or surgical treatment. This information should be provided clearly, precisely and integrally by a reproductive biologist, the oncologist (should this be the origin) and the treating physician, in coordination with the multidisciplinary team involved in the FP. If the patient is a minor, their parents or legal guardians must be present.

### FP in boys and adolescents

The prevalence of malignant pathologies in this age group is 17 per 100,000 children [12]. Survival is high in this group of patients: between 83% and 86%. Ninety-nine percent of patients re-

ceiving oncological treatment will probably have some gonadotoxic side effect that will manifest as oligospermia or azoospermia. In these cases, azoospermia can be as frequent as 15% to 30%, so it is quite justified to think about FP in this group of patients (children and adolescent boys). Spontaneous post-treatment recovery of the seminal parameters and therefore fertility (if that is the case), could take up to 5 years.

For prepubertal children, the most common methods could be testicular biopsy (freezing of testicular tissue). Protection with Gonadotropin Releasing Hormone (GnRH) agonists and testosterone is not possible, because these patients do not yet have spermatogenesis.

In the case of adolescents who could already provide a seminal sample by masturbation, this would be ideal. If this is not possible, it could be collected by vibratory stimulation and electroejaculation.

### Recommendation

In the case of prepubertal children and young people, FP methods are limited to testicular biopsy.

### Update of the Technical aspects from the consensus (2020)

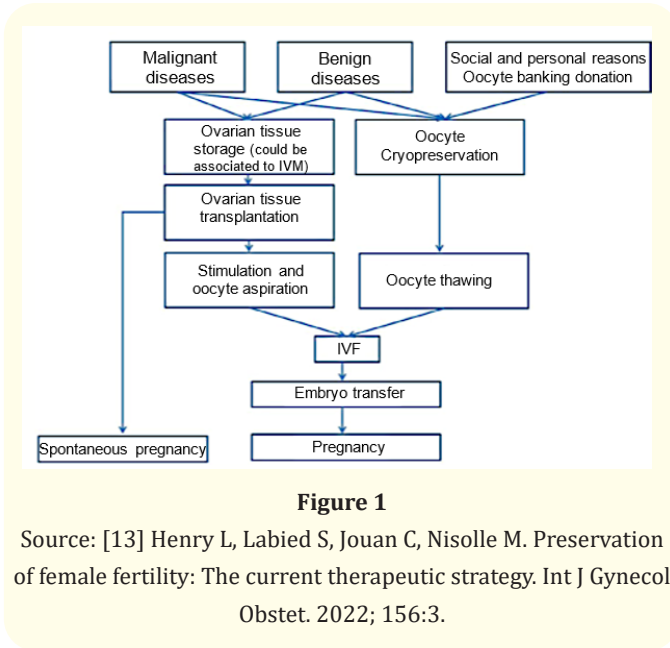
Ovarian tissue freezing is a technique that is no longer considered experimental. It was considered to have a recovery rate for ovarian function of up to 90%; however, with the accumulated clinical evidence, it should be adjusted and patients should be informed that this recovery rate is around 60%.

There is also the possibility of a double FP technique: cryopreservation of both oocytes and ovarian tissue, which can be done with the following procedures:

- Short-term Controlled Ovarian Hyperstimulation (COH) for aspiration of immature eggs and *in vitro* maturation with cryopreservation and, in the same surgical event of follicular aspiration, a biopsy of the ovarian tissue for cryopreserving.
- COH with cryopreservation of mature eggs and, in the same surgical event of follicular aspiration, a biopsy of ovarian tissue for cryopreserving.
- Collect ovarian cortex to cryopreserve ovarian tissue, but before cryopreserving it, trying to activate folliculogenesis *in vitro*, aspirate the oocytes and mature them *in vitro* and cryopreserve the eggs and ovarian tissue. This is still an experimental technique.

The future alternative for this patient should not be forgotten: transplantation of cryopreserved ovarian tissue with subsequent COH, collection of mature oocytes and the possibility of pregnancy.

**Options for preservation of female fertility**



**Recommendation**

In the case of patients who require FP for oncological reasons, to avoid the risk of the different HOC regimes on the evolution of the cancer, it should be remembered that all therapeutic decisions should be discussed by the multidisciplinary group of specialists (oncologist, reproductive biologist, etc.) who treats the case and these in turn with the patient, taking care and respecting the ethical and legal framework of each situation.

It is considered that the ideal for a good reproductive prognosis (at least one child) is to have between 8 and 12 metaphase-II eggs to cryopreserve. The prognosis of each case largely depends on this.

**Importance of counselling in male FP**

A man should not be denied the possibility of being the biological father of his children; as long as there is hope, it should be considered and explained clearly, precisely and completely to the patient. All information on FP, such as techniques, probability of success, etc., should be made available to the primary care physicians. All physicians, without exception, should be aware of this information in order to provide it to their patients (if they request

it and, if necessary) to refer them to a specialist who can provide this information in detail and specifically for their particular case.

For analyses carried out on a patient’s semen sample to be valid for reproductive counselling, these must be carried out in a certified andrology laboratory or in a recognised reproduction centre in order to ensure that the report is truthful, precise and up-to-date.

FP can be sought for oncological and non-oncological reasons. In the case of non-oncological FP (prior to vasectomy), should the man have a recent normal spermogram, we suggest collecting and freezing 4 samples for one attempt. The patient must be informed precisely and completely before the vasectomy that, although it is a potentially reversible surgical procedure, the cost of reversal is high, not covered by major medical insurance and not always with such good results. Alternatives include Percutaneous Epididymal Sperm Aspiration (PESA) or Testicular Sperm Extraction (TESE); however, the advantages, disadvantages and possible sequelae or complications of these procedures must be explained in detail by the andrologist or reproductive biologist before the FP.

There are cases that require special and detailed explanation, such as patients who are frequent users of anabolic steroids, since they frequently suffer from testicular suppression due to negative feedback. It is considered that up to 10% of patients no longer recover testicular function with the use of a single cycle. The andrologist should evaluate these cases and, ideally, preserve frozen semen before starting the use of anabolic steroids.

Other indications for FP in men, in non-oncological cases, are unilateral orchiectomy (severe trauma, infections, benign or malignant tumours limited to a single testicle and cured with surgery). Clear and precise information should be given to the patient to consider realistic expectations. The sperm recovery rate in semen from normospermic patients is not very good, and in testicular tissue it is even lower.

FP in oncological cases. Depending on the urgency of the case, semen can be cryopreserved as it is collected. Hence, the importance of communication between the entire multidisciplinary team (reproductive biologist, oncologist, andrologist, etc.) that cares for the patient and with the patient himself.

It is of utmost importance to ensure that the informed consents given by the patient are as precise, detailed and personalized as possible (CONAMED, 2020). If the patient is a minor, it is an essen-

tial requirement the consents to be signed by the parents or legal guardians. Upon reaching the legal age, all signed informed consents must be updated.

### Recommendations

It is of utmost importance to provide integrally, precisely and in detail FP counselling for males, regardless the origin (oncological or not), and by a specialist in the area.

Also, before FP, the patient must sign the informed consent forms that clearly explain the situation that justifies FP, the semen and storage conditions, and all possible future scenarios.

If the patient is a minor, the consent forms must be signed by the patient himself, his parents or guardians, and upon reaching the legal age, these must be updated and replaced so that the patient, who is now of legal age, is the signatory and sole responsible party.

### Ethical aspects of FP

Reproduction is a human right, it is a universal right. In all medical practice, including assisted reproduction issues, the four basic principles of bioethics must be respected [14]: 1. Autonomy, 2. Beneficence, 3. Non-maleficence, and 4. Justice.

In general, three indications for FP are distinguished: the non-oncological medical indication, the oncological medical indication, and the social indication. However, from an ethical perspective, all cases must be handled in the same way: providing complete, accurate, and detailed information, including advantages, disadvantages, risks, side effects, and possible complications of the particular case to patients and the legal guardians when the patient is a minor, and emphasizing the respect for the four bioethical principles.

All FP cases must be evaluated and authorized by the Bioethics Committee of the reproduction centre where the procedure will be carried out.

The informed consents signed must include in detail the measures to be taken in the future event when it is no longer necessary to continue keeping cryopreserved sperm, eggs and/or embryos, such as: who will make the decisions; the destination of the embryos, since these cannot be destroyed or subjected to research, but can only be transferred to the patient/wife or donated anonymously; the destination of both eggs and/or embryos in situations such as death of the person, divorce or separation of the couple; as

well as the destination of the eggs, sperm and embryos if the couple reaches 50 years of age and has not used them, must be specified (after the age of 50, there should be no more embryo transfer in this woman given the risks of maternal-foetal obstetric complications and the well-being of the future child with parents with a shorter life expectancy).

It is important to emphasize that all consents, as well as patient counselling, should include legal advice adapted to the local laws in force in that place.

When collecting and using post-mortem sperm, each case should be analysed by the Bioethics Committee of the centre where the sample will be processed to determine, from a bioethical perspective, whether this procedure applies in each particular case and under which conditions [15-17].

### Recommendations

The management of a patient who wants to perform FP should be handled on the 4 pillars of Bioethics in medicine.

There are no laws in Mexico that legislate who (husband/wife) has the right to cryopreserved gametes and/or embryos if one of them is missing.

Within the reproduction units, it is suggested to have well-established guidelines designed in coordination with the entire multidisciplinary group of the centre and with the Bioethics Committee, that serve as a guide to patients before any FP procedure, but remembering the bioethical principles.

The informed consent used in each case must be endorsed by the legal team in order to protect the physicians working in this area.

### Legal aspects of posthumous reproduction Posthumous use of germ cells as part of FP

In our country there is no legislation that deals specifically with these issues; the basis of all legal aspects in this area is the Article 4 of the Mexican Constitution. There is no draft law that has any chance of moving forward.

Given the lack of a draft law, clinics and medical organizations and associations must elaborate guidelines to standardize criteria and protect both patients and medical personnel from a medical and legal approach.

These guidelines must cover aspects to discuss with the patients before FP, such as: who makes the decision of the recipient of the embryo or the use of germ cells, how long the guardianship of the germ cells is held, consanguinity, LGBT affiliation, use of germ cells when after cryopreserving them the donor decides to change sex, etc.

The informed consent reviewed by both Bioethics and Legal Committees, by using clear, precise and detailed language, is what shall demonstrate Good Medical Practice with solid legal and bioethical foundations.

### Recommendation

We believe that in our country, complete, updated laws are required, designed by a multidisciplinary team of specialists in the subject.

The complete informed consent is mandatory, where each aspect of the procedure is clearly noted, from the medical, bioethical and legal perspective of the Fertility Preservation. While there is no formal legislation in our country, these informed consents must be designed, drafted and reviewed regularly by the Bioethics and Legal Committees of each reproduction centre.

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