

Regulatory framework in assisted reproductive technologies, relevance and main issues

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Abstract: Assisted reproductive technologies (ART) have changed life for the past 25 years and many ethical and social issues have emerged following this new method of conception. In order to protect individuals against scientific and ethical abuses without inhibiting scientific progress, a specific legal framework is necessary. The first French law on Bioethics was voted after an extensive debate in 1994 then reviewed in 2004. This review previously scheduled every five years is currently being discussed. Legal provisions applying to ART are part of a large framework including the protection of the patients' rights and biomedical research. The key principles consist of respect for human life and ban on commercial practices of human body parts, eugenic practices and any kind of cloning. These key principles apply to ART. Donation is anonymous and free. Created in 2004, the Agence de la biomédecine is a government agency and one of the main tools of the French regulations. The missions focus on improving the quality and the safety of the management of ART. Evaluation of activities is available to all from the annual report. The agency represents the French competent authority for medical and scientific aspects of ART. Substantial differences in European legislations exist from the open-up "laissez faire" to the most restrictive one. As a consequence a large reproductive tourism has developed particularly for egg donation or surrogacy. The medical and ethical conditions of management of patients and donors represent the main critical points. In order to avoid ethical abuses, homogenization regarding the key principles is necessary in Europe. It is an opportunity to reassert that human body parts should not be a source of financial gain.

Key words: assisted reproductive technologies, egg donation, French law on bioethics, regulations, cross border reproductive care

Introduction

Assisted reproductive technologies (ART) have changed life for over 25 years for many reasons, mainly because of the first direct access to embryos *in vitro* from human species and the possibility of conceiving outside the body. After the first rush of enthusiasm as regards to the latest scientific progresses, major ethical and social issues arose about consequences of this new method of conception. According to the general opinion, the perception and valuing of human life and family relationship have changed drastically. In the nineties ART have developed rapidly due to many progresses in knowledge and techniques as well as social pressure and patient's demand. However these treatments were still quite new for mankind. In order to protect individuals against ethical abuses without inhibiting scientific progresses, a specific legal framework was necessary.

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But all the stakeholders including the public, the patient lobby groups, the professionals, the members of the parliament and finally the government were soon convinced of the difficulties to comply with the two following issues: the absolute need for protecting individuals against the scientific and ethical abuses and the respect for the innovations and the enthusiasm of the researchers as well as their freedom.

An extensive and strong debate led to the French law on bioethics in 1994 and reviewed in 2004. Revision was scheduled every five years in order to take into account clinical experiences, latest development in the scientific knowledge, new techniques and society's evolving points of view. Currently France must review this law. In order to vote a law which is convenient to a majority, the government is organizing a large public debate in 2009 before voting on the new text.

Substantial differences exist from the open-up "laissez faire" to the most restrictive one. Consequently a large reproductive tourism has developed particularly for egg donation or surrogacy. The medical and ethical bad conditions in which ART patients and gamete donors are managed represent the main critical points.

First a general review will describe the existing French legal provisions in ART in the context of a large framework applying to healthcare. Then one of the main tools of the framework, the French government agency in charge of expertise and regulation in ART and pre implantation genetic diagnosis (PGD), will be presented. Some of the difficulties in applying the French law in ART will be exposed. Finally because of the development of a large cross border reproductive care, harmonisation of the legal frameworks must be discussed in Europe.

Existing French regulations

Legal provisions applying to ART belong to a large and relevant framework including bioethics [1], protection of patients' rights [2] and biomedical research [3]. The key principles consist of respect for human life and human body integrity. Any kind of commercial practices relating to the human body or element from the human body is prohibited. Eugenic practices and either reproductive or therapeutic cloning are also prohibited. Failing to comply with the law can include criminal penalties and revocation of authorization.

The 2004 law on bioethics regulates different domains such as genetic analyses, organ, tissue and cells procurement, donation and transplant, prenatal diagnosis, pre implantation genetic diagnosis (PGD), research on embryo and embryonic cells and finally ART. The ART specific provisions state that:

- payment to gamete donors for donation is prohibited. The donors can not be motivated by money. In the same way, donors can not be under any kind of pressure, from friends or family's members as well as from the medical sector.
- contracts for surrogacy are illegal
- anonymity is required between donors and recipients

In addition the access to ART is legally restricted to certain civil status and conditions as follow:

ART are intended to help heterosexual couples with medically diagnosed infertility to become parents. However couples who present a high risk of transmission of a severe disease to the children or to one of the partners can also have access to ART. In addition, the man and the woman who form the couple must be alive at the moment of the ART application. This means that posthume use of cryopreserved sperm or embryos in ART is forbidden, even if the deceased person had consented before. They must be married or able to prove that they have been living together for at least two years.

Both must be of a natural reproductive age even if it is very difficult to define limits particularly for men. Increasing demands from women over 42 years old who present a physiologic ovarian defect represent new society's concerns.

Finally both must have given prior consent to ART without any pressure. These consents are signed after having received fair, clear and appropriate information about the risks and consequences of the procedure. The couples must participate in the decision making. The consent signed by both members of the couple must be repeated before each attempt. The medical team must ensure that the information given has been fully understood, that the persons have been able to ask all the questions they wish and have had satisfactory answers.

With respect to these general conditions, ART should be accessible to everyone, regardless of financial and social conditions of life and whatever the place of residence.

The definition of infertility as a disease is very specific to France. Indeed the law on bioethics defines ART as medical care which are provided to infertile couples. In France, health care are covered by the national health insurance which is funded by national workers participation.

Consequently, ART services are provided within the organisational framework of the French national healthcare system and fully covered. Conditions for a free treatment are precisely defined in the national health insurance code.

Good practices in ART [4] applying to the management of patients and donors for all clinical and laboratory procedures complement the legal provisions. Regulating technical details, which are in constant evolution, are more flexible, easier and faster reviewed than the law. Conformity to guidelines is obligatory for both authorized establishments and licensed practitioners. Failing to comply with these guidelines can lead to a revocation of the authorization or license.

To conclude, the law stated some key principles which are in agreement with current cultural values and ethical considerations in France. However because the revision of the law was scheduled every five years, France must review its law. An extensive debate including the public at large and patient associations has started over the main issues at stake such as anonymity of donation, payment to egg donors, surrogacy contracts and embryo research. A few people would consider ART as a new mode of conception that could be granted to lesbian couples, single women or women up to 50 years old. So they lobby to lift the legal barrier to access ART. It will be to the members of the parliament to decide what the future law will be.

The French government agency in charge of expertise and regulation in ART

Established by the law on bioethics in 2004, the Agence de la biomédecine is a government agency under the authority of the health ministry. It was created to provide expertise and regulations in several main

domains of human biology and medicine with common major medical and ethical issues. Its missions focus on improving the quality and the safety of the activities. It represents one of the main tools in the French regulations applying to ART and PGD.

The agency draws its policy with

- an executive board of representatives from different ministries, public bodies and experts,
- a steering committee, which supervises the consistency of the policy and the compliance with the ethical principles. This committee is composed of society's representatives, ethical and philosophy specialists as well as parliament and legal representatives, patients representatives
- a medical and scientific committee composed of experts, representative from professional associations from the different domains regulated by the agency.

Finally the agency works closely with many specific groups of experts. Obviously the agency gives an important role to civil society representatives and ART practitioners.

First of all, the agency is the competent authority delivering a technical expertise. It must be reactive, ready to give a quick alert if necessary. Interacting with society, it provides much valid information and should contribute to reassure about such social or medical concerns.

The main objectives can be summed up as follow:

1. Development of homogenous practices in the best conditions of quality and safety everywhere in France:
 - contributing to guidelines
 - authorising practitioners
 - monitoring activities
 - training and information
2. Transparency:
 - making evaluation of the activities and have them available to the government, parliament, professionals and society. Complete information is available from the annual report available on the website [5]
 - conducting information campaigns with specific public website and guides in ART, oocyte donation and sperm donation [6]
3. Ethics and fair access:
 - ensuring that treatment is accessible to all

So the agency has become the referent competent authority for medical, scientific and ethical aspects in ART. The following missions assigned to the agency are detailed below:

- licensing practitioners involved in ART, as well as in genetics and PGD, taking into account their initial background and experiences
- giving advices to the state health regional agencies on the authorisation of the ART centres

- evaluating activities and procuring a national analysis in the annual report [7]
- organizing the collect of IVF data in a national register in order to perform specific analyses
- organizing a long term follow up of the health of the children born of ART and of the women who performed ART or egg donation
- managing a vigilance system to centralize adverse event declarations and give quick alerts if necessary
- participating in development of new regulations and guidelines; the agency worked with professionals to develop guidelines to harmonise practices
- authorizing research on human embryos and embryonic stem cells *in vitro*
- promoting of gamete donation

ART is organized and regulated in France and it is well known at the European level. The agency attends the European commission's meeting about all the aspects of the transposition of the European directive on tissues and cells [8] into the French law. It participates in many European projects including Eustite [9] which applies to ART vigilance and inspections. The agency is the second in Europe after the HFEA [10] in UK. There are many exchanges with the Human Fertilisation and Embryology Authority (HFEA) and European Society of Human Reproduction and Embryology (ESHRE) [11] particularly with the European Assisted Conception Consortium (EACC).

Main issues and need for harmonization in Europe

Very few people contest the key principles stated by the French law. But although the French law is not too restrictive compared to some other legislations, a few difficulties emerge with its enforcement. Just to quote some of them:

1. Because the law does not state anything about research in ART, it is considered as forbidden. So new techniques involving gametes and embryos are prohibited. Whereas some new techniques are used in other countries in a routine way improving the success rate, these can not benefit French patients.
2. The attempt to define the human embryo's status was unsuccessful. This leads to a certain inconsistency authorizing induced abortion and forbidding embryo research.

Substantial differences in European legislations exist. As a consequence a large reproductive tourism exists particularly for egg donation or surrogacy. In France, for many reasons egg donation is not developed enough to match the demand. This leads French people to travel abroad to benefit from egg donation.

In France ART activities are strictly regulated and conformity to standards is mandatory for all the

authorized ART centres and practitioners. Actually such level of standards about quality and safety do not apply to certain other countries including some European member states. This sometimes leads patients to perform ART in bad conditions. Lack of donor's testing before donation, false declaration of success rate, or high risks of multiple pregnancies with severe adverse outcomes constitute a few of the hazards for patients receiving care abroad.

Moreover French provisions applying to gamete donation anonymity and filiations rules are specific. The consequences of gamete donation or surrogacy performed abroad can be a disaster when back in France.

In addition donor's recruitment is strictly restricted in France in order to avoid gametes trafficking or exploitation of human body parts. However some countries have by-passed the difficulties to recruit donors by paying for donation. So oocyte donation provides earnings particularly for poor Eastern European women who represent now the main sources of oocytes in rich countries. For these women, information regarding the risks and consequences of the donation is often delivered in a foreign language they can not understand. In those countries where compensation is given in order to make up for the hardness of the donation, donors can repeat donation several times a year although egg donation and surrogacy lead to high medical risks for life and health. These women could have some difficulties to access healthcare when they come back home with an adverse event due to the donation. Particular attention should be paid to these women.

The law should reassert the following key principle: the products of the human body should not be a source of financial gain. Homogenization in legislations is necessary in Europe defining common ethical principles in order to protect people against abuses. The law should avoid technical details which are in constant evolution. It must be completed by mandatory good practices and professional guidelines which are more flexible, easier and faster revised.

In Europe, states are not isolated and Europe is currently being built. A new European legislation, making patients free to travel for healthcare, is in preparation. The 2004 European directive and its technical directives requiring the best quality and safety practices for tissues and cells are fully transposed in most of the member states now or in progress in the latest few countries. The mother-directive encourages member states to consider donation as a voluntary and unpaid action founded on altruism and solidarity.

Conclusion

ART activities have increased steadily for the last ten years in many countries worldwide. In 2007 in France, there were about 50,000 IUI cycles, 50,000 IVF or

ICSI cycles and 15,000 frozen embryo transfer cycles. As a consequence, 2.5% babies born in 2007 were conceived through ART in France. About 7% of the total ART attempts are performed with a donation from a third-party donor. These techniques could not be ignored. Very few people question the efficiency of the ART processes but afraid of the possible abuses they are convinced that regulations are essential.

ART, strictly regulated in France, is considered as a medical treatment for infertile patients. All the legal provisions converge to promote the best quality of the practices and the protection of individuals against medical abuses. However law is being reviewed and many sensitive issues are arising. It is difficult to imagine now what provisions will be modified, suppressed or added.

The policies were differently shaped between countries even in Europe. The differences in legal framework relating to ART have a huge impact on the allocation of the techniques in the world. The technologies used the social position of patients who have access to ART and the recruitment of donors are widely heterogeneous and unfair.

As most of the countries such as France are currently reviewing their existing framework, policies should be elaborated in order to make them homogeneous and relevant in Europe. Without ignoring each context regarding cultural values, ethical considerations, state secularism, public health issues and economic means, key principles have to be strongly asserted.

References

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- [4] Decree on good clinical and laboratory practice in ART 11 April 2008
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