Opinion N° 89

On preservation of the bodies of fœtuses and stillborn infants
Reply to a referral from the Prime Minister

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On August 2nd 2005, the Prime Minister referred to CCNE requesting an "appraisal of the rules governing the medical management of bodies of fœtuses and infants deceasing perinatally with due regard for ethical principles and legal and scientific issues."

Compared to the 1970s, fœtuses are viewed in a very different light. The changes are due on the one hand to advances in Assisted Reproductive Technology, but mostly to progress in fœtal imaging with ultrasound and MRI, improved diagnosis of genetic, chromosomal and infectious diseases and also advances in resuscitation of premature infants. The successive phases of fœtal development are increasingly observable. Mainly because of this advances, fœtuses have become beings recognised before birth, who sometimes have a name or receive treatment as an individual "patient". Birth has become an outcome rather than the beginning of an existence.

In the circumstances it is understandable that fœtal pathology, or more generally fœtology, have gradually gained ground although academia and hospital authorities have been slow to grant it the full recognition which this important speciality now deserves.

Progress in recognition of the fœtus has repeatedly mobilised the attention of the law and legislators, at the request of some sectors of opinion, to provide a legal status that would facilitate the handling of this new situation. The law and legislators have always steered clear of the subject and CCNE does not intend to reflect on this status in the present Opinion, even though the Committee has some understanding of society's reservations on contradictions introduced by the concomitance of a "parental project" giving parents full freedom — within the limits of the law — for the start or termination of a conception attempt on the one hand, and the very existence of a future being on the other.
Although in France opinions differ as regards the status that should or should not be given to a fœtus, there is not the slightest doubt in anyone's mind that a child born alive, even for an instant of time, is a person. Before birth, a child is not a person. This radical frontier in the eyes of the law does not certainly justify a binary attitude of absolute respect in one case and relative respect in the other, all the more so because this boundary may lie at different chronological ages. Premature birth is all that is required to suddenly change a fœtus into a newborn. Law has to be formalistic of course, but recognising the human origin of fœtuses imposes respect. Healthcarers must have due regard to this when dealing with the fœtus or the stillborn child's body.

In the last ten years or more, respect has motivated some professional practices to help and counsel families affected by fœtal death in uteri or stillbirth. Researching the causes of death for diagnostic and scientific purposes is essential to understand and possibly prevent a renewal of fœtal pathology in a subsequent pregnancy, but is no justification for systematic preservation of the bodies, particularly when families wish to observe rituals or practices for incineration or inhumation proportional to their grief for the loss of the fœtus or infant.

In this context, the discovery of a large number (over 300) of fœtuses and stillborn infants in the mortuary of a Paris hospital, came as a shock and led to queries as to whether these new demands for respect were matched by current practices.

1 - Background

For a long time, fœtal death in uteri or at the time of birth was, more often than not, left in silence; the mother was not allowed to see the fœtus and there were no funeral rites. This attitude frequently aroused, particularly in the 19th and the early 20th centuries, medical interest and a kind of fascination on the part of the medical profession and of society for "museums" and "collections" of fœtuses with major morphological anomalies. Gradually, beginning in the 1980s, it has become clearer that for parents, and mothers in particular, it is difficult to mourn a child when the fœtus had been made to "vanish" and that this may have serious repercussions on the psyche. Psychiatrists and obstetricians began to assist and counsel parents so that the dead child be granted recognition, affection and visibility before burial or incineration. Members of the clergy or chaplains were also present and attentive to requests for some form of ritual which are sometimes expressed in these circumstances. It is therefore rather difficult to compare the current situation with previous circumstances which had never received much attention.
There has also been noteworthy change in the last 20 years. Previously, society's relative indifference to what happened to a fœtus or a newborn struck down by accidental death was paralleled by the lack of

parental control over the decision to conceive an embryo and what became of it, since there were no reliable authorised methods of contraception and elective abortion was prohibited. Contraception and termination of pregnancy have reinforced the notion of a "wanted child" and "parental projects". The consequences of this new dimension have been to reinforce a family's emotional investment and representation of a child before birth and all the more so because medical imagery has given substance to this representation. It is understandable that in this context, the premature death of a fœtus or of a newborn should cause much more dismay and distress and should in some cases be the cause of new forms of mourning.

2 - The legal situation

I – A first distinction was made between the live fœtus or the stillborn, or between children who die before their birth is registered and those who die after some time has elapsed and after registration.

For the latter, the status of person (minor) is applicable as are the general legal articles regarding consent for the donation and use of elements and products of the human body as defined by the 1994 and 2004 laws.

II — As regards legal arrangements for the sampling or conservation of fœtal or embryonic tissue or other components, the situation changed after the entry into force of the law dated August 6th 2004. However, although the two fields of application are different, they coexist.

A – Before the law dated August 6th 2004:

Applicable texts are the following:

- the law dated January 8th 1993
- the circular dated July 22nd 1993
- the circular dated November 30th 2001

They cover: 1 - birth registration procedures and documents
2 - what becomes of the bodies

- The law dated January 8th 1993 based on Article 79-1 of the *Code Civil* stipulates the legal system applying in the case of a child dying before birth was registered. In that event, the Registry Office *(Etat Civil)* makes out a birth certificate, and then a death certificate delivered on the strength of a document certifying that the child was born alive and viable.
If such a document is not available, a certificate for a lifeless child is made out (this is not a birth certificate, it is simply a document established by the Registry) which covers cases when a child is born alive but not viable, or stillborn.

- In view of the above, precise viability criteria are required. A circular dated July 23rd 1993 provides them. It was drawn up for use by Registry Offices, based on WHO criteria, and gives lower limits of 22 weeks of gestation or 500 grams in weight.
- Repeating the above criteria, a circular dated November 30th 2001 (more specifically designed for healthcare institutions) draws the following consequences as regards what is to become of the bodies.
- Two main categories distinguish between the existence of some form of official registration or not.

a) A birth and death certificate for a child born alive and viable but having died subsequently.
A birth certificate and a death certificate are issued with a note appended to the family's official record book *(livret de famille*);
Transport of the body is regulated.
Inhumation or cremation are mandatory at the family's expense.

b) A certificate for a "lifeless child", stillborn or born alive but not viable
Inhumation or cremation are either at the family's expense or, in the event of hardship, at the hospital's expense, but are not mandatory. If information is unavailable, incineration is mandatory and at the hospital's expense. There is no entry in the space set aside for the rank in the family of that child on the family's official record book, but if the parents request it, a note can be made at the end of this document.

c) In the absence of any official registration, which is the case for a fœtus under 22 weeks or under 500 grams, in compliance with European legislation, bodies are incinerated at the hospital's expense except if local authorities accept the bodies of fœtuses in graveyards.

In the two latter situations (b and c) the healthcare institution must inform families of the various possibilities and if it does not receive a reply from the family within 10 days, it proceeds with inhumation or incineration.

B - The legal system regulated by the law dated August 6th 2004 deals with samples for medical research in the event of termination of pregnancy.

- The law dated August 6th 2004 in Article 27, deals with the use made of embryonic or fœtal tissues after a termination. These tissues cannot be sampled, stored or used without written consent from the mother, once she has been informed of the purpose, and only after the decision to terminate.

- Such samples cannot be taken if the mother is a minor or incompetent, except to find the causes of the pregnancy being terminated and only once the mother has been informed that she can refuse.

- Generally, the law provides for the establishment of a research protocol to be submitted to the Biomedical Agency and communicated to the Ministry in charge of research, concerning samples for diagnostic, therapeutic or scientific purposes, other than those for the purpose of finding the cause of pregnancy being terminated.

- Sanctions:

The August 2004 law in Article 511-19-1 lists sanctions of two years imprisonment and € 30,000 fine for violation of conditions set out in Article 1241-5 of the Code of Public Health, paras. 1-2 and 4, para. 1 specifically, regarding the purpose of sampling, information provided to the woman and her prior consent after she has taken the decision to terminate her pregnancy. "Embryonic or foetal tissues or cells cannot be sampled, stored and used after termination of pregnancy except for diagnostic, therapeutic or scientific purposes. Women who have undergone termination give written consent after being appropriately informed of the purpose of sampling. The information must be imparted after the woman has taken the decision to terminate her pregnancy."

In conclusion, without parental consent there are no circumstances in which storing tissues sampled from a child who survived birth is authorised. As regards a fœtus, before 2004, a simple regulation covered what became of bodies but there was no criminal sanction in case of violation. Since 2004, however, the law and criminal sanctions apply absolutely as regards consent being required.

3 – Good scientific practices based on consensual professional deliberation

A lifeless fœtus of any age must always be identified with a bracelet:

- be placed together with the placenta in a single-use container,
- with a summary of the medical report,
- to which are added:
    - a request for fœtopathological examination if parents have authorised the procedure. To this document must be appended a fœtal examination plus sampling authorisation signed by parents, together with a separate document giving or withholding authorisation for sampling for scientific purposes or cognitive research
    - a certificate regarding the future, to be signed by parents and stating whether they wish the hospital to take care of the fœtal body or donate it to science,
- be sent in containers directly to the department of anatomy and pathology for fœtuses of under 22 weeks and to the mortuary for those over 22 weeks or weighing less than 500 grams. The 2001 circular is perfectly clear on status criteria:
    - under 22 weeks, under 500 grams
    - under 22 weeks, over 500 grams
    - over 22 weeks.

I — A stillborn fœtus under 22 weeks AND under 500 grams together with placenta, although theoretically classified as a "surgical specimen", must still be noted in the laboratory's fœtopathological records. It is

photographed, described, measured and x-rayed. A request for fœtopathological examination and parental authorisation must be provided before examination. After examination the fœtus and organs are placed in a sealed plastic container and delivered to the mortuary as an identifiable anatomic specimen. At this point, depending on the family's wishes, the fœtus can be:

- recorded on the list of anatomic specimens by the mortuary and eliminated, at the expense of the institution, through the specific procedure for identifiable anatomic specimens;
- returned to the family, after autopsy repair, for incineration or inhumation as the family wishes.

II — The body of a stillborn child of over 22 weeks or weighing more than 500 grams, is listed in the fœtopathological records, photographed and x-rayed. Examination is subject to the provision of a request for anatomical pathology and parental authorisation. After examination and harvesting of scientific samples (if specific parental authorisation has been given), donation repair will be performed. The body many then be returned to the hospital for incineration or recorded in the register for lifeless children and laid to rest.

III – The body of a child of over 22 weeks or weighing more than 500 grams, born alive and then deceased, is registered as born and subsequently deceased. A funeral is mandatory. Autopsy is subject to regulations as provided by the 2004 bioethics laws.

In all cases, a maximum of 10 days after death is allowed for parents to claim the body before the healthcare institution proceeds with incineration.
So, from time of death to incineration or inhumation, parents must be kept informed of any request for fœtopathological examination for which their prior authorisation is in any case necessary; of a request for scientific sampling, for which their specific consent must be secured, and of the possibility of incineration by the hospital or of return to the family.

4 - Problem issues

I – Sampling

1.1 Sampling for scientific purposes include:

- Sampling for cytogenetic (karyotype) studies, which are subject to specific parental consent
- Bacteriological, virological or parasitological samples which do not require specific authorisation since they are part of the diagnostic examination for maternal infection
- Sampling of various organs.

1.2 Sampling of gonads for which specific consent is required because of the particular nature of ovaries and the presence of oocytes.

1.3 The brain, fixed in formol, can be preserved in the laboratory during three months (a longer period of time for fixation is needed than for other organs), or even longer if required for scientific reasons. The family must be informed of sampling and preservation, and give consent.

1.4 Whole organ samples (heart and lung, brain, digestive system) become anatomic specimens and later medical waste after dissection.

1.5 Preservation *sine die* in formol of identifying or identifiable anatomic components, such as the face, is totally unjustifiable except in special cases for which specific parental authorisation is required and a research protocol approved by a CPPR (Committee for the Protection of Persons involved in Research) and recorded as biobank or fœtal tissue bank materials (managed by a biological resources centre).

1.6 However, whole paraffin-embedded samples or slides can be kept indefinitely as is customary for anatomopathological specimens.

1.7 Fœtal corpses must be sent to the mortuary without delay.

II – Time limits

2.1 Within 10 days of death, the family may claim the body, whether or not it has been examined, depending on the kind of authorisation given by the family.

2.2 Anatomopathological examination need not necessarily be performed within 10 days, but it is recommended that it should. In any event, it must be performed within a reasonable time.

2.3 Once fœtopathological examination has been performed, the body must be inhumed or incinerated within 6 days.

2.4 These time limits do not apply to anatomic specimens which may be preserved whole in formol for several months, if authorisation has been secured, or as paraffin-embedded components or slides indefinitely.

2.5 These time limits do not apply to preservation *sine die* of fœtuses presenting severe morphological anomalies (at present very infrequent because of their early detection leading to elective abortion) which serve to keep scientific and medical records and as references. However, such practices are currently obsolete because of the possibilities provided by digital photography, CT scan and MRI.

III – Organisation

3.1 The fact that mortuaries are attached to a medical or administrative department complicates matters as regards responsibilities. To facilitate management, it would be preferable for them to be attached to a medical anatomical and pathology department or to a cytogenetic and histology department.

3.2 Fœto-pathological activities are not strictly regulated.
- The fœto-placental examination is a medical act which is not on the list of biological acts. Only the anatomopathology examination is on that list.
- The manner in which local hospitals run their histology, cytogenetic and anatomical and pathology departments conditions the various practices and is the reason for variation in procedures.

3.3 Fœtopathology is time consuming, labour intensive and demanding of laboratory facilities. The examination of three fœtuses takes two half days. A great deal of management time is required for scientific, morphological (reconstitution of body) and administration work. This still poorly recognised discipline numbers only a very few specialists. Furthermore, it is in a state of flux as it is passing from a more conservatory phase (limited to morphology) into a more scientific era (genetic studies, karyotypes, cell banks, DNA banks).

3.4 Fœtopathological research is essential to determine the causes of death, but above all to prevent possible subsequent pathological pregnancies, so that cognitive research can take place in a completely transparent procedural framework.

5 – Ethical and anthropological aspects

Regulations and practices may seem insensitive despite all possible precautions when they are applied in distressing circumstances.

The medical and legal attitude, necessarily analytical, to the objective characteristics of the deceased fœtus or newborn (chronological age, weight, viability, pathology, etc.) must not be allowed to contrast shockingly with the emotional expectations that parents had of their future child. For the afflicted parents, the situation can not possibly be summed up by the specific characteristics of the particular point in time when their child's development suddenly stopped. Similarly, the specific legal distinctions, even though their purpose is comprehensible (stillborn, born live, viable or non viable, child dying before or after birth was registered officially, etc.) in the face of the parents' expectations and distress take on an undeniably arbitrary dimension which cannot be ignored. The possible consequences of these distinctions, since they have an impact on the way in which the body is dealt with, do bear some resemblance to the consequences in times past of certain religious dividing lines regarding the fate of the soul and the burial of the newborn depending on whether the last rites had or had not been administered before death.

No attempt can be made to arrive at any universal anthropological truth and even less to define normative behaviour. Every couple must be able to react in total freedom abiding by their own values and sensibility. It must be remembered however that the history of civilisations and religions shows that the living have always been haunted by the question of what becomes of their dead. Nothing could be more natural than the question that parents of a prematurely dead fœtus may ask: "where is the body?". For some, the answer to that question may be given by funeral rites designed to help mourners gradually reintegrate everyday life as they move away in space and in time.

By instituting a ritualised separation between the live and the dead (both in space and in time) funeral rites can help to readapt a mourner to life in society. In this way the family can be given the psychological assistance that may, in certain cases, take on a spiritual dimension. But there is no reason to propose or impose such assistance to families who simply want to be left in peace or need a little sympathy.

The tragedy of perinatal death challenges our conscience on our duty to honour humanity. What is human must not be reified. A newborn, even dead, becomes a child, including in the eyes of the medical profession. To come into the world, alive or dead, is to be put in the care of human hands.
There should be no confusion between compassion and ethics. Ethics are in the attention given to suffering, not in practices, however ritualistic. The tragedy of the premature death of a fœtus or newborn demands a responsible attitude in the face of such circumstances.

6 - The Committee's proposed recommendations are the following:

1. - Although the fœtus may be considered "*res nullius*" in law, its human origin commands respect. It cannot in any event be seen as "hospital waste".

2. - The wishes, whatever they may be, of parents regarding what becomes of the body of a fœtus or newborn must be respected.

3. - Any foetus resulting from spontaneous abortion or termination for pathological reasons, at whatever gestational age, must be eligible for a request for anatomo-pathological expert examination by a fœtopathological unit with rigorous attention to exhaustive information being supplied before parental consent, specifying:

> - that parents authorise, or do not authorise, autopsy to be followed by other complementary examinations required to find the cause of death;
> - that they authorise, or do not authorise, examination and sampling for scientific purposes other than seeking the cause of death.

Information must be provided in all cases exercising tact and discretion to attenuate what could seem paradoxically excessively formal and in the primary interest of the administration.

4. - It would be a pity if excessive formalism were to hamper research on the cause of fœtal death and scientific investigation to avoid fœtal pathologies in the future, but ethics demand that the purpose of the research be clearly identified.

5. - Any element fully or partly identifying the fœtus should be incinerated or inhumed, after autopsy, within the short time limits prescribed. No medium term or long term preservation of fœtuses can take place except for major scientific reasons, in which case the parents' consent would be required. "Collections" are now obsolete and unethical.

6. - Any non identifying element (viscera, brain, heart and lung, etc.) can be kept in a laboratory based on scientific need and research protocols submitted to a CPP (Committee for the Protection of Persons) after parental authorisation.

7. - Any paraffin-embedded element or slide can be kept in a laboratory without any time limit and without requiring further parental authorisation after examination, since anatomical and pathological material of this kind is normally kept by such departments.

8. - Procedures for returning the body of fœtuses to their families after autopsy and repair should not be strictly and excessively determined by the age of the fœtus (under or over 22 weeks). Even under that time, parents should be given the possibility of proceeding with inhumation or incineration as they think fit.

9. - A code of good practices should be drafted so that every fœtopathology laboratory, be it attached to an anatomical and pathology department or a cytology, histology and cytogenetic unit, knows exactly what procedures must be followed in every situation. The very diverse forms for requesting authorisation to practice fœtopathological examinations used by the various establishments would deserve to be reviewed, clarified and harmonised (vocabulary, site of examination, commitment on the part of the establishment concerned as regards procedure).

10. - A medical professional should be designated to be in charge of the mortuary in establishments where autopsies, fœtopathological examinations or organ harvesting (cornea for example) are performed. Administrative facilities should be assigned to them. It would be essential that personnel working in mortuaries, both medical professionals and administrative staff, be given special training to help them attend to families. Such training could be given in Ethical Units and should give rise to special recognition for specialised personnel. In any event, these recommendations would require that specific facilities be allocated.

11. - Fœtopathology is a difficult discipline which must be encouraged by university or hospital recognition (fœtopathological acts to be listed in medical nomenclature) which entails the allocation of human and financial resources. As for any other complex ethical procedure if necessary resources are not allocated, the end result could well be the early disappearance of fœtopathology, which would be an important setback in the management of pregnancies interrupted by the death of the fœtus or the birth of a stillborn child.

In conclusion, meticulous medical and scientific practices, but also completely transparent procedures and attention given to informing and securing consent from parents are all required to satisfy ethical principles.

Many parents, when a fœtus or a stillborn infant dies, feel they have lost a child. This death must inspire medical and administrative staff with the full respect owed to the body and they must be able to provide counselling with understanding, compassion and devotion. Everything possible must be done to deal with the situation with humanity and for friends and relatives, parents particularly, to live through their loss surrounded by society's sympathy instead of being made to feel guilty or the objects of judgment and stigma.

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