

# SEF CODE OF ETHICS

## CLINICAL ETHICS AND GOOD CLINICAL PRACTICE GROUP

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# INTRODUCTION

## 1. Justification of a Code of Ethics for SEF

The proposal to draft a code of ethics for the Sociedad Española de Fertilidad (SEF) began with the conviction that health professionals need to stop and reflect on their own work, on the values that support or discourage said work, on the services they provide to society, on the goals and consequences that are derived from these goals, etc., to guide their medical practice and deliver quality and excellence. If what we seek is excellence, merely complying with legal norms is not enough; we are obligated to be more demanding.

In the field of reproductive medicine, this reflection is necessary to prevent strictly financial criteria from taking precedence over a responsible commitment to a medical approach, which could result in health professionals setting aside the elements that legitimise their actions in favour of a benefit or a service exchange practice.

Assisted reproduction has experienced enormous and previously unthinkable medical and technological progress. These advances have opened an infinite number of ethical questions that the profession has attempted to address by means of different guides and recommendations from scientific associations in several different countries, which have arrived at different conclusions depending on the cultural characteristics and background of each place.

Assisted reproductive technology (ART) normally involves two moral agents: the healthcare team on the one hand and the patients on the other. Both parties agree to use medical technology with a specific goal: having a child. They reach this agreement by means of dialogue and an exchange of ideas and information. Thus, this approach binds the specialists in reproduction to offer a careful bedside manner and respect to the patients and to the potential children born by means of this technology.

There are a series of ethical principles that must also be taken into consideration in the context of assisted reproduction. The principle of beneficence binds professionals to maximise care. The principle of non-maleficence demands that the practitioner prevent possible harm to the patients and their potential offspring. The principle of autonomy, in contrast, binds the health professional to respect the patient's right to self-determination, guided by their rights, preferences and values. The principle of justice seeks equitable and non-discriminatory treatment and an appropriate management of resources. These ethical principles can come into conflict with one another under different circumstances, which is why they should be considered carefully.

The objective of drafting a code of ethics, however, goes beyond addressing only the essential principles mentioned here. It is also necessary to take into consideration the group of values that are affected on a case-by-case basis.

The performance of reproductive medicine professionals is centred on a particularly sensitive aspect for many citizens: their wish to reproduce. Excessive expectations following technological advances, the uncertainty of the results, the temporal limits of these treatments, the movement towards desire-driven medicine, etc., could generate tensions that require an in-depth analysis.

Clearly, general reflections on these issues exceed the objectives that the SEF's Clinical Ethics and Good Clinical Practice Group could address; however, an important service must be provided by the SEF in the form of some guidelines with which to analyse the situation and facilitate some direction for professional activities.

We must take into consideration that a code of ethics is not the same thing as a standards and practices code. This proposal comprises a code of ethics, and our understanding of such is that it does not establish binding minimum accountability and legal sanctions; instead, it establishes good practice guidelines that are considered valid for quality professional practice and that attempt to promote important values based on the conviction that they improve healthcare.

It is evident that a code of ethics must take into account the code of standards and practices. However, the code of ethics is defined as an attempt to go beyond the code of standards and practices. Thus, the code of ethics addresses advice and suggestions on maximising efficiency and quality rather than practice norms and eschews the language of sanction and the law in favour of language focused on the promotion of ideals and the development of responsible attitudes in accordance with values that are considered appropriate.

## **2. Objectives of the Code of Ethics**

- 1.- Have a document available in which a commitment is made to promote quality and good practices at either the professional or institutional level.
- 2.- Make the ethical commitment of reproductive medicine professionals practicing their profession clear to institutions, health authorities and society as a whole.
- 3.- Promote reflection on the values that drive the work of health professionals, specifically those in the reproduction field, and the services they render to society.

## **3. Document structure**

This code is structured under four broad sections that analyse different scenarios of responsibility that affect or are related to the work of reproductive health professionals.

This responsibility approach was chosen for a number of reasons: (1) first, professional activities and practices provide a specific service to society, generating goods and services that are of great interest, yet at the same time these services also have consequences that imply the responsibility for and commitment to the search for the best result possible and, if necessary, the assumption of any damage or harm derived from the proceedings. (2) Responsibility is the ethical category that should be emphasised in a medical field in which situations involving vulnerability, anxiety or uncertainty are frequent. (3) Addressing responsibilities in lieu of obligations implies an emphasis on the ethical commitment that is demanded of the health professional in quality issues, plus the legal duty that is presumed to be assumed and complied with.

The reproductive health professional, whatever the field of his or her work, makes a commitment to provide quality service to the patients, whom he or she must treat with respect, and seek their greater benefit. This is why patient responsibility is the first of the fields of analysis that are addressed in this document.

When carrying out their work, reproductive professionals also commit to a broader range of responsibility, that of service to society as a whole. This is why the second level of analysis is one of commitment to society. In addition, the professional must perform his or her tasks with the greatest diligence and at the highest level of quality and practice and not be satisfied with the simple compliance of minimum requirements, but rather seek to conduct the work in the best manner possible.

The preceding paragraph implies a commitment by the professional to him or herself, to the profession, and to all collaborators because reproductive medicine cannot take place outside of a team framework. This is the topic of the third section of this document.

Finally, the work of the reproductive medicine professional takes place within the framework of institutions and centres, whose responsibility is also essential given the services they render to society, the guarantees they must offer professionals, and their ability to promote values. Professionals must support the quality of the institutions and centres in which they work, and they must also prove loyal and committed to said institutions. These are the matters analysed in the fourth and final section of the document.

## RESPONSIBILITIES OF REPRODUCTIVE HEALTH PROFESSIONALS TO THEIR PATIENTS

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### **1.- Introduction**

When discussing the responsibility of professionals to patient reproduction, not only in the specific case of assisted reproduction but also in every field, we must remember that the protection of human rights is the basis for pertinent moral and legal reasoning. In Spain, there is an expansive set of norms that regulate the field of assisted reproduction in great detail.

This provides the basic framework within which the analysis of these issues needs to be developed; however, are sufficient guarantees established before making any decision on new technologies? Which ethical considerations help us to make this decision?

It is not only the medical doctor but also all of the specialists who participate in the assisted reproduction process who are faced with conflicts posed by the possibilities offered by new reproductive technologies, conflicts that are sometimes difficult to resolve and that force us to reflect from a bioethical perspective.

### **2.- Communication and clinical relations with patients**

Taking into consideration that the standards and practice codes already establish compulsory minimums and that ethics aims to go beyond this standard by promoting quality professional behaviour, we consider that the clinical relationship between patients and health professionals in assisted reproduction should be based on a structured process that would include the following steps:

- Assume the basic objective of resolving the patient's reproductive problems.
- Take into consideration the classic bioethics principles: the principle of beneficence, the principle of autonomy, the principle of non-maleficence and

the principle of justice – and the group of values that could coincide in every clinical situation.

- Follow a method, such as the information and dialogue method, seeking mutual understanding and respecting the patient's self-determination.
- Respect professional obligations such as confidentiality, discretion, veracity, loyalty, etc.
- Cultivate virtues such as prudence, humanity, patience, good temperament, generosity, compassion, firmness, sincerity, trust, empathy and impartiality, thereby preventing paternalistic and imposing attitudes.

It must be taken into account that the patient is able to make his or her own decisions whenever the patient can:

1. Understand his or her situation
2. Understand the information given
3. Calculate the risks/benefits of his or her decision
4. Make and express a decision
5. Reason to make his or her decision: accepting or rejecting these reasons, discussing alternatives
6. Provide a motive to support his/her decision

If these conditions are not met or if they are met only partially, then the patient's autonomy is not guaranteed and the patient's freedom to make decisions will be weakened.

## 2.1. Right to information and contents

In the field of assisted human reproduction, it must be recognised that the traditional obligations that medical teams have to inform patients involve much higher demands than those of other medical specialties.

Prior to the required signing of the informed consent document for the realisation of the procedures and to effectively arrive at that consent, patients and donors in assisted human reproduction procedures must be adequately informed of, at the very least, the aspects established in the following paragraphs:

### *General aspects:*

- What the technologies or techniques used entail and what their consequences are, in terms sufficient for the user or patient to be able to evaluate the case's clinical options.
- Probabilities of success in achieving the proposed medical objectives, both for the general population and for the specific case of the patient being treated. Comparative information with European and/or national records would also be desirable.
- Real and personalised success rates for each treatment, presented as a function of factors such as age and prior diagnoses, without masking the results and encouraging false expectations.

- Potential unexpected results such as medical complications, multiple pregnancies, abortion and the failure to conceive, for which situations the patients need to be prepared realistically.
- The existence of other alternative options, such as adoption.
- Health risks and contraindications that can result from reproductive treatments based on science practices and the state of the science or that are directly related with medical interventions, especially those directly related to the personal circumstances of the patient and those risks that can affect both the pregnant woman and her offspring (including the possible complications resulting from maternity) at an age and for medical conditions that are clinically inadequate.
- Conditions for the application of the technology, with particular attention paid to the options available regarding the embryos that are not used and the legal status of the same. Under the assumption that donors participate in the procedure, conditions that affect this relationship, including costs, the formality and confidentiality of the donation, protocols of tests that the donor must take, the limit to the number of donations and the possibility of revoking the donation.
- The biological, legal and ethical conditions of the reproductive techniques.
- The economic conditions of the patient treatments as well as specifications for economic conditions for the donors of gametes.

*Aspects connected with information privacy*

- Rights of access, correction, opposition and cancelation that reflect the norms regarding the protection of personal information as well as an explanation of how the data will be treated, who will have access to the data, how confidentiality will be guaranteed, and whether there is an expectation that the data will be transferred to third parties.
- Requirements of the centre to transfer information on its patients, donors and born offspring to the corresponding health authorities.
- In the case of the donors, the legal provisions on how far the confidentiality of the data extends and on the exceptions to the preservation of anonymity.

*Aspects specific to the execution of genetic testing of the parents, directed towards making a pre-implant diagnosis*

- The state of the science with respect to the detection of the genetic pathology being treated and the probability of avoiding its transmission to offspring through the use of the pre-implant diagnosis.

- Legal conditions for the practice of pre-implant diagnosis and the commitment of the medical team to providing genetic counselling before, during and after the testing.
- The purpose of the genetic analysis, the location and equipment involved in said analysis and the destination of the biological samples of parents or relatives, as well as the persons who would have access to the results.
- Warnings regarding the possibility of unexpected discoveries and their possible consequences for the patient, as well as the patient's power to decide whether they wish to know these discoveries; and warnings regarding the implications of the data that will be obtained for their relatives, as well as the convenience of informing them.

All of the data related to the use of technology will be collected in individual clinical histories and will be treated with all due confidentiality guarantees regarding the identity of the donors, the data and conditions of the users, and the circumstances surrounding the origin of the offspring.

The clinical history data referred to above, except for the identity of the donors (when donors take part in these procedures) will be placed at the disposal of the woman receiving the implant and her partner, or of the child born from these technologies and that person's legal representatives whenever they reach legal adult age, if so requested.

Independent of the number of informational aspects referred to above, both before carrying out these medical procedures and once these are practiced, the medical team must continue to provide the patients with the therapeutic information required by the treatments; the duty of healthcare professionals to inform does not end after the patients sign an informed consent document, but it is instead a continuous process until the end of the treatments, after which time completing the clinical report is urgent.

## 2.2. Identity of the health professional

An essential element in the information that the patient should be provided is the identity of the health professional that will be caring for the patient at every moment. It is recommended that all of the staff at the centre should be duly identified (either with their name on their uniform or with a badge stating their name and position). The patient or user should know not only the name of the person taking care of them but their professional training (i.e., whether that person is a medical doctor, biologist, nurse, etc.).

## 2.3. Attention by the health team.

Given the type of healthcare required for reproduction, a team of several health professionals could be in place. However, teamwork will not prevent the patient from knowing who the medical doctor responsible for the attention given to the

patient is and who will, therefore, become the patient's primary spokesperson with the health team.

#### 2.4. Ethical principles for information and communication.

Assisted reproduction technologies are unique among medical procedures because they specifically help to generate new individuals and make possible new family relationships. This is why ethical principles within assisted reproduction need to be understood within a social context and not only in the physician-patient relationship. In fact, even though the majority of fertility treatments are undertaken by a couple or by a woman by herself, several persons can play a role in the reproduction process, for instance, the donor of spermatozoids, the donor of ovules, the expectant mother, the receiving couple, and the medical doctor. Each party in this process possesses a series of rights and duties.

To provide ethically correct information and achieve ethical patient communications, these actions must be guided by the following requirements:

- The information needs to be accurate, complete, without bias, open to dialogue, progressive and adapted to the patient. The information also needs to be sensitive to the psychological aspects of the patient, which will evidence the patient's understanding of this information.
- Assisted reproduction in heterosexual couples has historically comprised a situation that has been almost exclusively faced by the woman. Modern societies have evidenced the importance of the active participation of the man in this undertaking, rather than simply acting as the carrier of the male gametes. Therefore, it is important that in\_so\_far as it is possible, the man should participate both in the sharing of information and in the decision-making process that will take place throughout the entire process.
- The professional must not allow the patient to "close her eyes" to the problems or possible risks derived from the treatments to have a child.
- During the information management process (both diagnostic and prognostic), the professional must always provide detailed explanations of all of the possible options with their potential side effects. All of these options and their effects must be included in the "informed consent" document.
- The professional must always guide decision-making based on the patient's opinion, no matter the patient's level of education and knowledge.
- The professional must consider the possible pressures that the family, the environment and even the partner can exert on an individual at the decision-making time.

#### 2.5. Informed consent

Informed consent must always be considered a process of dialogue between the health professional and the patient, which requires information sharing, understanding and willingness.

It is imperative that the medical doctor provides an advanced detailed explanation and report to both members of the couple on existing diagnostic and therapeutic options. In every case, the information needs to be clear and simple, using words adapted to the level of understanding of each patient.

Once the patients have been verbally informed, they will be given an informed consent document that they must read carefully, expressing any doubts they might have and, if they agree, sign before undergoing any procedure. The informed consent document must comply with the following requirements:

- It is advisable that the written information given to the patient and the informed consent both be in the same document with the pages numbered consecutively.
- Patients have the right to revoke their consent at any moment, without any need to provide explanations for their decision and knowing that this will not involve any penalties or discrimination. This revocation may apply to any treatment carried out or may be specific to particular parts of a treatment (for instance, the freezing of embryos).
- Informed consent must anticipate the rights and protection of personal information.

### **3.- Psycho-emotional support for patients**

- An infertile couple may have emotional problems that are attributable not only to their sterility but also to their own search for solutions and the consequences of the chosen treatment. Consequently, assisted reproduction centres should be able to facilitate the psychological support required by their patients.
- Given that specific illnesses, such as schizophrenia, have an acknowledged hereditary component, we recommend the disqualification of potential donors of oocytes and sperm with these illnesses. Additionally, we advise the psychological evaluation of donors to eliminate candidates that might act in ill-advised ways that could be harmful to themselves (for instance, a background of suicide attempts, abuse).
- The loss of the capacity to procreate constitutes, particularly for many women, a difficult situation to absorb. It is advisable to provide this type of patient the psychological support that will help them face their emotional problems before using gametes or embryos from donors.

### **4.- Counselling and promoting responsibility to offspring**

Independent of any personal beliefs, it is necessary to affirm that there is a responsibility to any offspring and that it is important to adopt prudence when facing any reproductive decisions that might affect the quality of life of said offspring.

- Professionals must develop clinical actions and procedures that are coherent and proportionate and that will adequately address both the persons who seek these technologies as well as the embryos, as both entities are linked yet independent.
- Every possible measure must be attempted to prevent multiple gestations given the higher risks that these entail. Embryo reduction must not be presented *a priori* as an alternative to the prevention of multiple gestations. Further, the generation of a clinically adequate number of embryos to provide reasonable success probabilities for the patients is ethically recommended, given that obtaining a clearly excessive number of embryos via in vitro fertilisation supposes that many of these would have an uncertain reproductive fate. Independent of any other uses that legislation allows for these embryos, health practitioners should be mindful that that the fundamental goal that justifies their creation is their reproductive use.
- It is important to offer information and counselling (genetic counselling, reproductive counselling, etc.) to the patients, thus promoting responsible decisions.
- It is necessary that the parents' decision about the future of the untransferred embryos be made explicit and that the decisions that must be made regarding the abandoned embryos in situations such as couples who no longer share the same reproductive project, the death of one of the parents, etc. also be anticipated.
- While respecting the decision of the parents and insofar as there is no common reproductive project, it would be advisable to promote the donation of the remaining embryos for the reproduction of other couples prior to their destruction.

## **5.- Confidentiality**

The professionals who intervene in health practices have the obligation to preserve the confidentiality of information that affects the patients. This obligation governs the field of human-assisted reproduction with a special intensity, taking into consideration the relationship between said information and the central core of personal and family privacy (for instance, donor intervention).

Medical confidentiality is one of the primary duties of the practice of medicine. Nevertheless, the obligation to maintain confidentiality affects all of the professionals

that work in the field of assisted reproduction. Despite the strength of this obligation, in practice, conflicts may arise between the duty of confidentiality and other professional duties that may justify the breach of the former, for instance, infectious diseases that may affect the couple and justified exceptions to confidentiality in the donor information.

In every case, the professional must weigh the interests and benefits in conflict, permitting the patients, insofar as it is possible, to provide the solution.

### 5.1. Privacy and protection of personal information

- Reproductive health professionals must make the safeguarding of confidentiality and the protection of personal information one of their principal commitments, independent of obligatory standards and practices and the legal obligations regarding privacy, confidentiality and information protection. With this, the greatest trust possible between professionals and patients is possible. The entire staff (medical doctors, laboratory personnel, psychologists, nurses, assistant nurses, orderlies, administrative staff, etc.) who have access to any patient information are obligated to maintain the confidentiality of said information.

- The implementation of many reinforcement measures considered timely in this matter is desirable. For instance, confidentiality agreements between the centre and employees, the centre and providers, etc. All of the staff members affiliated with a reproduction centre that have access to patient information must sign a confidentiality agreement.

- The confidentiality of the patients' information begins with their clinical history, which must be protected in an appropriate manner, accessible only to authorised personnel linked to the healthcare of said patients. In this light, it is critical to safeguard patient lists and clinical histories from free access by third parties in every location and situation, maximising precautions with the movement and destruction of documents and/or computerised repositories to comply with the above-mentioned duty to maintain confidentiality. Any references to clinical information on other patients must be prevented at all times.

- When there is a desire to use photographs of newborn children who result from the technologies carried out at the centre, prior authorisation must be requested from the parents or legal representatives, and they should be informed of their rights regarding the protection of their personal information.

- Patients must sign an authorisation if the other member of the couple, a relative or a close friend of the family wishes to withdraw the result of some of the tests carried out at the centre.
- Patient privacy must be preserved in every field. This begins with the patient's first contact with the centre and must be maintained at all times: in waiting rooms, in common spaces, when the medical history is performed, during exploration, at the moment of information sharing, in conversations between health professionals, in the nursing controls at hospital wards (on bulletin boards), in puncture procedure rooms, in telephone conversations, in intercom communications, etc.

## 5.2. Managing clinical history

The clinical history of a patient is the biographical and documentational support of the healthcare provided to that patient, which is why it is the most private document existing about a person at the centre.

The clinical history reflects not only medical practice or medical actions but also compliance with one of the primary duties of healthcare personnel regarding the patient: the duty to assist, the duty to inform, etc., which can become documentary evidence that evaluates the level of healthcare quality in circumstances that demand the responsibility of the healthcare professionals and/or healthcare institutions.

From an ethical point of view, the clinical history can be considered a basic instrument of good healthcare practice, as without it, it is impossible for the health professional implicated in providing healthcare to have a complete and general vision of the patient over time to be able to provide adequate and correct healthcare. On the other hand, the elaboration and maintenance of the clinical history is considered a right of the patient linked to quality medical healthcare. Given that this is a faithful reflection of the doctor and patient relationship as well as a record of the healthcare provided to the patient, studying the clinical history and valuation allows for the establishment of the quality of healthcare that was provided.

The following aspects must be taken into consideration in the administration of the clinical history:

- 1.- Confidentiality: as we have mentioned before, it is a binding obligation to maintain medical confidentiality and the patient's right to privacy.

2.- Security: the identification of the patient as well as that of the medical doctors and the healthcare personnel who are involved throughout the healthcare procedure must all be duly recorded.

3.- Availability: even though the confidentiality and privacy of the information of this document must be preserved, this must also be a document available in legal cases. Special care must be taken regarding patient access to any clinical documentation, remembering that this information must only be provided to the person who requests it.

The centre is bound to provide a detailed report of all of the diagnostic and therapeutic treatments carried out in the centre whenever these are requested.

4.- Uniqueness: the clinical history must be unique to each patient. Given that reproduction treatments may simultaneously involve several persons, the histories will frequently include information from the patient, the couple and possible donors. This fact justifies that, in the case of couples, mechanisms are provided that allow professionals to group them under reproductive projects.

5.- Legibility: a disordered clinical history with poor legibility harms everyone; it makes the health professional's work more difficult and it harms patients due to the possible errors that could be derived from an inadequate interpretation of the data contained in the history.

6.- Veracity: the clinical history must be an accurate document, as this is considered to be the right of the user.

7.- Accuracy: it must contain true, verifiable and precise information.

8.- Technical rigour of the records: the data assigned to these records must adhere to objective and scientific criteria, respecting and not including harmful statements about the patient, other professionals or the institution.

9.- Contemporary nature of records: the clinical history must be recorded simultaneously with the healthcare provided to the patient, and it must be kept updated at all times.

10.- Completion: the history must review the information relevant to the patient's pathology, reflecting it in the stages that comprise every clinical and healthcare practice. At the same time, it must include all complementary documents, such as administrative data, consent documents, healthcare reports, special protocols, etc.

### 5.2.1. Computerised clinical history

The advent of the computerised clinical history represents important changes compared to the traditional clinical history with respect to confidentiality, availability and security.

The computerised clinical history must be treated the same as the conventional paper clinical history, that is, it must be complete, current, objective, protected and

secure; security is an ethical imperative, which is why information protection and control measures must be maximised.

In this sense, it is fundamental to restrict access to the computers in the centre as well as maintain encrypting measures (including passwords and policies on data transmittal: to whom, how and why) and remind persons at the centre of the importance of all of the institution's policies and habits by means of a temporary agreement.

It is necessary to carry out routine assessments of the computerised systems to detect any technical or legal irregularities or any human negligence. The organisation has to rationalise and think about access to information, considering who must know what, why and how to access these data, and permitting separate access to personal, administrative and clinical information.

## **6.- Prescription Ethics**

Therapeutic prescription in assisted reproduction is a scientific, ethical and legal practice that comprises the rational use of pharmaceuticals and other treatment means and procedures, chosen as suitable based on their effectiveness, safety, acceptability and accessibility.

- According to ethical principles, a medical doctor must try not to harm the patient with the prescription, have the medicine benefit the patient and respect the patient's autonomy. The expectations for the prescription must be shared with the patient, and it must be verified that the patient is aware of the risks she will be exposed to achieve a therapeutic goal, that this risk-benefit relationship is acceptable to both and, lastly, that the patient's consent is collected.
  
- The therapeutic behaviour of the medical doctor must be proportionate, that is, the benefits expected by a patient with a specific diagnosis and prognosis have to be proportionate to the therapeutic effort, the patient's suffering, every type of cost involved and the risks assumed.
  
- The principle of minimum invasiveness in medical action is a demand that is not only technical but ethical, as it is not legal to carry out excessive diagnostic or therapeutic procedures. More invasive and potentially dangerous procedures must be reserved for after all other less risky options have been exhausted.

- In accordance with the principles of medical ethics, under which no patient can force a health professional to carry out an inappropriate action, assisted reproduction healthcare professionals must not accept petitions for treatments that are not indicated for by medical criteria. Prescriptions must be made with respect for the patient's autonomy to consent to these procedures and to decide among the possible alternatives.

## **7.- Charges for services**

- In the informed consent process, the costs associated with the treatment must be explained with complete transparency.
- It is not advisable to carry out "conditional agreements," that is, agreements in which compensation from the patient depends on the achievement of gestation, as a medical treatment is always one of means and not of results.
- Clinical judgement and behaviour must not be ruled by financial criteria or become compromised by commercial interests. The aspiration to economic viability of the assisted reproduction activities, although completely legal in the private healthcare field, must not conflict with the patient's interests, nor must it impede thoughtful and objective reasoning on the efficiency and security of the proposed treatments.
- Professionals must not ignore the complications that might arise for the patients as a consequence of the procedures that were carried out.
- The economic status of the patients cannot be a motive for carrying out technologies that are not recommended medically, that is, economic status cannot be the reason for limitations or excesses in use of these procedures.

## **8.- Patient non-discrimination**

In the case of reproductive medicine and from an ethical point of view, medical professionals will deny a patient access to technologies solely in the case that this is contraindicated medically or could place the health of the woman or the future child in grave danger.

## RECOMMENDATIONS

- The users, patients and donors in assisted human reproduction must receive adequate information pertaining to their diagnosis and treatment. The information must be accurate, complete, non-biased, open to dialogue, progressive and adapted for the patient, attentive to the psychological condition of the patient and highly understandable.
- The actual rates of success for each treatment must be presented based on factors such as age and prior diagnoses, without masking the results or encouraging false expectations.
- The patient or user must know not only the identity of the person that takes care of him or her but the caregiver's professional training.
- Teamwork will not prevent the patient from knowing is the identity of the responsible medical doctor that assists him or her and who will be the primary spokesperson for the healthcare team.
- Patients must sign an informed consent agreement before undergoing any procedure.
- Informed consent agreements must have a clause on data confidentiality.
- Assisted reproduction professionals must evaluate the possibility of psychological support in cases when this counselling is advisable.
- The professionals who are involved in health practices have an obligation to preserve the confidentiality of information that affects patients and users. The implementation of as many reinforcement measures as are considered timely in this matter is desirable (for instance, confidentiality agreements between the centre and employees, between the centre and providers, etc.).
- All of the personnel (medical doctors, laboratory staff, psychologists, nurses, assistant nurses, orderlies, administrative staff, etc.) who have access to any information on the patients and/or users are obligated to maintain the confidentiality of said information.
- When a clinical history is created in a computerised format, the protection and control measures for this information must be maximised.
- In accordance with ethical principles, the medical doctor must try not to harm the patient with a prescription and instead have this prescription benefit the patient while respecting the patient's autonomy.

- The behaviour of the medical doctor must be therapeutic.
- The principle of least invasiveness in medical action is not only technical but also ethical.
- It is not advisable to have "conditioned agreements," that is, that the provision of compensation by the patient is dependent on the achievement of gestation, as medical treatments are always of means and not of results.
- The economic conditions of patients cannot be a motive for the modification of the medical recommendation of treatment.
- For the case of reproductive medicine, the professionals will deny the patient's request, from an ethical point of view, solely in cases where this request is contraindicated medically, placing the health of the woman or of the future child at risk.
- Reproductive medicine professionals must support a responsible attitude by the patients towards their embryos and their potential offspring.
- Promoting the donation of embryos for reproductive purposes is considered a positive ethical value before their destruction without any other purpose.

# RESPONSIBILITIES OF REPRODUCTIVE HEALTH PROFESSIONALS TO SOCIETY

1. Professional practice in reproductive medicine
2. Access to reproduction in specific situations:
  - Homosexual couples and single parents
  - Disabled persons
  - Immigrants
3. Health education and preventive care
4. Administration of healthcare resources in reproductive medicine
5. Relationships with pharmaceutical and health technology companies
6. Conflicts of interest in medical practice
7. External communication
8. Publicity and treatment offers
9. Responsibility in healthcare for patients residing in other countries (*transnational*)

Reproductive medicine has acquired some fame in developed societies as a consequence of notable technological advances and a growing demand, the latter caused in part by the progressive tendency to postpone the age of reproduction. This promotes the emergence of new ethical conflicts that affect both professionals and patients. The proximity of different cultures, as well as legal or social factors, mean that professionals must carefully debate any possible conflicts within this topic and agree on a response based on solid ethical behaviour principles, preventing or minimising any discriminatory, party-favouring or financial actions.

## 1.- Professional practice in reproductive medicine

The characteristics that must precede any actions by the reproductive medicine professional are as follows:

- As a member of society, these actions must have a solid ethical basis in their application and execution of healthcare, as well as in the dissemination of knowledge. To this purpose, society must provide adequate conditions for proper professional development.
- There is a responsibility to society. This responsibility cannot be limited exclusively to the demands of the legal framework but must instead bind itself to an ethical framework, thus demanding of him or herself the maximum level of excellence in the performance of the profession.
- He or she has the final goal of preserving or recovering the reproductive health of his/her patients, using to this purpose current, efficient and validated practices. Therefore, society must demand that the professional know his or her trade and how and when to carry out these practices, uninfluenced by any consideration that might interfere with or modify his or her correct action, be it due to economic, political,

racial or sexual preference status or to any other motives.

- He or she must be committed to society to make maximum progress in therapeutic activities, while at the same time he or she should attempt to design projects that will research, analyse and prevent possible risk factors in the deterioration of fertility of different persons.
- He or she must have independence in his or her professional execution, making autonomous decisions and respecting the criteria that the profession demands of him or her and that regulate his or her work under this commitment and responsibility to society.

## **2.- Access to reproduction in specific situations**

Currently in society, there are several family models, such as those composed of homosexual couples and single parent households, who with some frequency seek help to have children.

The professional will treat all of his or her patients equally, respecting their wishes and without any discriminatory consideration or behaviour.

Reproductive medicine professionals must have a special sensitivity towards disabled patients, facilitating their access to assisted reproduction technology and providing them with any specific support they might require.

Current migration patterns in society are generating an important sector of the population that possesses different languages, cultures, traditions and religions, which at times can generate the appearance of integration and communication issues, which reproductive medicine professionals must avoid so that there is no chance for discrimination to take place. In addition, members of these populations must be provided with information in the most comprehensible manner, and an attempt must be made to overcome language barriers.

The ethical obligations of assisted reproduction professionals with regard to the donors of gametes do not differ from those contracted with patients who use their own gametes in their treatments or those who require the donated gametes. More to the point, the patient who is a gamete donor should benefit from a particularly high protection of her safety, given that the balance between effectiveness and safety does not include an expected benefit of the treatment in itself for the donor.

Faced by any situation that might favour the exploitation of some individuals, which could take place in situations with gamete donors, reproductive medicine professionals must use all of the means at their disposal to avoid any type of abuse.

Frequently, the complexity of reproductive studies and treatments demands the scheduling of appointments on specific dates, which may generate some conflicts with work schedules for some patients, which is why reproductive medicine professionals should do their utmost to coordinate treatment with the patient's work schedule. At the same time,

they should attempt to influence society to acknowledge and accept these patients' rights to adequate healthcare without any anxieties or pressures.

### **3.- Health education and prevention**

Reproductive medicine professionals have the responsibility to collaborate in sexual and reproductive education as well as in prevention in this health field, working on the following:

- Disseminating the state of the science and its advances in reproductive medicine.
- Acknowledging the differences between chromosomal, genital, somatic, psychological, social and legal sexes, accepting that a correspondence between these is not always present.
- Education about responsible sexuality to avoid unwanted pregnancies and prevents the transmission of diseases, as well as facilitates access to their diagnosis and treatment.
- Reproductive counselling, respecting a persons' freedom.
- Responsible paternity, which implies taking into consideration the consequences for the offspring in any decisions made.
- Respect for gender equity.
- Respect for diversity in sexual preferences.
- Awareness of the potential medical and socioeconomic effects of the transfer of an excessive number of embryos and of the risks due to multiple pregnancies that could result from this practice.

The professional must be willing to collaborate in the campaigns for reproductive health sponsored by government agencies.

### **4.- Administration of healthcare resources in reproductive medicine**

Even though, in essence, all of the systems for the administration of healthcare resources (public and private systems, insurance companies, etc.) must be equal regarding their professional goals and demands, there is no doubt that the economic resources at the disposal of each can vary and affect their provisions. Given that these resources are limited, their administrations must pursue a balance between equity and efficiency.

To achieve this balance, the professional must strive for the rational and thoughtful use of material and human resources. The professional must also act with efficiency and honesty when evaluating possible work handicaps, preventing those that lack a sufficient medical recommendation. In this way, the professionals will contribute to preventing unnecessary social costs.

The professional in reproductive medicine will have at his or her disposal resources adequate to their level of healthcare provision to provide the best care to their patients. In the same way, they must be able to receive continuing training to guarantee having the latest knowledge.

The professional will avoid favouring some patients to the detriment of others, except

for very exceptional situations that should be established in a fair, reasoned and personalised manner.

Reproductive health professionals are obligated to provide the best possible healthcare to their patients, preventing the imposition of other, non-medical interests, both by administrators and by professionals.

Any persons or groups should never allocate healthcare resources to for-profit activities when there is a clear detriment to the patients.

## **5.- Relationships with pharmaceutical and health technology companies**

There is a close collaboration between the pharmaceutical and technological material industries and professionals. This collaboration goes in both directions, and its ultimate goal is to improve the quality of medical care. These collaborations must comply with strictly professional criteria and not imply any commitment to exchange or reciprocity by the professional, nor must they imply an incentive arising from the prescribing or use of specific products.

The reproductive medicine professional is obligated to be honest when prescribing, doing so for the benefit of his or her patients and equity of treatment, and guaranteeing independence in any decision-making. Any assistance must solely pursue the objective of increasing the professional's training and research capacity, and any type of incentive that may interfere in their professional performance should be rejected.

To guarantee that the patients will have access to the best and most advanced procedures, it is wrong to withhold them in an exclusive or excluding manner once they have been validated.

## **6.- Conflicts of interest in medical practice**

The term "conflict of interests" applies to those situations in which a secondary and personal interest—be it economic, ideological or professional—can overcome a primary interest—e.g., the wellbeing of the patients, the obtaining of valid generalisable research knowledge, the interest of science or of society—and affect the presumably independent judgement of the health professional. The secondary interest does not need be illegal or bad in itself, it could even be desirable, but what is questioned is the relative importance of those interests compared to the primary interest.

Reproductive medicine professionals must perform their work with an eminently positive, rigorous and practical vision, seeking to help their patients with the maximum efficacy and efficiency to achieve the greatest possible benefit for their health and that of their families within a minimal time period and at the least possible cost.

Conflicts of interest must be stated explicitly if they ever occur. The following are examples of conflicts of interest: if a professional belongs to an ethics committee in which a particular topic will be discussed, when a professional simultaneously holds a position of responsibility in a private or public institution, when a professional publishes the results of

research funded by a specific entity, and when a professional prescribes treatments within the context of a research project he or she is part of.

## **7.- External communication**

Communication media can and should be an excellent information and training platform for society on topics specific to reproductive health. However, reproductive medicine professionals must be responsible with this information and aware of the repercussions entailed.

A diversity of opinions and plurality in the information related to reproductive medicine is desirable. To this end, the professional must be transparent and honest in relaying information to society. It is not acceptable to present as scientific information that which could fundamentally be characterised as promotional practices.

Every news item, interview or statement to any communications medium (press, radio, television, web pages, social networks, forums, etc.) must adhere to strict accuracy, shying from any sensationalism or the possible creation of false expectations in patients; at the same time, professionals are bound to uphold absolute respect for the image and dignity of other professionals.

## **8.- Publicity and treatment offers**

Publicity must be based on a strict dissemination of information that is correct, serious, respectful and responsible, avoiding images that may deteriorate or diminish professional prestige. Offering “guarantees” of success must be avoided, as well as any offers that are clearly unattainable that can generate false hopes and induce future conflicts.

To avoid the exploitation of vulnerable members of society, publicity directed towards recruiting gamete donors must avoid every possible commercial and mercantile reading. It must not reflect the magnitude of possible economic compensation to the possible donors. On the contrary, it must emphasise the donation as an altruistic and disinterested action.

To avoid trivialising and perverting the essence and goal of reproductive medicine, it is not acceptable to link its practices, regarding both treatment and the recruitment of donors, with offers and campaigns clearly linked to other non-reproductive objectives, such as tourism or leisure activities, etc.

For the same reason, it is not appropriate for a professional to provide services that will be offered as a prize in contests or business promotions of any type, as the medical act must be a process resulting from mutual knowledge and trust and, therefore, must be preceded by a *lex artis* physician-patient relationship. As in other medical specialties, any treatment in reproductive medicine must be based on strictly clinical criteria, not on a medical practice designed for indulgences.

## **9.- Responsibility in healthcare for patients residing in other countries**

## **(transnationals)**

When a patient decides to undergo a study or a treatment in another country, the professional must apply identical protocols, as well as psychological support, costs and informed consent, as are provided to the rest of his or her patients.

As long as this is appropriate for better healthcare for the patient and with the patient's consent, communication and collaboration will be maintained with the professionals from the patient's country of origin to improve the results and safety of the treatments and to avoid the repetition of unnecessary tests that may make the patient uncomfortable and make the study more expensive.

Accurate, complete and understandable reports must be provided in case complications arise that must be treated by other professionals upon the patient's return to their country of residence.

If the patient requests it, the professional will collaborate with the patient to, if possible, move any cryopreserved gametes and embryos that were not used to the patient's country of origin. The professional will guarantee the shipment and will verify that the destination centre complies with all pertinent requirements.

## RECOMMENDATIONS

- The performance of reproductive medicine healthcare must be based on the maximum acquisition of knowledge and on its application with ethical behaviour that goes beyond the legal framework, seeking excellence in its highest form.
- The reproductive medicine professional must commit to the following:
  - o Pursue the goal of preserving or recovering the reproductive health of his or her patients, without regard for any political, religious, social, racial or sexual preference considerations.
  - o Act independently, respecting the patients' decisions and with maximum sensitivity, particularly toward specific groups such as the disabled and immigrants, preventing at all times any type of discrimination.
  - o Assist with sexual and reproductive education promoting responsible sexuality, the pursuit of desired gestations and avoidance of unwanted pregnancies, and the avoidance of the transmission of diseases.
  - o Strive for the rational and thoughtful use of material and human resources, acting with maximum efficacy and honesty and seeking a balance between equity and efficiency.
  - o In relationships with the pharmaceutical and health technology industries, seek the benefit of the patient, guiding every collaboration towards the expansion thereof and the acquisition of the latest knowledge, yet always conserving the professional's total and honest independence.
  - o Act with seriousness, respect, honesty and transparency towards all communications media, preventing improper publicity campaigns that may induce the trivialisation or deterioration of the essence and goal of reproductive medicine.
  - o Attempt to facilitate healthcare, communication and treatments for patients residing in other countries as much as possible.

## RESPONSIBILITY OF REPRODUCTIVE HEALTH PROFESSIONALS TO THE PROFESSION AND TO OTHER COLLEAGUES

1. Need for on-going training and the dissemination of the latest knowledge
2. Personal attitudes and manners
3. Pursuing excellence
4. Conscientious objections
5. Teamwork: mutual respect and collaboration
6. The medical doctor as an expert
7. Professional encroachment and competence limits
8. Research
9. Scientific publications

Traditionally, the medical profession has been structured in a very hierarchical manner such that decisions habitually fell on only one professional.

With the rapid increase and diversification of scientific knowledge and its clinical applications, performing medicine has become much more complex. It is not possible to be an expert in all aspects of health and know all of the potential treatments for a specific pathology, which is why modern medicine generally requires the coordinated action of different specialists and health professionals.

Reproductive medicine is a discipline that covers many specialty fields, which requires a multidisciplinary team of physicians, biologists, psychologists, nurses, laboratory technicians, social assistants and others for its correct practice. Each member of the team has a well-defined role, even though all must coordinate in constant interaction and dependence.

The relationships that health professionals must maintain amongst themselves are framed within the structure that a cohesive community must maintain based on principles of fraternity and mutual respect, over which only the rights of the patient will have preference.

### 1. **Need for on-going training and the dissemination of the latest knowledge**

Reproductive medicine professionals must be aware of the latest advances in their field. This updating can be acquired in different ways:

#### *a) Individual on-going training*

Given the rapid advance in knowledge in the reproduction field, professionals must examine this knowledge critically and keep abreast of emerging knowledge in the field of reproductive medicine.

Reproductive medicine professionals must regularly update their knowledge by means of professional literature as well as participate in on-going training programmes for the study, diagnosis and treatment of reproductive problems.

On-going training in the specialty must cover both knowledge and technical skills, such as the development of attitudes that agree with the ethical postulates of the profession.

#### *b) Advisability of sharing knowledge:*

There must be a clear attitude and predisposition towards the sharing of knowledge and experiences between the members of a team as well as with other professionals to contribute collectively to the advance of reproductive medicine.

Attending specialised meetings could be a very useful and important instrument for the reproduction professional to gain the latest practical knowledge.

## **2. Personal attitudes and manners**

Reproductive medicine professionals must treat their colleagues with respect and represent the qualifications, opinions and obligations of said colleagues in an accurate and fair manner.

When communicating with patients or with other professionals, unfounded criticisms towards colleagues must be avoided. These duties around behaviour and education do not cancel the professional's right to freedom of expression and critique; however, they do advise that said freedom should be exercised in appropriate venues, be it in private or in appropriate sessions.

Unacceptable criticisms also refer to humiliating comments regarding not only the level of competence of colleagues but also personal attributes such as race, ethnicity, nationality, colour, sex, sexual preference, age, legal status, political beliefs, religion and physical or mental disability.

People act according to the habits that they have learned and accepted as good, either after reflecting on their value and ethical correctness or due to their passive adaptation to that which is commonly performed (customs). This is why, in the realm of personal manners, those responsible for reproductive medicine must respect individual liberties and tastes within the limits established by the duties of each professional, by the patients with which the professional is in contact, and by the cultural and business habits of the professional and of any third parties. It is the responsibility of each of the parties to acknowledge and respect these criteria by caring for their presentation, personal appearance, hygiene, behaviour and respect in everyday interactions.

Reproductive medicine professionals promote a series of hygiene and behaviour habits with their attitude, behaviour and image that also influence the health education of the population. This is why this aspect of professionalism cannot be neglected.

## **3. Pursuing excellence**

Reproductive health professionals must assume the value of quality, service and the culture of excellence by means of an attitude of continuous improvement of the services provided and compliance with all common norms and regulations that are internationally acknowledged.

Aspiring for excellence means that the reproduction professional makes a moral commitment to the patient or user, to his colleagues and to society, constantly improving the quality of his or her performance.

In accordance with these principles, reproductive medicine professionals must, aside from having all of the technical and intellectual competencies required for the practice of their profession, also display ethical behaviour. To this purpose, first, it is necessary to define

a system of values that identifies them and then to disseminate said values among the other professionals.

Within the framework of the relationships of reproductive medicine professionals with colleagues, the principles that must be followed to reach this degree of excellence are as follows:

- 1.- Integrity and coherence between what is communicated and what is performed.
- 2.- Confidentiality of the information shared between colleagues.
- 3.- Trust and respect for the work performed.
- 4.- Independence in actions.
- 5.- Veracity and transparency of the information.
- 6.- Respect.
- 7.- Dialogue: participative attitude between professionals.
- 8.- Cooperative commitment and responsibility.

Implementing a system that manages quality is the appropriate procedure for improving and seeking excellence in an assisted reproduction programme.

External evaluation and certification is advisable to achieve a continuous improvement of results and the patients' trust, as well as that of society and other professionals. A continuous effort to innovate already-developed activities and designed and applied processes in such a way that they improve in terms of efficiency and agility is also advisable.

#### 4. **Conscientious objections**

Conscientious objection is individual and is understood to be the professional's refusal to engage in a behaviour that demands his or her compliance either by law, by the direct mandate of an authority or by an administrative resolution based on ethical, moral or religious convictions and because obeying said command would seriously place the professional's conscience in conflict.

Given that one cannot claim a conscientious objection for everything, the reasons given by the professional to refuse to carry out specific diagnostic or therapeutic actions must always be sincere, serious, coherent and honest. Economic, social or commercial interests cannot influence these decisions in any way. The conscientious objection cannot be directed in such a way that it would result in discrimination due to race, sex, social situation, sexual preference or other characteristics.

Thus, reasoning by the objector is based on the belief that the behaviour demanded by a law or directive is not ethically correct, yet the objector understands that he or she has no right to impose his/her conviction on other people and therefore requests an exemption from

acting. On the other hand, when a patient requests a specific medical action to which the patient has a right, this request cannot go unmet, and the professional must guarantee that the patient will be duly assisted by another equally well-qualified professional.

The limit to the conscientious objection of the professional is determined by the obligation to avoid serious harm to the patient, to aid the patient in an urgent situation and by the obligation to collaborate with a colleague when faced with an urgent and grave situation.

Objections should not be used to avoid obligations out of individual interests, nor because there is a wish not to provide objective, true and complete information and thus facilitate access to the provision of services by other professionals.

The conscientious objection is always an individual right. In addition, it is not the best mechanism by which to solve conflicts derived from scientific, technical and professional issues. The inevitable discrepancies produced by a specific scientific or technical application should not be exposed as a mode of objection.

##### **5. Teamwork: mutual respect and collaboration**

Multidisciplinary cooperation between professionals who form the same team is a desirable goal in assisted human reproduction processes in which the patient requires integrated healthcare.

A work team must share not only knowledge and skills but also attitudes, that is, an *esprit de corps* or team spirit where agreements prevail without limiting the personal freedom of the individual professionals.

When team work is required, the group coordinator may establish the actions that will take place in either a hierarchical or collegial manner, considering the best way in which to assist the patient and based on factors such as capacity, skills and competence, the degrees of the professionals, reciprocal trust between the latter, specific tasks to be performed, and accessibility and continuity in the healthcare of the patients.

Without harming the possibility of maintaining a respectful dialogue within the teams, before, during and after the different actions, once the manner of proceeding in a specific case is decided, all of its members must accept these proceedings with a good attitude and responsibly collaborate to achieve the sought-after results.

In no case can personal vindications or disagreements with the adopted decisions affect the normal development and finalisation of the initiated treatments. In this regard, the health of the patient must be considered as being above any personal or individual position, no matter how legitimate.

Acting as a team must be preceded by mutual trust in such a way that it may be presumed that every one of the team's members is acting correctly as long as there is no evidence to the contrary. However, if at any moment any of the members of the team senses incorrect behaviour (due to a lack of knowledge or expertise, negligence, neglect,

etc.) of another member of the team, then this professional has the duty to warn the team and prevent a process from continuing that could place the patient or offspring at risk or risk the success of the treatments.

The delegation of tasks within the team is an adequate way to function as long as it is accredited with the capacity to carry out tasks by whomever is in charge of delegating and insofar as this leadership and the conditions under which said delegation or distribution of tasks are carried out have been previously established within the team.

## **6. Interprofessional cooperation**

Professionals must cooperate with other professionals in reproductive medicine and from other fields or professions when said cooperation is for the welfare of the patients. Corporatism and an attitude that is defensive of group interests must be avoided.

Patient medical information that might be useful at the time of presenting a new treatment must form part of the communications between professionals as long as there is prior consent by the patients.

In the specific case of gamete donors, as long as there is no information system originating from an official donor registry, it is imperative to provide information on the number of cycles executed and on the offspring obtained from the gametes of a donor that is requested by another accredited centre to carry out assisted reproduction treatments. This can occur as long as it can be proven that the same donor wishes to make new donations with the centre that is requesting the information. Information must also be provided on the health of the offspring obtained, on any complications or adverse effects that the donor may have experienced, or on any other relevant clinical circumstance for the acceptance of the candidate as a new donor.

Special mention must be made of the transfer of gametes between centres. In this sense, the fact that the gamete must not be an object of commercialisation and speculation must always be taken into account, thus preventing the selection of the gamete by criteria different than those that are strictly medical. Said assignment must be reflected in the corresponding informed consent document.

## **7. Evaluation of the behaviour of other professionals: the professional as expert.**

Health professionals acting as experts or inspectors is an activity framed as a variation on the healthcare actions pertinent to each profession. The purpose of this activity is to aid justice and is incompatible with professional healthcare given to the same patient or with any other conflict of interest.

To act as an expert, certain specific conditions are required that include adequate medical training, respect for the patient's rights, knowledge of the corresponding legal responsibility and specific personal conditions such as objectivity, impartiality, rigour, honesty and critical careful judgement; these are the conditions that allow for an appropriate expert report.

In the event that some medical error or incompetence is detected, this should not be hidden. Incompetence and harmful or bad behaviour by a colleague must be communicated to the appropriate authorities, especially if they incur in fraud or deception.

If within the course of this action the expert or inspector obtains any additional data that represents an important risk to the patient's health, this information must also be communicated.

## **8. Professional encroachment and limits of competence**

Responsible professional practice implies being in possession of the corresponding professional degree, which is acquired by means of initial and on-going training programmes. However, every professional must know and respect the limits of his/her competence without overreaching, taking into consideration that a degree by itself does not award the necessary competence in an indefinite manner.

In the field of reproduction, the differences in competencies between professionals are not always well defined, which can give rise to conflicts on the limits of those competencies. Thus, the following guidelines should be followed:

- The physicians who carry out surgical or invasive acts related to reproductive diagnosis and pathology must be in possession of the official medical specialty that enables them to carry out such procedures (obstetrics and gynaecology, urology, radiology, etc.) and have such specific training accredited, as well as have evidenced experience in this area. The same consideration must be applied to invasive nursing techniques.
- Every reproduction laboratory must have a responsible person with a degree in biomedical science with demonstrated experience and capacity.

Given all of the above, professionals in reproductive medicine are obligated to keep up with the latest knowledge, to not exceed their capacity and to not incur any errors due to a lack of preparation or excessive confidence.

In addition, acting in a monopolistic manner with specific diagnostic or therapeutic techniques is considered inappropriate if it is performed in such a way that the appropriation of these techniques by some professionals prevents their development and application to a population of patients that would otherwise benefit from the technique.

## **9. Research**

Research must be an activity that complements the professional exercise of reproductive medicine. Its guiding principle should be as follows: the scrupulous respect of internationally accepted ethical principles, their approval by the corresponding ethics committee and by the competent authority; the acquisition of informed consent, the guarantee of respect for the personal privacy and confidentiality of the patient's information, etc.

Knowing that research in this field sometimes takes place with human biological material (gametes, embryos and gonad tissue), specific care must be taken regarding the respect and protection of this material. In the case of research involving embryos, certain limitations must be taken into consideration, including not reusing these embryos for reproduction.

The reproduction professional has a moral obligation to contribute to the increase of the scientific knowledge on which the profession is based to improve the quality of professional attention offered to the patients as well as to improve the content of the explanations provided to the patient and their relatives and all of those who benefit from this activity. Therefore, scientific research, be it basic or clinical, is also a professional ethical requirement.

Within the field of assisted reproduction, biomedical research is a topic of growing interest given that scientific advances offer numerous exploration possibilities that continue to develop and generate controversy. The techniques that have been developed for one purpose can be used for others, particularly in the case of techniques whose purpose is therapeutic and yet are used with other objectives (for instance, the pre-implant genetic diagnosis associated with the election of gender). This is why an ethical vision is even more necessary and must take into consideration each of these potential innovations. In this regard, the following basic recommendations are appropriate:

*1.- Evaluate possible innovations before their application in clinical practice*

Changes in treatments or the introduction of new procedures in reproductive medicine may have medium- or long-term consequences for the children born or for the patients involved in these procedures. Therefore, no assisted reproduction procedure should be modified or introduced in any way from that already employed in healthcare procedures without an initial evaluation of its safety and efficacy, as follows:

- Safety: an assisted reproduction procedure will be considered safe when quality scientific testing adequately evidences its harmlessness, this being understood as the absence of a significant increase of adverse effects on the patients and their offspring. Regarding the latter, the procedures that are qualified as safe will be those whose evaluation has demonstrated that they do not significantly increase the risk of perinatal mortality, the risk of congenital defects or the risk of transformation of chromosomes or genetic bases, taking into consideration other studies from all geographic areas and of the greatest scientific calibre possible.

- Efficacy: An assisted reproduction procedure will be considered efficient when there are scientific studies evidencing the quality of this practice. For such an evaluation, the value of clinical assays must be emphasised, as well as the fact that a single study fails to generate established knowledge until the results are reproduced by similar studies.

*2.- Do not carry out any type of research in the field of human reproduction without the necessary informed consent.*

This is particularly evident in the case of the use of embryos, even after they have

been donated to this end. It is important to emphasise that informed consent is required even in cases in which the biological samples that will be used come from patients or donors being researched (follicle liquid, etc.) and will be discarded.

The documents of informed consent must be different from those given for clinical practice, and the researchers must offer all of the information required for the research study's purpose, methods, risks, inconveniences and possible consequences (including the possibility of publication of the obtained results).

### *3.- Maintaining the records of the obtained data*

Researchers must record the procedures carried out, the materials and the methods used and the obtained results in a safe and updated manner.

### *4.- Submit the research to independent ethical evaluation*

The research projects must be submitted to an independent ethics evaluation by the committees established for this purpose.

### *5.- Communicate the results to the patients (affected, donors and possible beneficiaries).*

If during the course of the research positive or negative findings are observed that could be relevant to the health of the subject participating in the research study, then these findings should be communicated.

The fact that the results of the study can be provided to the participants is an added value. This is morally binding in the case that said results could be of direct benefit for the participant and his or her family.

## **10. Scientific publications**

Scientific knowledge should be disseminated, preventing exclusivity and promoting its access and dissemination to the entire scientific community. This permits a growth in knowledge in this specialty, which also supposes an improvement in quality and therefore in patient service.

Someone will only be considered the author of a scientific publication when they have contributed in a relevant manner to propose, design, carry out, analyse and discuss the contents of the study.

As a practical rule, the author of a scientific publication is the person able to defend the same before an external evaluator.

The order of priority of the authors listed for a scientific manuscript should correspond to the proportion of the contributions of each author to the final product.

The status of hierarchical or institutional leader of the research team or leader at the centre where the study was carried out does not necessarily mean that that person will be automatically considered as an author, nor as a principal author.

Both the omission from the author list of persons who made relevant contributions to the study and the inclusion of persons who, due to imposition or conflict of interests, fail to meet the condition of author under the terms defined herein, are both considered contrary to ethics.

It is very important to emphasise the need to publish true, original and complete data and avoid the publication of the same information with slightly modified formats in different journals or scientific publications.

It is ethically unacceptable to have total or partial plagiarism of results from other colleagues, whether these have been previously published or not.

Editors must publish any study correctly carried out on important and pertinent aspects for the purposes of the journal whether the results are positive or negative. The publication of studies that are not conclusive is problematic given that they contribute little to biomedical knowledge and consume journal resources.

Scientific work should always be valued on its own merit, without any prejudice towards its origins, authorship or funding.

Health professionals that act as reviewers in research programmes must demonstrate respect for scientific information, knowledge of the discipline and goodwill so that quality, equality, justice and veracity criteria are met.

The reviewers are obligated to maintain the privacy and confidentiality of the works under evaluation.

Likewise, possible conflicts of interest must be regulated in all scientific publications, including those of the editors and other reviewers.

## RECOMMENDATIONS

- The relationships between health professionals must be framed within a cohesive community united by the principles of fraternity and mutual respect.
- Continuing training, which is essential in the field of reproduction, should be contemplated from both the individual and collective points of view.
- Care must be taken when relating to colleagues, avoiding unfounded criticisms and, above all, critiques in the presence of patients, relatives or any third parties. Care should also be given towards the manner of dress, hygiene, behaviour, etc.
- Reproduction programmes must seek excellence, which supposes assuming a moral commitment to the patient, colleagues and society.
- Not everything can be a conscientious objection; the limit for this is marked by the obligation to avoid serious damage to the patient, to aid the patient in any situation of urgency and by the obligation to collaborate with the patient when faced with a grave and urgent situation.
- Multidisciplinary collaboration is a desirable objective. However, teamwork must not prevent the patient from knowing which doctor is the medical doctor responsible for his or her care and attention, and said physician will be the patient's primary spokesperson with the healthcare team.
- Cooperation with other professionals is particularly relevant in the field of reproduction, facilitating information on the patients and/or donors and every aspect that could improve attention to the patients.
- The transfer of gametes between centres cannot be an object of commercialisation and speculation, and the selection of gametes by any criteria except for the purely medical should be avoided.
- Taking into consideration that a degree does not automatically nor indefinitely provide the necessary competence, professionals should know and respect their limits.
- Research in the field of reproduction necessitates a special care with respect to and for the protection of the biological material with which these professionals work, including gametes, embryos and gonadal tissue.
- Publications must be original, with accurate and complete data, and their access and dissemination to the entire community should be promoted.
- Reviewers must value submitted works based on the works themselves, avoiding conflicts of interest and without any prejudice toward authorship, origin or funding.

## RESPONSIBILITY OF THE CENTRES AND OF THE SEF AS AN ORGANISATION

1. Introduction
2. Centre ideology compendium and action protocol
3. Benefit limits (for patient petitions)
4. Protection and control of professionals by the organisation
5. Healthcare Ethics Committee
6. Centre records and activities
7. The SEF as promoter of values (Code of Ethics)
8. Different contexts for the SEF as an organisation
  - a) Pharmaceutical industry
  - b) Communications media
  - c) Government agencies
  - d) Scientific associations
  - e) SEF Foundation

### 1.- Introduction

The Spanish Fertility Association (*Sociedad Española de Fertilidad*, SEF) is an independent scientific non-profit association whose goals are to promote general interest in its topic. The purposes of its actions are not limited, therefore, to benefitting the professionals that are its members (for whom it provides continuing training, research, scientific meetings, etc.); the ethical and social commitment of the SEF is also extended in an equal manner to society as a whole. The SEF promotes reproductive health in all citizens by means of the dissemination of existing scientific knowledge in the field of human reproduction and the publicising of the range of medical treatments and techniques in this field, as well as the medical, bioethical, psychological and legal implications of assisted reproduction.

The services, units and fertility centres do not form part of the SEF. Nonetheless, the actions of said centres are also considered as part of the Code of Ethics of the association, as this code aspires to serve as a guide to all entities where assisted reproductive medicine professionals work and to influence their institutional actions equally.

Consequently, this chapter of the Code sets down the ethical action bases for the SEF and for the group of fertility services, units and centres where assisted reproductive medicine professionals work who are affiliated with this society.

### 2.- Centre ideology and action protocol

The ideology and action protocols of the centres are a good opportunity to forge a common spirit and philosophy among all professionals and workers and to communicate with outsiders a manner of action as well as assumed values, ideas, beliefs, commitments, etc. that evidence a concern not only to provide correct medical actions from a technical point of view but also to leave a differentiated mark or stamp.

When these ideologies and protocols are inspired by ethical norms that have been considered and designed to improve the quality of medical attention, they then can serve as instruments to reach high levels of professional excellence. It is then that reproductive services, units and centres having these ideologies are recommended (when they have taken into consideration the group of principles and operational guidelines that the Code of Ethics of the SEF incorporates).

It is recommended that the actions of the centres should have a unifying protocol to prevent ethical conflicts or to duly guide them in the right direction in case such conflicts take place in matters such as the following: informed consent, the evaluation of patient capacity, requirements for access to technology, privacy and professional confidentiality, religious and cultural beliefs and their repercussions for clinical practices and conscientious objections, genetic counselling.

### **3.- Benefit Limits**

The principle of autonomy, the freedom to decide, is no doubt one of the fundamental values of our western culture in all aspects of life. Its manifestation in the health world through the establishment of informed consent has modified the axis of the health professional-patient relationship, shifting it from the former towards the latter, thus making the patient into the primary actor in healthcare procedures.

However, it is only fair to acknowledge that the autonomy of the patient, as any other principle or right, has its limits when this autonomy somehow conflicts with other values or interests that also need to be respected. From a general perspective, within the public health systems, the right to receive healthcare can be found to be in conflict with the need to operate an administration with limited resources and the need to equitably distribute the means at its disposal. We are saying, then, that the principle of justice wins over the principle of autonomy.

Another limit to the patient's autonomy is derived from the guidelines assumed by society within a normative range, in which case we can talk about prohibitions as an ethical rule. For instance, we can cite the agreement that not everything that is scientifically or medically possible is ethically admissible.

In the worst case, there is no doubt that health professionals must be acknowledged in their position as moral agents when their relationship with patients is taken into consideration, not in the sense that they must impose paternalistic attitudes over their patients, but in the sense of the nature and responsibility of the healthcare activities that they conduct, a factor that weighs heavily in clinical decisions.

In the end, in the field of reproductive medicine, it can be affirmed that patients have the right, after being informed, to accept or decline the technologies and treatments that the professionals might propose. In no case are the professionals bound to take any actions they might not believe are medically indicated.

#### **4.- Protection and control of professionals by the organisation**

The social and cooperative responsibility of the reproductive centres demands that, within these priorities, there also be concern for the interests of the professionals who work in them. In this regard, beyond the aspects related to the just remuneration for work, measures are desired that could promote the comfort and acknowledgement of the professionals within the centre, their protection against biological risks, non-discrimination and especially a balance between work and family life.

In the same way, the centre can demand an attitude from the professionals toward the centre that would promote its proper operation both in complying with its goals and/or values and in creating a good working environment.

#### **5.- Healthcare Ethics Committee**

Undoubtedly, an important role for ethics committees as consulting organisms is their obligation to advise on the resolution of conflicts that emerge in healthcare procedures, the elaboration of guides and protocols that facilitate dealing with specific clinical situations, as well as training on bioethics material at the centres.

Due to the above motives, the linkage of services, units and reproduction centres with healthcare ethics committees is desirable as a factor that will contribute to better quality in healthcare activities.

#### **6.- Centre records and activities**

The field of assisted human reproduction techniques is known for an asymmetry in information between the patients that demand their application and the health professionals and centres that apply them. The necessary balance and compensation in this situation leads to the public powers demanding that the reproduction centres make a special effort to render their data as transparent as possible.

Aware of this social demand and as an act of voluntary collaboration with this goal, SEF has a staunch commitment favouring the release of information by means of the maintenance of their centre activity records, which is an essential objective.

For the same reason, professionals in reproductive medicine are observed as obligated to support and encourage the centres where they work to actively collaborate, with rigour and honesty, with the communication of the data from their records, allowing all interested parties to have an accurate and updated knowledge of the reality of healthcare in this field.

#### **7.- The SEF as promoter of values**

The SEF, as a private entity with a vocation of public service, has a responsibility to society to conceptualise and benefit the following groups: members of this society and those who are in any way concerned with its activities and who have expectations and legitimate rights derived from the SEF's actions, such as employees, patients, providers, health administration, staff and society in general.

From this focus, the SEF's purpose is to serve citizens by means of the development of the goals that it promotes (reproductive health) and the ethical values that drive it, avoiding, in any case, harm to the community by either action or omission. To do so, the SEF must work on earning trust and credibility from the citizens based on the quality of its operations and a search for excellence, in which scientific rigour and ethical sensitivity are combined as its best external publicity. Within this perspective, the SEF must serve as a structure that brings the centres that compose it together by providing a space for communication, the sharing of knowledge, the dissemination of good practices, the promotion of intercentre relations and, generally, the development of everything that could contribute to improving the professional role and promoting a sense of a scientific community.

To promote the aspects referred to above, the components of the Governing Board of the SEF, as well as any member with representation in the same, must observe the Code of Ethics very strictly and has the responsibility to ensure its compliance.

## **8.- Different contexts for the SEF as an organisation**

When the time comes to consider specific guidelines for the SEF's actions as a responsible organisation within society, we can carry out an analysis in different spaces: the relationships with the pharmaceutical industry, with the communications media, with government agencies, with other scientific societies and with the SEF Foundation.

### **a).- Pharmaceutical industry and other providers**

The support given to scientific society by the pharmaceutical industry constitutes today an important factor for the development of these societies' goals, as it allows for the funding of projects and activities within these societies, particularly in the field of continuing information and research.

Now, the situation described cannot compromise the scientific independence of the SEF with regard to setting or supporting the contents and criteria of formative proposals, meetings, conferences, symposia, round tables, committees for prizes or fellowships, that may be funded by the pharmaceutical industry, nor does it compromise the impartiality of the contents of the publications that are also paid for by the laboratories. In this respect, it is indispensable that all decisions for all circumstances be made in advance within the governing board of the SEF, based exclusively on the technical and scientific valuation of these initiatives, without any other consideration.

In this work, the members of the Governing Board of the society must state any possible conflicts of interest that they might run into for every decision on this matter so that, if required, they may abstain from the decision-making phase of each discussion.

#### **b).- Communications media**

The SEF will give particular regard to the dissemination of its opinions to the media, working towards a single voice from the institution. To do this, members of the Governing Board of the SEF, in their declarations to the media, will prevent their personal opinions from being confused with those of the SEF and will provide adequate warning for each case or circumstance in which they give personal opinions.

#### **c).- Government agencies**

Collaboration with the State agencies, autonomous communities, municipalities and other public and private institutions in subjects related to human fertility, with special reference to those in Spain for the use of assisted reproduction technologies as well as advising in scientific and legal matters for the elaboration of pertinent legal norms, are among the bylaw goals of the SEF.

This involvement with the public sector is desirable and can manifest as specific commitments in the form of agreements or contracts. In this manner, the general interests of the SEF are emphasised as well as its power in its public activities.

#### **d).- Scientific associations**

The SEF's relationships with other scientific associations, both national and international, with interests analogous to those of the SEF, should be observed as a factor that enriches assisted reproduction activities. The possibility of establishing agreements or alliances with these associations must in no case be assumed to represent a loss of the organisational autonomy or the free will of the SEF.

Connections among scientific societies that work on sexual and reproductive health is considered particularly useful, such as those currently featured in the Federation of Associations for the Study of Reproduction [Federación de Asociaciones para el Estudio de la Reproducción], of which the SEF forms a part. One of the SEF's objectives is to promote, coordinate and conveniently channel the participation of all of these societies in the study of human and animal reproduction and fertility into health policies and into the training plans on this material. Additionally the SEF's further objectives are to provide advice in debates, reflections and decision-making and to seek, when necessary, points of agreement with public or private health institutions on those conflicts that may arise in relation to reproductive health.

### **e) SEF Foundation**

The SEF Foundation is a non-profit organisation incorporated as an initiative and with starting funds from the Spanish Society for Fertility and which is ruled by the will of said society as well as by its bylaws and regulations. Its primary objective is to promote the reproductive health of all citizens in Spain.

The support provided by the SEF to the SEF Foundation also constitutes a manner of carrying out the objectives of the former organisation, which are related to promoting the public interest and facilitating a more direct and intense contact with the citizens at whom the Foundation's activities are directed.

## **RECOMMENDATIONS**

The postulates of the SEF Code of Ethics must be taken into consideration not only by professionals of reproductive health but also by the services, units and centres where these professionals work.

Drafting a protocol for actions in reproduction centres is a way of anticipating solutions to ethical concepts that may arise, and consequently, this is a potential formula to improve professional quality and excellence.

The patient's autonomy must be considered as a fundamental value in current health assistance but cannot be understood in absolute terms, as it also has limits.

An attitude that favours the quality operation of the centres can be demanded both by those responsible for the centres and from the professionals who provide services in them.

The connection of the reproduction centres with a committee of ethical healthcare is desirable, with the benefit of greater quality in health provisions.

The role and the involvement of the SEF must be acknowledged and supported, favouring informational transparency of the professionals and centres of assisted reproduction.

The members of the SEF Governing Board and any other partner with responsibilities in this partnership must be the first to ensure compliance with this Code of Ethics.

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