

# Opinion on sampling of dead human embryonic and foetal tissue for therapeutic, diagnostic, and scientific purposes. Report.

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## Contents

### Opinion

I. The embryo or foetus must be recognised as a potential human person who is or was alive and who must be respected by all concerned

II. Objections based on ethical considerations as regards the legitimacy of dead embryo or foetus tissue sampling are principally connected to their source when death is due to elective abortion

III. Only an embryo or foetus below the viability threshold, the decease of which has been previously established, shall be used for the above mentioned purposes

IV. Embryonic or foetal tissue sampling for therapeutic or scientific purposes may be prohibited by the mother or father who are entitled to oppose the action.

Conclusion

### Report

Preliminary remarks

Definitions

Objectives for the use of human embryo organs and tissue  
human embryo "expulsion" circumstances

Ethical and legal problems

Connection with elective abortion

Definition of embryos which may be used for therapeutic or research purposes

Is new legislation appropriate ?

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## Opinion

Considering :

the therapeutic, diagnostic, and scientific utility of embryonic or foetal material sampling in the present state of progress of research and therapy,

the potential human person status of the embryo or foetus (1) from the moment of conception onwards,

plurality of expressed ethical opinions and conflicting values raised by embryonic or foetal tissue sampling,

legal aspects of the problem,

The National Consultative Ethics Committee for Health and Life Sciences recommends that the following directives be observed as regards :

consequences resulting from the use of human tissue,

ethical and medical consequences of embryonic or foetal sampling, with due regard to their source (elective abortion)

the definition of allowable embryonic and foetal sampling

consent to be requested

## **I - The embryo or foetus must be recognised as a *potential human person who is or was alive and who must be respected by all concerned.***

As a result:

a) A living embryo or foetus can never be the object of in utero experimentation. Only therapeutic action aiming to enhance the development and birth of the child is acceptable. Life in an embryo or foetus must not be maintained artificially so that therapeutic research or sampling can take place.

b) Commercial or industrial uses of the human embryo or foetus is forbidden. Tissue samples taken from a dead embryo or foetus in legitimate circumstances cannot give rise to remuneration.

c) The only legitimate uses and samples are those which are made for therapeutic, diagnostic, or scientific purposes according to conditions set out in II, III, and IV below.

## **II - Objections based on ethical considerations as regards the legitimacy of dead embryo or foetus tissue sampling are principally connected to their source *when death is due to elective abortion.***

Persons who, for whatever reason, are called upon to carry out or cooperate in such sampling may plead conscientious objection as a reason for declining to participate in such action.

Those who do not plead conscientious objection must observe the following directives:

### a) ETHICAL DIRECTIVES

Use of the embryo or foetus for *purposes of diagnosis* (discovery of the cause of spontaneous abortion, confirmation of in utero diagnosis) is legitimate.

Use of embryonic or foetal tissue *for therapeutic purposes* must be exceptional and, in the present state of scientific knowledge, justified by the rarity of the disease to be treated, absence of any other equally effective therapy, and a clear benefit, such as survival, to be derived by the recipient of treatment,

Use of embryonic or foetal tissue *for research* must be of special importance or usefulness to further progress of therapy,

Use of an embryo or foetus with therapeutic or research objectives must be submitted to the appreciation of an Ethics Committee who will evaluate either the exceptional nature of therapy, or the usefulness of research envisaged, and will be entitled to make sure at all times that directives set out by the present Opinion are observed.

### b) MEDICAL DEONTOLOGY DIRECTIVES

Decision to undertake, and circumstances (i.e. timing and technique, etc...) of elective abortion must not in any way be influenced by possible or desired later use of the embryo or foetus. The termination technique must be selected on purely obstetrical criteria whilst taking care to preserve the mother's obstetrical future.

Total independence must be established and guaranteed, under the supervision of the Ethics Committee, between the medical team who perform elective abortion and those who could subsequently be using the embryo or foetus.

**III - Only an embryo or foetus below the viability threshold, the decease of which has been previously established, shall be used for the above mentioned purposes :**

- tissue sampling can only be performed on an embryo or foetus for which non-viability is a certitude, i.e. before the 22nd week of gestation (20th week after the probable date of conception);

- arrest of blood circulation is the recognised criterion for death. Sampling can only take place once death is declared and confirmed.

**IV - Embryonic or foetal tissue sampling for therapeutic or scientific purposes *may be prohibited by the mother or father who are entitled to oppose the action.***

**Conclusion**

It is essential that authorities confine therapeutic or scientific use of a human embryo or foetus as well as embryonic or foetal tissue sampling to authorised establishments. They must have demonstrable competence and an Ethics Committee whose composition and mode of operation should be defined by regulation.

The authorisation of such establishments should be submitted for approval to the National Consultative Ethics Committee for Health and Life Sciences.

## Report (April 1984)

### Preliminary remarks :

1 - From an ethical point of view, the use of human embryos raises problems which are common to various concrete situations (dead embryos, in vitro fertilisation, prenatal diagnosis...) and may have aims which are just as diverse (scientific, therapeutic, commercial and industrial).

It appears essential that opinions concerning these diverse situations should be coherent since they are all connected. This coherence should be based on the unequivocal recognition of the human character of the embryo.

It should be recognised that although the embryo may be dead, it is not an ordinary laboratory product. It is, or was, *a potential human person*.

This human quality puts an obligation on researchers and therapists to respect the embryo. Only the manner in which this respect is expressed may vary according to the aims

pursued.

This human quality leads to forceful condemnation of any commercial or industrial use of human embryos, in whatever circumstances.

2 - The use of human embryos for therapeutic or scientific purposes gives rise to serious and divisive ethical disputes. On the one hand, there is an opinion that any kind of use should be condemned. For others, on the contrary, the embryo once dead is no more than biological material which may be handled without any regard for ethical considerations. Yet other opinions incline to believe that a middle course is preferable and strive to preserve the respect owed to the embryo by defining legitimate use.

In view of the conflicting nature of ongoing public debate, all data must be carefully examined and an Opinion drafted which reflects all the opposing dimensions and plurality of ethical opinions on this subject in France.

As a result, an analysis and an evaluation of conflicting interests involved must be made so as to arrive at a compromise based on a ranking of such interests in view of the aims pursued.

If one is to take into account serious reservations on the part of some sections of public opinion, then no free rein can be given to scientific and therapeutic uses for which legitimacy must depend on the higher objectives pursued. It seems mandatory that strict rules apply to one and all.

To incorporate ethical plurality and its respect may lead, furthermore, to legitimise for certain sectors of opinion the conscientious objection clause for all those who, in whatever function and for whatever finality, would be called upon to manipulate human embryos.

3 - In legal terms, the problem of the embryo's personality is a difficult one. Therefore, the applicability of the law of 22nd December 1976 on organ procuring for transplants is doubtful.

The human embryo is, in principle, a human person endowed with a legal personality from the moment of conception on the condition that it is born live and viable and that the effects of this personality are in its favour. This principle is of little help when rules are made to govern the use of a dead embryo which can hardly be defined as a cadaver, particularly if death has occurred before the embryo reached the viability threshold.

For technical reasons, the law dated 22nd December 1976 cannot be applied indiscriminately to situations which are not included in the law and, there is insufficient similitude between the two kinds of situation to justify it.

However, the principles and spirit of the law should be kept in mind : prohibition of any trade, limiting the use of products of the human body to strictly scientific and therapeutic purposes, non exclusion of obtaining consent from those concerned. It does therefore seem necessary to respect these principles but it should be possible to disregard certain technicalities and modalities which are contingent on the concrete cases to which they apply.

On the basis of the foregoing considerations, the subject of this report is the use of dead embryos for therapeutic and scientific purposes. Some terms require defining before examining the ethical and legal problems involved and their consequences.

# Definitions

the expression " **human embryo** " includes all phases of development of the zygote, from fertilisation of the ovum to full maturation when autonomous life becomes possible outside the mother's body, i.e. around the 25th week of gestation (600 grammes). In view of the difficulty of establishing scientifically the moment when embryo becomes foetus, the expression " embryo " will alone be used.

As far as we are now aware, there are two phases in embryonic development separated by implantation of the fertilised ovum in the uterine endometrium :

a) the *progestational stage* , when the fertilised ovum is an unattached organism which possesses a potential for development and viability if it encounters a uterine host. This period lasts 7 days.

b) the *gestational stage* , after implantation. The embryo is now a living organism and develops in a " parasitic" fashion. As soon as it is separated from the uterus, the embryo has no potential for viability.

As far as ethical problems arising out of the use of human embryos are concerned, they are of a different nature in each of the two phases which must therefore be dealt with differently.

Problems connected with the progestational phase will be considered together with those relating to in vitro fertilisation and embryo transfer.

## **Objectives for the use of human embryo organs and tissue**

There are various categories :

*Diagnosis* : biological identification of possible anomalies in an embryo can serve to inform and advise parents on their offspring's future outlook.

*Cognition* : progress of knowledge on the biology of development and human genetics which requires research on human embryonic cells, tissues, and organs.

*Therapy* : as far as we are now aware there are indications, generally exceptional, for transplanting embryonic tissue.

Industrial uses of human embryonic tissue and organs are inadmissible.

## **Human embryo " expulsion" circumstances**

A human embryo may be available as a result of :

- *spontaneous expulsion*

This is generally due to spontaneous abortion which normally occurs in 15% of clinically recognised pregnancies.

The pathological nature of such accidents and the fact that most of them are the result of genetic anomalies (in particular chromosomal abnormalities) should be kept in mind when considering using the tissue.

- *induced expulsion*

In this case, the cause is induced abortion performed in accordance with the law (articles 162-1 to 162-14 of the Code of Public Health) :

Elective abortion before the 12th week of gestation, induced abortion after the 12th week for medical reasons; amongst such medical indications, a large number are genetic anomalies diagnosed through amniocentesis.

Gestation time is calculated as from the date of the last menstrual period which adds another two weeks or so to time calculated from the probable date of conception. The expression " gestation time" is frequently (albeit misguidedly) used, and is generally acceptable to obstetricians whereas the law and jurists refer to the probable date of conception.

## Ethical and legal problems

Medical or scientific utility of using human embryos should be evaluated and appreciated in the light of ethical and legal requirements. The latter should permit a definition of legitimate uses of embryos.

Difficulties arise on the one hand, because of ethical differences of public opinion over the fact that embryos which are used or usable for therapeutic purposes are available following elective abortions, and on the other hand because of legal hesitancy as regards the human person status of the embryo and the applicability of the law dated 22nd December 1976 on organ procuring. Such difficulties can be overcome; to find a solution three essential matters must be considered :

- the connection between elective abortion and the use of embryos,
- the definition of a befitting embryo, taking into account the various phases of its development (life, viability) and the notion of death applied to an embryo,
- the problem of consent.

### - **Connection with elective abortion**

1) *The source of embryos is the main reasons for ethical differences of opinion ;*

- in spite of the fact that induced abortion is now legal, it is still denounced by some sectors of opinion and consequently it is thought that use of the embryo:

in most cases is due to voluntarily induced death in an embryo whose life should have been respected as soon as it was conceived

encourages abortion.

This opinion can be taken into account by a conscience clause, but cannot justify as society stands today and in the light of therapeutic utility, a general and absolute condemnation of all use of embryos.

- The majority (it seems) opinion is that the really important point is to avoid any use of embryos which might constitute :

generally, a *cause* for development of induced abortion which legally is still reprehensible since it is a threat to the concept of respect for life, except in two circumstances based on necessity (distress or therapy),

individually, a moral *justification* of induced abortion through the donation of the embryo,

a *motivation* to adapt abortion techniques to the needs of users.

Such objections seem to be entirely justified and lead to the following consequences.

## 2) *Ethical consequences of the use of embryos*

Various possible uses should be considered separately.

- *Diagnosis* : use for this purpose seems totally justified since the object is to find the cause of spontaneous abortion or confirm results of medical investigation which motivated therapeutic abortion.

- *Therapy* (graft of embryonic tissue) : this is also justified as long as such use is exceptional and supervised by an Ethics Committee.

Exception must be the rule here so as to avoid use turning into pressure for widespread abortion and becoming just another routine procedure.

The exceptional nature of the procedure must be defined as follows :

by the low number of potential patients who might benefit from an embryonic tissue graft and the low number of embryos necessary for each recipient,

by the absence of any other equally effective therapy.

In this way, embryonic tissue graft treatment for immuno-deficient children is justified in the present state of therapeutic knowledge, whereas the use of embryonic pancreatic tissue for experimental treatment of insulin-dependent diabetics should be rejected.

- *Scientific uses* : The human embryo must not be handled like ordinary laboratory material. Research must be confined to a dead embryo on the condition that animal research is an impossibility and that an Ethics Committee considers the research to be sufficiently important.

Teratogenesis or experimentation on the embryo in utero is obviously blameworthy. Any experiment on a live and non viable embryo which does not aim to be of benefit to the unborn child and enhance its development must be rejected.

## 3) *Consequences for medical deontology*

- *obstetrical conditions*

A decision to terminate a pregnancy by mother or physician must not, in any circumstances, be influenced by possible use of embryonic tissue and organs.

In case of termination for medical indications, obstetrical expulsion techniques must be chosen in each case according to purely obstetrical criteria and the mother's obstetrical future must be of primary concern. The needs of embryo " users" must never have any influence on the decision to terminate or the method of termination.

- It is important to establish and guarantee total independence between the medical team who perform elective abortion and those who will or could subsequently be using the embryo.

- Any move on the part of users to influence the method or timing of elective abortion so as to modify normal procedures must be prohibited.

**Definition of embryos which may be used for therapeutic or research purposes**

### **1) Problems raised by viability**

Although a non viable embryo does not enjoy the status of human person fully recognised by law, and is only recognised as being a potential and conditional person if it is born live and viable, a viable embryo becomes independent of its mother's body and can be considered as a person in its own right.

An embryo, albeit a dead embryo, who could previously have become viable, should not qualify for use, except with a view to diagnosis.

It is therefore advisable that use should be limited to embryos whose non-viability is certain. Consequently, the cut off date for elective abortion must be at latest during the 22nd week of gestation (i.e. 20 weeks starting from the probable date of conception).

### **2) Definition of death**

Embryonic tissue or organs can only be removed from dead embryos.

Arrest of blood circulation is the recognised criterion for inevitable imminent death, death at this point being an absolute certainty.

However, in order to overcome objections regarding possible embryo suffering and eliminate the notion (dwelt upon in some cases) of embryo vivisection, it would be reasonable to wait a while (an hour perhaps ?) after death has been established, before taking a sample.

Life must not be maintained artificially so that experiments or sampling can take place.

### **3) Consent to be obtained**

A preliminary question arises : does the law dated 22nd December 1976 on the subject of organ procuring apply here ? It is clear that the law did not foresee the case of sampling a dead or live embryo. Therefore, it is only through analogy and interpretation that the law's scope could be extended to the case in point.

The analogy seems doubtful regarding the specific consequences of consent to be requested. The law of 1976 stipulates that explicit consent of the legal representative (father and mother) is required for sampling to be performed on the cadaver of an under-age child. To consider an embryo, deceased before the 22nd week of gestation, as a child under the age of majority, is neither indisputable nor fitting. On the one hand, the embryo has never lived or for that matter could not have lived autonomously and independently of the mother. On the other hand, if the mother's consent was an obligation, the impression might be given that donation of the embryo is a justification of elective abortion or a price to be paid for being allowed to abort, which should be avoided.

For this reason, it would seem desirable to give the mother a veto instead of systematically demanding her consent.

In practice, a fitting approach would be to judge on a case by case basis whether the mother's consent is to be requested. It should be so in cases of spontaneous or therapeutic abortion. In such cases, requesting the mother's consent before sampling is recommended. In the case of elective non therapeutic abortion, requesting consent is disputable. It is thought by some that since the mother has decided that the embryo is to die, she loses any rights over the embryo's fate. This seems excessive. The right to refuse must be retained since the use of human tissue is the subject under discussion.



A mother could be informed of her right to refusal on her first visit to discuss elective abortion.

In this way, regardless of the reason for which elective abortion is sought, a single rule could be adopted. Moreover, the rule could be flexible and implementation could depend on the specific circumstances of abortion.

If elective abortion were to take place after the 22nd week, consent expressed by both father and mother should be required.

## Is new legislation appropriate ?

- A draft bill is under consideration jointly by the Ministry of Health and the Ministry of Justice. The Committee might wish to take the initiative of discussing whether it is appropriate to legislate on the subject.

- The main point of legislation in this respect is not so much principles and rules which could be set out (the Committee's directives are in fact in agreement with the draft bill except that they are more specific), as the possibility of imposing sanctions which, in the case of penal sanctions, are the prerogative of the law.

- At first sight, there is no evidence of any reprehensible behaviour which needs to be curbed. Enquiries made in Bordeaux and Lyons by judicial authorities did not lead to any prosecution.

However, the existence of penal sanction may be a deterrent to users disinclined to follow the Committee's directives, and reassuring for public opinion.

The joint commission created by the two above Ministries to study the possibility of legislation could well consider a co-ordination of their work with that of the Committee. The directives drafted by the latter could then be incorporated in whatever legislation or rules are enacted if needs be.

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### Notes

1. the words " embryo" and " foetus" *cover all developmental stages* of the zygote from fertilisation of the ovum to full maturation when autonomous life becomes possible; these words are used because of the difficulty in establishing scientifically the moment when embryo becomes foetus. This terminological option is in no way a statement of the Ethics Committee's position on the status of the being in the process of gestation.