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Assisted reproduction practice in Europe: legal and ethical aspects

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This report describes the ethical and legal aspects of assisted reproductive technologies (ART) that have been instituted in European countries. The data were collected from questionnaires circulated to fertility centres in 39 countries in Europe. Ninety six ART centres were located in 30 of these countries. Nine countries do not offer ART services. According to the survey, there are approximately 516 centres in Europe, which represent approximately 60% of the world ART centres. The survey included information regarding regulation of ART services, access to these services, attitude toward genetic material donation, cryo-preservation of pre-embryos, surrogacy, manipulation of gametes and pre-embryos, research on pre-embryos and multiple fetal pregnancy reduction. At present, the majority of countries in Europe do not have established legislation pertaining to the various aspects of ART practice. The study reviews the ethical and legal aspects of ART practice in Europe.

Key words: assisted reproduction/Europe/legal and ethical aspects

Introduction

The advances in reproductive biology that have made it possible to produce human pre-embryos *in vitro* have been among the most significant scientific achievements of the past 25 years. For many couples who were previously considered sterile, the emergence of these new techniques to alleviate infertility has offered new opportunities to conceive. Moreover, although there is a wide variation in standards, patient selection criteria and treatment protocols, assisted reproduction technology (ART) has become a routine tool in the treatment of infertile couples in most European countries. After the initial enthusiasm, however, in many European countries society realized that, concomitant with the great advances, limitations had to be established. Along side the scientific achievement, a public debate has been held in many European countries concerning questions such as the setting up of regulation or legislation, the right to ART treatment, the cost of assisted conception, resource availability, who should control the quality of ART practice and how, and whether donation of genetic material should be practised.

From the beginning of this new therapeutic approach, Edwards (Edwards and Sharpe, 1971; Edwards, 1974), who was the pioneer of ART, emphasized the importance of resolving the ethical issues involved. Nevertheless, in European pluralistic society it cannot to be expected that any single set of principles will be completely acceptable to everyone, and different attitudes have been adopted even by those countries belonging to the European Community. Recently, a report on the ethics, law and practice of artificial procreation was prepared by the European Commission for a Concerted Action (Evans and Evans, 1996) sponsored under the Commission's BIOMED programme. Thus, the purpose of our study was to review the ethical and legal aspects of ART that have been instituted in those European countries practising ART.

Materials and methods

The data were collected by circulating questionnaires to centres with ART programmes in Europe. A total of 96 centres in 30 countries were located, as summarized in Table I.

The ART centres were requested to complete a questionnaire that was designed to collect information regarding the ethical and legal aspects of the practice of

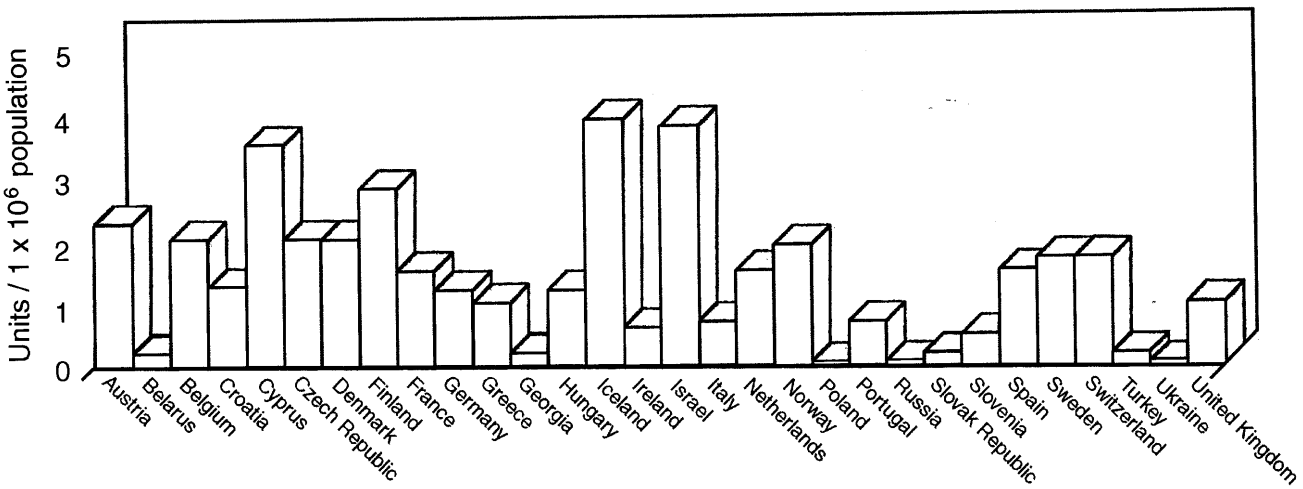

Figure 1. Number of units practising assisted reproduction per 1 000 000 population in European countries.

ART in each country. The survey included information regarding regulation of ART services, access to these services, attitudes towards donation of genetic material, cryopreservation of pre-embryos, surrogacy, micromanipulation, research on pre-embryos and multiple fetal pregnancy reduction. Each of these issues was further divided into sections and the respondents were asked to answer a number of questions, most of which required a yes/no answer (Table II).

Results

Out of 39 countries in Europe, only the following nine do not offer ART services: Albania, Bosnia, Estonia, Latvia, Lithuania, Luxembourg, Macedonia, Malta and Yugoslavia.

The estimated population of Europe is ~600 million, i.e. <15% of the world's total population. Nevertheless, there are 516 ART centres in Europe, which represent ~60% of the world's ART programmes. The number of units per head of population varies in the different countries, e.g. 2–3 units per million in the Scandinavian countries, 1–1.5 units per million in Western European countries, compared to 1 unit per 10–30 millions in the former USSR (Figure 1).

The explanation for this difference in the availability of ART services between the European countries can be sought in the differences in the standard of living between the population of the different countries, especially between Western European countries and Eastern European countries and between north and south, as expressed by gross domestic product per capitum (GDP).

Regulation of the practice of ART

There is an ongoing debate in society, especially among members of the medical profession, as to the necessity for jurisdiction, regulations and public control of the practice of ART. At present, the majority of centres in Europe do not have established legislation pertaining to the various aspects of the practice of ART. It is assumed that this is because the law tends to lag behind social changes and scientific achievements.

Regulations through the process of law arise from two sources: statutes and judge-made law. Statutes are decided upon by legislatures, while judge-made laws develop either where the courts are called to interpret and apply written law, or where such law does not exist, by analogy or otherwise.

The issue of ART has received attention in the parliamentary assembly of the Council of Europe, although insufficient agreement has been achieved in the Committee of Ministers for a legal instrument to be drafted (Council of Europe, 1990).

Table I. Countries in Europe where assisted reproduction techniques are practised

Austria	Greece	Portugal
Belarus	Georgia	Russia
Belgium	Hungary	Slovak Republic
Croatia	Iceland	Slovenia
Cyprus	Ireland	Spain
Czech Republic	Israel	Sweden
Denmark	Italy	Switzerland
Finland	Netherlands	Turkey
France	Norway	Ukraine
Germany	Poland	United Kingdom

Table II. An example of questions regarding surrogacy (part I) used in the questionnaire

Surrogacy	Possible answer	
1. Practised	yes	no
2. Government regulations	yes	no
3. National Helsinki Committee	yes	no
4. Local Helsinki Committee	yes	no
5. Commercial	yes	no
6. Full surrogacy (IVF programme)	yes	no
7. Partial surrogacy	yes	no
8. Surrogate mother: anonymous	yes	no
9. Any limitations on surrogacy	yes	no
10. Legal status of the offspring	_____	
11. Cost	_____	

Table III. Legislation on assisted reproduction practice in Europe

Nation	Legislation
Austria	The Austrian Act on Procreative medicine (No. 275, 1.7.92)
Denmark	Danish Law on Medical Research (No. 503, 24.6.92)
France	The French bioethic Law (29.7.94)
Germany	An Embryo Protection Act (199
Israel	In Vitro Fertilization Health Law (1987);
	Surrogacy Law (17.3.96)
Norway	Norwegian Law on Artificial Reproduction (12.6.87)
	Norwegian Law on Medical Use of Biotechnology (5.8.94; 7.6.95)
Spain	Spanish Law of Assisted Reproduction (No. 35, 1988)
Sweden	In Vitro Fertilization Act, 1988
Switzerland (according to Cantons):	
Aargau	Law of Health Art. 50, 1987
Basel	Law of Human Reproductive of Medicine, 1990
Geneva	Regulations concerning the Conditions governing the Practice of IVF and ET in
	Private Medical Establishments, 1986
Glarus	Resolution concerning Art. 33 of the Law of health, 1988
Neuchatel	Directives concerning the Artificial Insemination by Donor and IVF, 1986
St. Gallen	Decree concerning Interventions in Human Reproduction, 1988
Ticino	Law on Health Art. 13, 1989
Vaud	Law on Public Health Art. 72, and Art. 13/4, 1986
	Amendment to Federal Constitution inserting Section 24 novies, 1992

Sperm donation and ART

Artificial insemination with donor semen (AID) is indicated in cases of male infertility or when the husband is a carrier of serious inherited diseases or abnormality (Schenker, 1995b). AID is used extensively throughout the world, and today thousands of infertile couples have children who were conceived through an AID programme.

Recent advances in the treatment of male infertility by ART (fine-needle aspiration of testicular and epididymal spermatozoa for oocyte intracytoplasmic injection) will reduce in the future the requirement for the practice of AID (Lewin *et al.*, 1996).

The practice of AID is opposed by many religions and is not morally acceptable to all infertile couples or their physicians. Many countries in Europe in which AID is practised do not have specific legislation on this matter. In countries where ART is available to single women (Table IV), AID is allowed.

At present, legislation regarding ART exists in only 10 countries in Europe (Table III). In Switzerland there is no federal law, but each canton has different legislation according to the cultural division of the Swiss population and their attitude to ART (Stepan, 1990). In some countries, ART is practised according to regulations which have been laid down by professional bodies appointed by governments (Ministry of Health/Social Security) or by Medical Associations. In other countries, spread over the continent, ART centres impose their own ethical standards, often through ethical committees that act on a case-by-case basis, and some groups practise according to their own standards (Schenker and Frenkel, 1987). Legislation pertaining to ART practice is usually based on debates by professional and ethical committees. In most countries where legislation has been introduced, practice of ART is usually much less liberal compared to those countries where legislation does not exist (e.g. Nordic countries; Hazekamp, 1996). This has led to circumstances where children have been conceived and born with the approval of ethical committees, but subsequent legislation has banned or placed a moratorium on any further treatment using the same methods (e.g. France; Lansac, 1996). This could create problems for children and immense frustration for parents and ART practitioners.

Marital status

One of the basic human rights is that of a woman to decide when and how to conceive. Under the European Convention, a single woman or even a lesbian couple is entitled to have children, even though these children may have no legal father (European Convention, 1978).

Most professional bodies and legislation in the various countries of Europe have recommended that ART should be restricted to heterosexual couples, legally married, or at least living in a stable relationship. Even in countries that have no national regulations, ART is only applied to married or co-habiting couples (Table IV).

Table IV. Assisted reproduction practice in Europe according to marital status

Only married couples	Co-habitant couples	Single woman
Cyprus	Austria	Belarus
Germany	Belgium	Israel
Hungary	Belarus	Italy
Georgia	Croatia	Netherlands
Ireland	Czech Republic	Russia
Norway	Denmark	Spain
Poland	Finland	Ukraine
Portugal	France	United Kingdom
Slovak Republic	Greece	
Slovenia	Iceland	
Turkey	Israel	
	Italy	
	Netherlands	
	Russia	
	Spain	
	Sweden	
	Switzerland	
	Ukraine	
	United Kingdom	

According to legislation in most European countries, only children born to legally married couples are considered legitimate, while children born out of wedlock are regarded as illegitimate. In these latter instances, the mother alone acts as parent for all purposes. The arguments for restriction of ART to married couples, or even co-habiting couples, is that children raised in a family framework have an advantage over children living with a single parent. According to statistics, co-habiting couples are inclined to get married once the child is born. On the other hand, the structure of our society is rapidly changing; there is an increasing divorce rate and, furthermore, there is also an increasing number of single women who wish to become a mother and establish a single-parent family. These drastic social changes force discussion of the question as to whether ART programmes should be legally denied to single women.

Most of the regulations and recommendations laid down by professional bodies regarding AID do not make any legal or ethical distinctions between the practice of AID with 'natural conception' and that concerned with ART. In some countries it had been suggested that a limit should be set as to how far to go with the use of manipulation to remedy infertility. In some countries where legislation has been enacted, e.g. Sweden and Germany, it has been decided that the combination of AID and ART goes beyond the limits of therapy permissible for infertile couples and that this should be forbidden (Law 711, 1988; Law Germany, 1990).

The main problems associated with the practice of AID and ART are (i) the legal status of the children born; (ii) the rights of donors; (iii) the rights and obligations of the social father; (iv) the physicians' responsibility with regard to selection of the donor, limitation of the use of donor and liability to donor, recipients and any resulting child; (v) the licensing of sperm banks, centres and physicians allowed to perform AID; (vi) the keeping of records.

One of the major problems for donor insemination centres is the recruitment of suitable donors. In most European countries, donors can be either single or married. According to the Israel Health Law, 1987, the donor must be single (on the grounds of religion; Schenker, 1996a), while in Poland and France the donor must be married. The guidelines in France are that the donor should be living in a stable couple relationship, with at least one living child, and consent for the donation must be giving by his spouse.

Sperm donors can be either anonymous or known to the couple. The present survey showed that, in most European countries, anonymity of the donor is preserved and the donor cannot be either a member of the recipients' family or a friend of the recipients (except in Cyprus, Germany, the Netherlands and Finland). Most centres disapprove of donation by family members or friends, since this can cause problems in the family structure of the recipients, e.g. ambiguous emotions between the donor, the child and the legal parents. In other cases where the donor is not a relative or a friend, the donor's anonymity is crucial in order to protect family privacy; in most cases, anonymity is also in the donor's interest. A donor may feel that he may be considered legally liable for the child's welfare, or that there may be claims to inheritance rights (Schenker, 1995b).

There are many reasons why the donor's anonymity is not in the child's interest. First, each individual has the right to know his or her origin, and, second, there are certain medical conditions for which it is vital to have important medical or genetic information concerning the parents of a patient. Such information is missing for a child conceived with donor's spermatozoa when the donor is anonymous. This obstacle has been overcome in many cases by record keeping and informing the child that he was born following sperm donation.

Although Swedish law does not permit sperm donation in ART, the Swedish Committee for 'Children Conceived by Artificial Insemination' decided that it is the child's right to obtain information about the donor (Law Sweden, 1985). In the UK, the Human Fertilisation and Embryology Authority (HFEA) has recommended that there should be

central record keeping of donors. Nevertheless, providing information about the donor's identity is prohibited. In these cases, no information may be disclosed that links the donor's identity to an individual who was, or may have been, born as a result of treatment with that donor's gametes (HFEA, 1990).

In many countries, record keeping is performed by the physician or the institution practising ART. In these countries, identifying information (full name, address, date of birth etc.) and non-identifying information (physical and ethnic characteristics, medical history, social characteristics etc.) are separately stored. Access to non-identifying information is usually given by the medical team according to the regulations in each country.

Table V. Genetic material donation in assisted reproduction practice in Europe

Sperm donation	Ovum donation[a]	Embryo donation[a]
Austria	Belgium	Belgium
Belarus	Czech Republic	Finland
Denmark	Finland	Greece
Belgium	France	Russia
Croatia	Greece	Spain
Cyprus	Israel	Ukraine
Czech Republic	Italy	United Kingdom
Denmark	Netherlands	
Finland	Russia	
France	Spain	
Greece	Ukraine	
Georgia	United Kingdom	
Hungary		
Israel		
Italy		
The Netherlands		
Norway		
Poland		
Russia		
Slovak Republic		
Slovenia		
Spain		
Ukraine		
United Kingdom		

[a]In some countries gamete or embryo donation is prohibited by legislation.

Age

In order to avoid inheritance of age-related genetic disorders, donors should be young (Benshushan and Schenker, 1993a). Age-related genetic disorders usually represent new mutations that may cause severe diseases if the donor is >40 years. However, donation is limited by age only in some countries in Europe (Belgium, Croatia, Czech Republic, Denmark, Finland, France, Hungary, Israel, the Netherlands, Poland, Ukraine, UK), and the age limit ranges from 30 years in Israel up to 55 years in France.

Payment

Statements from most international ethical committees have stressed that semen donors should not be reimbursed for their donation. However, the severe shortage of sperm donors has generated an increasing interest in the need for their motivation. The present survey shows that donors in almost all European countries are initially attracted by the opportunity to earn money.

A solution to this ethical and practical dilemma was provided by the decision to reimburse the donor only for his time, travel expenses, absence from work etc. The payment differs from country to country and is approximately $30–100 per donation. For example, in the UK, the HFEA allows donors to be paid a maximum of $40 for the donation plus payment for reasonable expenses, while French legislation states that a donation is gratuitous and the donor is only refunded for expenses (Lansac and Le Lenaou, 1994).

The status of children born following AID

The status of children resulting from AID has been under discussion for some years. In many countries legislation concerning the practice of AID does not exist (yet), and the legitimacy of the child is determined by the courts in cases brought before them. The usual recommendation on this matter, including that of the Council of Europe, is that a child conceived by AID with the consent of the mother's husband should be treated under the law for all purposes as the legitimate child of the husband. In most European countries where AID is practised, the identity of the donor is unknown to both the prospective parents and to their children and, even if they are informed about the circumstances of their conception, these children are not entitled to know the identity of their father. The exception is in Sweden, in the case of 'natural' conception (AID in ART is forbidden in Sweden). Furthermore, the Council of Europe recommends that all precautions should be taken to keep secret the identity of all the parties involved, and the identity of the donor must never be revealed even in court. The present trend is that the child should be informed by his parents of his conception by AID, following the principle that an adopted child should be placed in position of this fact.

Table VI. Type of manipulation of gametes and pre-embryos permitted ineach country

Research	Micromanipulation	Pre-implantation diagnosis
Belgium	Austria	Finland
Czech Republic	Belgium	Israel
Denmark	Denmark	The Netherlands
Finland	Finland	Spain
Greece	Germany	United Kingdom
	Greece	
	Italy	
	Israel	
	The Netherlands	
	Poland	
	Russia	
	Spain	
	Switzerland	
	United Kingdom	

The donor has no rights, obligations or interest with regard to the child born as result of AID, and the child has no rights of ligation or interest toward the donor in any current system.

The legislation and regulations of AID practice in most European countries require the consent of the donor, the recipient and the recipient's husband. In cases of sperm donation, the need for formal consent by the husband or co-habitant of the recipient is more prominent. The consenting husband is listed on the birth certificate as the father and has the rights and duties for rearing the child, so that the offspring becomes his legitimate child.

It is strongly advised that a medical and family history is obtained from the donor, and that a physical examination is performed, to evaluate the quality of semen and to screen for sexually transmitted diseases. In some ethnic groups it may be necessary to apply genetic screening tests. In countries where legislation exists (Table III), the screening of donors is mandatory. In addition, there are many countries in Europe where screening is performed according to institutional standards.

It seems logical that the extent to which the genetic material from a single donor is used should be limited. The reason for restricting the number of children born of the same donor semen is to lessen the danger of incest and to prevent the transmission of inherited diseases. The policy regarding the issue of limiting the number of children born to each donor should be determined after considering the size of racial and/or ethnic groups, mobility of the donor, and the number of couples participating in the ART programmes in each centre. In certain countries the number of donations each donor may make is stated in the jurisdiction and authorization for each centre, e.g. 10 pregnancies/donor in the UK and seven pregnancies/donor in Israel (HFEA, 1990; Mor-Yossef and Schenker, 1995).

Oocyte donation

Patients requiring oocyte donation fall into two major categories (Schenker, 1991): (i) women with ovarian failure and (ii) women with loss of gonadal function.

It seems that, where AID is already accepted, oocyte donation should not constitute any ethical problem, since with the latter method there are fewer controversial issues than with AID. Oocyte donation has an advantage over AID in that both the infertile woman and the husband or partner contribute to the birth of the child. Furthermore, from the point of law, oocyte donation can be dealt with in the same manner as AID. The child born is considered the child of the mother who gave birth. In all countries in Europe the oocyte donor has no rights or obligations with respect to the child. At present, oocyte donation is practised in only 12 countries in Europe (Table V), and is forbidden by legislation in Austria, Germany, Norway, Sweden and in all the cantons of Switzerland. Oocyte donation is not permitted in several European countries by governmental regulations, e.g. Croatia, Slovenia and Poland.

Most of the oocytes available for donation are obtained from women who are themselves undergoing in-vitro fertilization (IVF) procedures. However, with the improvement in pre-embryo cryopreservation techniques, most women participating in IVF programmes are not willing to donate their 'spare' oocytes (Benshushan and Schenker, 1993b).

Table VII. Permitted duration of storage of cryopreserved pre-embryos[a]

1 year	2 years	3 years	5 years	10 years
Austria	Belarus	Norway	Belgium	Finland
Denmark	Netherlands	Sweden	Croatia	Israel
	Russia		France	Spain
	Switzerland		Iceland	
	Ukraine		United Kingdom	

[a]There is no time limitation in countries that are not mentioned in the table.

An ovum can be retrieved from other sources, such as from women undergoing an elective gynaecological procedure (i.e. sterilization in the UK). In some countries the donors are volunteers, family members or friends (e.g. Belgium, Finland, the Netherlands), but this practice is very limited.

The possibility of medical risks to the volunteer donors should be taken into special consideration. These risks could be associated with induction of ovulation, the use of anaesthesia, or the surgical procedure of oocyte retrieval (Schenker and Ezra, 1994).

Confronted with the growing demand for donated oocytes and the diminished number of donors, clinicians all over the world have suggested the use of ovarian tissues from live donors, cadavers, or from aborted fetuses as potential sources of female gametes for donation. None of these sources has been used yet (Shushan and Schenker, 1994). The HFEA in the UK approves of the use of ovarian tissue only from live donors. It does not in principle object to the use of tissue from cadavers of adult women, but this has not yet been approved. The potential use of oocytes from aborted fetuses raises some fundamental ethical and social questions and is therefore not acceptable in the treatment of infertility.

Table VIII. Countries in which selective fetal reduction of multiple pregnancy is practised in Europe

Austria	Netherlands
Belarus	Norway
Belgium	Russia
Czech Republic	Slovenia
Denmark	Spain
Finland	Sweden
France	Turkey
Germany	Ukraine
Greece	United Kingdom
Israel	

Selection of donors is of critical importance to the prospective parents and the resulting child. The following guidelines are acceptable in most European countries where oocyte donation is practised: The donors should be (i) in the age range 18–35 years, preferably with proven fertility; (ii) healthy, as determined by medical examination; (iii) screened for hereditary disorders and sexually transmitted diseases. The screening procedure differs from country to country.

Oocyte donation to menopausal women is practised in several centres world-wide, especially in Italy. The oldest woman to deliver was 60 years old. Recent surveys that have assessed community attitudes towards ovum donation to post-menopausal women have revealed that there is only minimal support for this practice. The FIGO Committee for the Study of Ethical Aspects of Human Reproduction has limited ovum donation to women of reproductive age (Schenker, 1996b). At present, only France has a bioethic law (1993) prohibiting the gift of oocytes to women after menopause (Cohen, 1995). The HFEA in the UK states that it is neither necessary nor advisable to fix an upper age limit for the treatment of infertility. Each case should be considered individually, bearing in mind the welfare of the child and all the implications for the couple concerned. In most European centres, at present the practice of oocyte donation is limited women not older than 40–45-years of age.

Most international ethics committees state that gamete donors should not be reimbursed for the donation. Since in most European centres oocytes are obtained for donation from women undergoing an IVF procedure, payment for the donation is not required. According to the legislation in Denmark, France, Israel, Spain and the UK, no money or other benefits should be given for donation. Some centres in the UK and two private centres in Israel offer benefits to women donating oocytes in the form of treatment services, including free sterilization in the UK and free IVF treatment in Israel. In certain countries in Europe, some benefits to donors are unofficially offered.

Embryo donation

The issue of embryo donation is more complicated than that of sperm or oocyte donation since there is no direct link between the embryo and the future rearing parents, even though there will be a gestational link (Schenker, 1995a). In embryo donation the relationship is analogous to that of adoption, and the only difference is the time at which adoption occurs. Embryo donation is practised in only eight countries in Europe (Table V). In most countries it is prohibited by legislation or by governmental or professional bodies.

The arguments against embryo donation are connected with its affect upon the child and society. The arguments in favour of the practice are that it is preferable to adoption, since the rearing mother contributes the uterus and the rearing father commits himself to the child even before implantation. In all European countries where embryo donation is practised, informed consent is obtained both from the gamete donors and from the recipient parents. The donors are not informed of the outcome of their donation, and they will not have any knowledge or control over the child who is their genetic offspring. The recipients are informed of all the risks and uncertainties of the procedure.

The circumstances of his birth are not disclosed to the child. The child may accidentally discover data regarding his/her conception. According to the legislation in the UK, the child may obtain these facts when reaching the age of 18 years.

Surrogate pregnancy

A surrogate mother is defined as a woman who carries a fetus and bears a child on behalf of another person or persons, having agreed to surrender the child to this or those persons at birth or shortly thereafter. There are three forms of surrogacy: partial-natural, partial and complete. Surrogate motherhood may be utilized in cases of uterine infertility or in cases of severe maternal disease during pregnancy (Schenker, 1992).

Surrogacy poses a great controversy in society and in the medical profession. The objections to surrogacy are based on the following: surrogacy takes advantage of the surrogate woman, who is frequently of low socio-economic class, from developing countries, or a family member put under stress; surrogacy absolves the woman of responsibility; surrogacy impairs the woman's honour; surrogacy has a commercial aspect; there are medical, physical and mental dangers to the surrogate mother (Mordel *et al.*, 1993).

The advocates of surrogacy base their case on the following statements: it is the right of humans to do what ever they please, as long as they do not harm other humans; child-bearing is the right of every person in society; surrogacy will make people happier; since surrogacy exists and will do so despite legal negations, it should not be prevented.

Currently, the legal practice of surrogacy in Europe is limited. It is practised according to legislation only in two countries in Europe, i.e. the UK and Israel. In all other European countries the practice of surrogacy has been prohibited by legislation, governmental regulations or the statements of ethical committees. In the UK, surrogacy may be practised on a non-commercial basis, and only to benefit women for whom a surrogacy agreement represents the only chance to have a child. In Israel, legislation is currently (1996) being enacted. By legislation, surrogacy in Israel is limited to complete surrogacy, and payment to the surrogate mother is forbidden. Legislation gives the right to the surrogate mother to appeal to the District Court during the first 7 days after delivery to be allowed to break the contract and keep the child. When the surrogate does not object to handing over the child, the responsibility for the child born is that of the commissioning couple (Israeli Law, 1995).

Pre-embryo research

Recent advances in the field of reproduction have made it possible to obtain pre-embryos and to use them for research. Pre-embryo research is desirable at present for the following purposes (Schenker, 1993): (i) to promote advances in the treatment of infertility, (ii) to increase knowledge about the cause of congenital diseases, (iii) to increase knowledge about the cause of miscarriages, (iv) to develop more effective techniques of contraception, (v) to develop methods for detecting the presence of gene or chromosome abnormalities at the stage of pre-implantation. The potential benefits of pre-embryo research may be outweighed by the risk involved. Nevertheless, most societies share fears concerning the threatening social results of free, unrestricted research on potential human beings.

The following research should be prohibited: (i) keeping or using an embryo after the appearance of the primitive streak, i.e. 14 days after fertilization; (ii) placing a human embryo in an animal; (iii) altering the genetic structure of an embryo; (iv) replacing the nucleus of a cell of an embryo with the nucleus of a cell taken from another person or another embryo, and the subsequent development of such an embryo.

There are several potential sources for obtaining pre-embryos for research: (i) spare embryos obtained from IVF treatment; (ii) defective pre-embryos from IVF treatment; however, this source is not suitable for some areas of research where normal pre-embryos are required; (iii) aborted pre-embryos or embryos obtained by flushing methods; (iv) pre-embryos created for the sole purpose of research.

The legal status of the pre-embryo is difficult to establish. If it is regarded as a person, or even a potential person, then it has no legal status according to the law of most countries. If the pre-embryo is to be regarded as property, ethical principles would be offended. Questions concerning the right to use, dispose of, sell and purchase the embryo would then arise. The pre-embryo is not considered a human being for the purpose of criminal law. Deliberate destruction of a pre-embryo is not considered a criminal abortion act.

Pre-embryo research is performed in eight European countries (Table VI). In Denmark, Spain, Sweden and the UK it is allowed by legislation; in Austria, France, Israel, Germany, Norway and Switzerland it is prohibited. In Belgium, the Czech Republic, Finland, Greece and Russia embryo research is performed to a limited degree. In the UK, the pre-embryo used for research must be a spare

pre-embryo. It is viewed as morally wrong to intentionally create a pre-embryo for research, and any pre-embryo used for research should not be transferred to a woman for further development. However, pre-embryos may be created for research purposes provided this research aims at developing either techniques or diagnosis related to infertility, contraception or genetic anomalies. Such research must be approved by monitoring bodies established for this purpose.

Sweden allows pre-embryo research. Spain restricts pre-embryo research to non-viable spare embryos, that is, pre-embryos that do not have the potential to become live offspring. Maintaining pre-embryos beyond 14 days postfertilization is considered an offence.

According to The German Parliament Protection Act 1991 embryo research is prohibited on the following grounds: (i) fertilization other than for the purpose of pregnancy is prohibited; (ii) the fertilization of a human egg for any purpose other than to start a pregnancy in the woman who produced the egg is prohibited; (iii) to allow spermatozoa to penetrate an egg other than for the purpose of producing a pregnancy is prohibited.

The French Bioethic Law of 1994 states that any experimentation on the human embryo is forbidden.

In the Scandinavian countries legislation on embryo research varies from it being totally forbidden in Norway to being permitted under strict conditions in Denmark and Sweden. The Danish law states that fertilized eggs may only be kept *in vitro* for up to 14 days, excluding any period of cryopreservation. Fertilized human eggs that have been subject to research may not be returned to the uterus, unless this can be done without the risk of transmitting heritable diseases, defects, abnormalities or similar deformities. The last statement allows preimplantation diagnosis of genetic diseases. The act prohibits cloning and the production of individuals by fusion of genetically different embryos or parts of embryos prior to implantation; it also prohibits cross-species fertilization in order to prevent production of human–animal hybrids.

The Swedish law permits research only on non-viable embryos from a therapeutic programme, but has no monitoring body to approve or reject research proposals. No research is allowed beyond 14 days of development.

The ethical committee for Belgium, founded for medical research, allows embryo research to be undertaken, but it is practised only in two centres.

It should be mentioned that in most countries where there is no legislation the ethical committees prohibit research on embryos, e.g. The Netherlands, Italy and the Eastern European countries.

Cryopreservation

Human embryo cryopreservation is a fully established adjunct to ART. While many embryos may be produced during a single IVF cycle, the common code of practice allows physicians to transfer to the uterus only three embryos in any cycle in order to reduce the likelihood of multiple pregnancy. Therefore, the extra embryos are cryopreserved for transfer in a future cycle. Embryos may also be frozen when the woman's health may be at risk if any embryos are immediately replaced. Cryopreservation of embryos may have a function in enhancing implantation, pregnancy and birth rates.

The ethical, legal and religious aspects associated with cryopreservation of embryos were discussed by professionals and by the public prior to implementation of this procedure. In some countries, the procedure was heavily criticized by the public and was stopped until a law or regulation was passed, e.g. Norway and Germany. Those arguing against cryopreservation of human embryos felt that the practice would threaten the dignity of humans. In all European countries the couple must give their consent to the storage and use of the embryos, whether for their own treatment or for treatment of others or for research. Frozen embryos may be donated to another couple or for research in only eight countries in Europe (Table VII). If a couple decides to donate embryos to another infertile couple, storage authorities should also ensure that there is a sufficient time for the donating couple to be appropriately counselled and screened. The cryopreservation of embryos raises some judicial aspects. Judicial protection of cryopreserved embryos may be difficult to achieve, except through legislation. Legislation regarding storage of embryos in some European countries, and regulations in others, gives the gamete donors the right to decide the embryo's fate. According to the wish of the gamete's donors it can be disposed of, or donated to other couples, or given for research. However, in Austria, Ireland, Israel, Norway and Switzerland the embryo cannot be donated to another couple or given for research.

The legal status of the cryopreserved embryo is difficult to establish if it is considered to be a person, or even a potential person; it has no legal status according to the law in most countries. There is a suggestion that the pre-embryo is property. However, this definition is not consistent with ethical principles.

The above suggestions thus leave open the legal question of the right to use, dispose of, sell or purchase pre-embryos.

The maximum storage period in European countries for cryopreserved embryos is determined by legislation or

regulations covering ART practice in each country (Table VI). Thus, a maximum 10-year storage period is set in Finland, Israel and Spain. On the other hand, in Austria and Denmark the period is 1 year. The majority of European countries practice cryopreservation with no limitation on the storage period.

Several ethical committees have recommended that embryos should not be stored for >10 years due to the legal and ethical complications that may arise if the couples whose gametes had been used died, separated or divorced, and because there is little knowledge about the possible effects of long-term storage. As legislation currently stands, if cryopreserved embryos have not been used for any purpose for which consent has been given by the end of the maximum storage period, they should be allowed to perish. A pre-embryo seems not to be a human being for the purpose of criminal law. Deliberate destruction of a pre-embryo is not a criminal 'abortion act'. There is a general consensus that the preimplantation pre-embryo is not a person. Nevertheless, it should have its own legal rights and should be treated with respect.

Physicians practising ART in the different European countries are concerned at the prospect of letting a large number of embryos perish when they cannot be used for treatment. The question of extending the maximum storage period has been raised. The UK HFEA has recently concluded that the storage period for medical or social reasons can be extended up to 10 years. An option to allow extension beyond 10 years in exceptional cases would place women who may wish to store embryos in the same position as men, who can store spermatozoa until they are 55 years old.

The time is approaching when society will need to determine who (if any one) should receive relinquished embryos. Embryo donation or usage of the cryopreserved embryo is medically and ethically justified. Research programmes should be encouraged, instead of permitting the destruction of cryopreserved embryos.

The regulations in most European countries state that only couples who still desire to have a child together can receive the thawed pre-embryos. If the couple disagrees, if they divorce or if one of the couple has died, the pre-embryo must be destroyed. The UK HFEA states that if embryos produced using the eggs of a woman who has since died are used in treatment, the woman who provided the egg is not to be recognized by the law as the mother of the child. The Israeli Health Law of 1987 states: (i) donation of stored pre-embryos is forbidden; (ii) in the case of the death of the husband, the embryo can be transferred to the wife for only 1 year after his death, following the special recommendation of a social worker; (iii) in the case of divorce, the pre-embryo can be transferred to the ex-wife only after consent is given by her ex-husband; (iv) if the wife dies, the pre-embryo cannot be transferred to another woman. At present, the Supreme Court for Appeals of the State of Israel is discussing an appeal concerning whether a husband can prevent transfer of a cryopreserved embryo to his wife.

Note added at proof

The Supreme Court decision in this specific case allowed the woman to use the stored pre-embryos.

Fetal reduction

The frequency of multiple gestation has increased as a result of the relatively wide-spread use of induction of ovulation and ART. The overall multiple pregnancy rate for ART is 22–28%, most of which are twins (20%), triplets (4%) and, occasionally, higher-order gestations. The multiple pregnancy rate increases to 35% when five or more pre-embryos are transferred. The medical and social problems associated with multiple pregnancies have been recorded. There is an increased frequency of maternal complications together with higher perinatal morbidity and mortality (Benshushan *et al.*, 1993). It is now common for women who are carrying a pregnancy of high order, even of triplets, to have the number of fetuses reduced to two or three by selective abortion of the excess fetuses (Table VIII). In order to prevent the need for selective termination, the number of embryos transferred into the uterus should be limited to three or even two. Some countries have already regulations that limit the number of embryos transferred into the uterus (e.g. the UK).

The ethical and legal status of multiple-fetus pregnancy reduction depends largely on views of morality, religion and legal status of abortion. In countries where abortion is legal for any reason, there should be no legal barrier to selective reduction. In countries where pre-viable abortions are illegal, except to save the life or health of the mother, selective reduction might be permitted. Religious attitudes concerning abortion play a paramount role in counselling couples on the selective reduction of multiple pregnancies. The attitude of the Catholic Church towards therapeutic abortion is that any direct attack on the fetus is considered to be murder. Therefore, from this standpoint there seems to be no medical condition that merits multiple fetal reduction. The Protestant view is that abortion must be regarded as destruction of a living being and is only acceptable in some medical conditions to save the mother's life. Therefore, it seems that in some cases selective reduction of fetuses may be permissible. The Jewish law

permits the reduction of high multiple pregnancies as a protective measure in view of the increased risk to the mother and the fetuses, with the stipulation to leave the optimal number of fetuses.

National registry

ART is increasingly available to infertile couples in Europe. As a result, questions have been raised concerning the effectiveness, safety and cause of ART procedures, as well as the many ethical and legal aspects of their use. Collection of national data on the outcome of ART can assist the infertile couple seeking treatment, the public health authorities and the medical professions. There are national registers in 16 countries in Europe. Nevertheless, they are required by law in only France, Israel, Spain and the UK In other countries the registers are organized by medical societies on a voluntary basis.

A recent publication by the UK HFEA, 'Patients' Guide to Donor Insemination and IVF Clinics', raised a serious debate concerning the national collection of data from each IVF unit and especially the publication of the data by the central governmental authority (Deech, 1996; Jones, 1996).

Conclusions

The development of new methods of ART, including micromanipulation, preimplantation diagnosis and genetic manipulation, continues to provide major breakthroughs in the treatment of infertile couples. Since we are dealing with a field that is continuously developing, control of the various aspects of the medical or laboratory details of ART practice by parliamentary legislation is less desirable. In spite of the cooperation of the European countries at political, economical and other levels, there are still prominent differences in legislation on ART practice. It is quite evident that a European consensus on legislation cannot be achieved, since the whole area of infertility treatment by ART touches fundamental issues of life, family and society structures that are influenced by religion and tradition, which differ vastly among the ethnic groups that constitute the population of modern Europe. In view of these complicated and sensitive issues involved in the practice of ART, the Federation of European Societies of Obstetrics and Gynecology should establish a working group to set up medical and laboratory guidelines for the application of the practice of ART. This working group could approach politicians of the European countries in order to attempt to reach a European consensus on the legislation for certain issues involved in the practice of ART. This approach may lead to the highest standard of medical practice and protection of all parties involved in ART, especially the infertile couple.

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