Spanish Regulations on Assisted Reproduction Techniques

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INTRODUCTION

The Spanish regulation on Assisted Reproduction was passed into law in November 1988, Law 35/1988 (1). Even though some countries had Documents or Recommendations about this field, Spain was the first country with a separate law only concerning this item.

The law 35/1988 regulated the main important aspects of assisted reproduction techniques (ART) and established that some other aspects like the creation of a National Register and the constitution of the National Committee of Human Assisted Reproduction will take place within 6 months following the promulgation of the law. After some years of inactivity, three Royal Decrees and one Ministerial Order were promulgated in 1996 and 1997:

- Royal Decree 413/1996 (2) about the requirements for the institutions undertaking ART.
- Royal Decree 412/1996 (3) and Ministerial Order of March 25, 1996 (4) about requirements for donors and the creation of a Donation Register.
- Royal Decree 415/1997 (5) about the creation of a National Commission of Assisted Reproduction.

Although Law 35/1988 provides for the creation of the National Committee of Human Assisted

Reproduction, nearly 9 years elapsed until its constitution in March 1997. Up to now, the Committee has produced two reports with some recommendations about the most important issues that were considered as high priority to be dealt with. Even though, modification of the current rules was recommended in the majority of the cases, up to now, the government and the health authorities have not promoted any change in the legal framework.

SPANISH LAW ON ART (LAW 35/1988)

Aim of ART (Articles 1, 3)

Assisted reproduction techniques have as their aim medical action against human infertility to facilitate procreation when other therapeutic methods have been rejected as inadequate or ineffective. These techniques may also be used in the prevention and treatment of diseases of genetic or hereditary origin, when it is possible to make use of them with adequate diagnostic and therapeutic guarantees, and provided that they are strictly indicated. Fertilization of human eggs for any purpose other than human procreation is prohibited by this law and by the Penal Code, Article 161 (6).

Users of ART (Article 6)

Any woman may be recipient or user of the techniques regulated by the present law, provided that she has freely knowingly and expressly given her written consent to the use of these techniques. She must be of 18 or more years of age and of sound mind. A married woman must obtain her husband's formal consent, unless she is legally separated or divorced, or separated de facto or by mutual consent.

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Centers and Teams (Articles 1, 18, 19)

Human assisted reproduction techniques must be performed by specialized teams in authorized centers only. The law and with more detail the Royal Decree 413/1996 (2) describe the requirements for the institutions undertaking ART as well as the procedures to follow with the patients.

Cryopreservation (Article 11)

Sperm cryopreservation is allowed but sperm may be kept frozen in authorized banks for a maximum period of 5 years. Cryopreservation of oocytes will not be allowed unless their viability, once thawed, is guaranteed. The embryos not transferred in an in vitro fertilization (IVF) and embryo transfer procedure will be cryopreserved in authorized centers for a maximum period of 5 years. Two years after they have been frozen, those gametes or embryos not obtained from donors shall be made available to the corresponding banks.

Donation (Article 5)

Donation of human gametes or embryos is a formal, free, and secret contract between the donor and the center. Under no circumstances will a donation be made for lucrative or commercial ends. Donation shall be anonymous. The medical team will select the donor. It must guarantee the maximum degree of phenotypical and immunological similarity and the maximum degree of compatibility with the recipient and her social environment. Details of the identity of the donor shall be kept in the strictest secrecy, and with access subject to security procedures in the respective Banks and in the National Register of Donors. In no case will the Civil Register reflect data from which the character of the birth may be inferred. Children born as the result of the use of these techniques have the right either personally or through their legal representatives, to obtain general information regarding the donors, excluding the donor's identity. Recipients of gametes shall also enjoy this right. Under no circumstances will the donor be subject to legal claims of paternity. The Royal Decree 412/1996 (3) and the Ministerial Order of March 25, 1996 (4) establish the donor's characteristics and the standard screening required against genetic, hereditary, or infectious diseases transmission.

Research (Articles 14, 15)

Gametes can be used for research purposes but after this, they must not be used to obtain embryos to be used in procreation. In vitro research on "viable embryos" will only be allowed in the case of applied diagnostic research seeking prevention or therapeutic ends and if the genetic inheritance is not modified. In vitro research with other ends than preventive or therapeutic ones will only be allowed with "nonviable embryos." Experimentation on embryos in the uterus or the Fallopian tubes is forbidden.

Postmortem ART (Article 9)

Notwithstanding any previous provisions, the husband shall be able to consent, by written public declaration or by will, that his reproductive material may be used in 6 months following his death to fertilize his wife. Under these circumstances, the legal effects will be those derived from marital filiation.

Surrogacy (Article 10)

No contract which provides for gestation, with or without payment, by a woman who renounces her maternal bonds in favor of the contractor, or of a third party, shall have any legal validity whatsoever. The filiation of children born by substitute gestation will be determined at birth.

Prohibitions and Sanctions (Article 20)

The law establishes a list of serious and very serious infractions. The most important ones are detailed below.

- The fertilization of human eggs for any purpose other than human procreation.
- To obtain human embryos by uterine flushing.
- To maintain live embryos after Day 14, not excluding the cryopreservation period.
- To mix semen from different donors or to use oocytes from different women for IVF or gamete intrafallopian transfer (GIFT).
- To transfer gametes or embryos without biological guarantees of their viability.
- To create identical human beings by using cloning techniques or any other procedure.
- Sex selection or genetic manipulation for nontherapeutic or unauthorized therapeutic purposes.

- To produce chimeras by embryo fusion or any other procedure.
- To obtain hybrids by genetic interchange with other species.
- To perform ectogenesis or to create an individual human being in the laboratory.

NATIONAL COMMITTEE OF HUMAN ASSISTED REPRODUCTION (CNRHA)

The Spanish National Committee of Human Assisted Reproduction has a multidisciplinary composition. It consists of 25 independent members appointed by different Ministries, scientific societies, and social organizations and it has an advisory role to the Health Ministry. The Chairman is the Deputy Minister of Health and the vice-chairman, the Director of the Public Health Department of the Health Ministry. The Committee is responsible for the update of the law, the evaluation of any project for research on human gametes and embryos, and orientation when conflictive situations occur.

The Committee started bringing up to date the state of development of the Register of Centers, the Register of Activities and also, the preparation of some models of consent forms. At present, the Register of Centers has been fully developed by the Health Ministry. The Register of Activities is still in the preliminary stages of development and the proposal of the CNRHA to implement a voluntary self-assessment questionnaire is still not available.

During the first years of activity, the main issues that were reviewed by the Committee because they were considered to need an urgent ethical and legal revision were

1. Sperm cryopreservation: legal period of storage.
2. Oocyte cryopreservation: current possibilities.
3. Embryo cryopreservation: legal period of storage and future alternatives.
4. Research on human embryos.
5. Human cloning: evaluation of recent scientific achievements.
6. Gamete donation: payment of donors.

The discussion about these topics and the conclusions reached by the Committee were referred to the Government in two different reports. The first report was finished in October 1998 and referred to the Government. It was made public at a press conference, in March 1999 (7). The second report was completed

in April 2000 and it was placed in the Government's hands in November 2001.

The main important aspects of both reports are summarized below.

Sperm Cryopreservation

Spanish law on ART states that male gametes cannot be stored frozen beyond 5 years. However, there is scientific evidence that sperm, spermatozoa, and testicular tissue can be kept frozen for longer periods of time neither losing its efficacy nor increasing the risks. Men suffering from illnesses that may lead to infertility or submitted to treatments that may cause it, would benefit from the storage of sperm and spermatozoa, as a preventive measure. For these reasons, the Committee recommends abolishing the restrictions in the storage time contained in the law and to allow preservation for an unlimited period. Furthermore the Committee recommends the strict compliance of the sperm banks with the existing protocols and their enforcement by the responsible authority.

Oocyte Cryopreservation

Even though oocyte cryopreservation is currently forbidden in Spain, until scientific evidence exists and scientific guarantees are produced concerning oocyte viability after thawing, reasons to recommend oocyte and ovarian tissue freezing for their use in ART exist. The main indications are preservation of fertility (i.e., after treatments such as chemo and radiotherapy in young oncology patients), asynchronous oocyte donation and occurrence of ovarian hyperstimulation syndrome. Oocyte cryopreservation has also been considered as a way to reduce supernumerary embryo cryopreservation and storage, in some cases. Since the evidence of the safety and efficiency of oocyte and ovarian tissue cryopreservation is still limited, the CNRHA advises to proceed, for the time being, on an experimental basis and to promote experimental research to evaluate the technique before clinical application is allowed. In the view of the CNRHA, the law needs no changes to permit oocyte and ovarian tissue cryopreservation. Nevertheless regulations are required to allow the experimental work. A general authorization is not envisaged but rather a limited authorization to some centers to conduct experimental protocols before clinical use.

Embryo Cryopreservation

Law 35/1988, Article 11 authorizes the storage of frozen embryos for a period no longer than 5 years, giving no indications of the final destiny of such embryos after this time has elapsed. Today, the number of frozen embryos increases with time and in Spain, it is estimated to be no less than 25,000 and approximately 15% of them have been frozen for more than 5 years. Urgent decisions have to be implemented to face this situation.

Embryos Frozen for More than 5 Years, Exceeding the Legal Storage Limit Allowed. The CNRHA proposes to contact the couples in such situations and ask them for embryo donation to other couples if they do not have a parental project anymore. If contact is unsuccessful or both members of the couple have died, the embryos can be used for donation to other couples. If there is any circumstance that does not allow donation (advanced maternal age, increased genetic risk, more than six children born, etc.) the embryos have to be destroyed. To adopt these measures, a transitional period should be established.

Embryos to be Frozen in the Future. Taking into account that there is no scientific evidence to support the limitation of embryo storage to 5 years, the Committee supports the idea that this storage period should be extended to the end of the reproductive life of the mother, around 50 years old. For that purpose, the law has to be changed to prolong the time limit. At the same time, the CNRHA proposes a series of measures to encourage the participation of the parents in every stage of the storage and to promote embryo donation. The couple has to agree on the destiny of the embryos before and during the treatment period even though this consent may be revoked at any time. The informed consent has to be signed by both members of the couple at the start of the treatment cycle. They should consent to use the embryos for a new transfer if the first one does not succeed. In case of pregnancy, they may choose either to use the embryos for a new trial or to donate them to other couples. Donation of those embryos that are not going to be used should be encouraged and destruction should be the last measure to be contemplated.

Embryo Research

The Spanish legal framework is bound by the European Convention of Human Rights regarding Biomedicine (8,9) that was ratified by Spain and which establishes that no human embryos will be created for

research but the Convention allows research in embryos of less than 14 days, when it is nationally authorized. Spanish law 35/1988, Article 15 forbids research on human viable embryos. However, the majority of the CNRHA considers research as an alternative to destruction. Even if the proposed measures suggested above are fully implemented, there will still remain a significant number of embryos for which there is no other fate but destruction.

Nowadays, there is an increasing demand for human embryos for research purposes. Besides the research to improve ART, stem cells research is becoming a very important scientific issue for the future of regenerative medicine. The use of surplus embryos will provide an important source of stem cells in order to obtain cell lines for transplantation. The possibility of using them for this purpose is considered as a great valuable contribution for the development of future regenerative medicine. Having in mind all these considerations, the majority of the members of the CNRHA thinks that to carry out research on frozen embryos, when all other possible alternatives have been tried and when the only alternative is their destruction, is not against the respect that all human embryos deserve. In consequence, the Committee recommends that research on surplus frozen embryos should be authorized as an alternative to destruction when the legal limit period has expired and considers that a modification of the current rule is necessary.

Human Cloning

Reproductive cloning of human beings is forbidden in Spain both by the law on ART (1) and the Penal Code, Article 161.2 (6) as well as by the Convention on Human Rights and Biomedicine (8,9). According to an ethical viewpoint, the CNRHA opinion is that humans should not be considered as a means to an end. Furthermore the right not to be genetically programmed is a powerful argument against reproductive cloning. In consequence, the Committee adheres to the already existing prohibitions on reproductive cloning of human beings and only proposes to correct Article 161.2 of the Penal Code in order to avoid interpretative misunderstandings.

Nonreproductive cloning opens up a wide range of possibilities to obtain cell lines for transplantation. Concerning the use of human embryos as a source for cell line growth, consensus was not achieved. The Committee considers that if the same type of products can be obtained from adult tissues, there will be no need to obtain them from embryonic cells so

it recommends the use of nonembryonic stem cells whenever possible.

Payment for Gametes

Spanish Law 35/1988, Article 5 states that donation of gametes should be a formal, secret, and free of charge contract between the center and the donor and should under no circumstances have a lucrative or commercial nature.

Donor's sperm samples are stored in authorized banks for its use in ART. The current practice in Spain is to pay a small amount of money (35 Euros) to male gamete donors. Different situations occur in oocyte donation. Oocytes can be donated by patients performing IVF cycles (egg sharing) and this can result in a reduction in the fees the patients have to pay, or by young and healthy donors who will get some financial compensation. It would seem that oocyte quality should be better when donated oocytes come from young healthy donors when compared to infertile IVF patients. Considering that if no compensation is given to donors, gamete donation would decrease significantly, that it is advisable at least to maintain gamete donation at present levels and that donation should not be costly to the donor, the CNRHA recommends establishing a standard payment. The Health Authorities should control the establishment of this compensation. In the view of the Committee the payment for sperm donors is just a compensation for the inconveniences suffered by the donor related to the donation. Concerning oocyte donation a similar procedure applies taking into account the circumstances derived from ovarian stimulation and follicular puncture. The Committee decided to establish a rate for oocyte donors 20 times the amount given to sperm donors, that is about 700 Euros for every oocyte donation. The basis for that rate is that oocyte donors suffer many more inconveniences than sperm donors do and the donation requires a higher number of visits to the clinic. The CNRHA thinks that this compensation is not in contradiction with the principle of the

“nonprofit and commercial character of the donation” and therefore no changes in the law are required.

At the moment of publishing this manuscript, a new Royal Decree (RD 120/2003) has been promulgated in Spain, allowing controlled experiences on fertilization of cryopreserved oocytes and ovarian tissue for reproductive purposes.

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