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The birth of a child is one of the most important events in the life of a family. However, for centuries the moment of birth was often also a time of death because many mothers died in childbirth and neonate mortality was considerable.

Depuis Since the 60s, this historic situation has been transformed by remarkable medical and scientific progress : breakthroughs in developmental biology, cerebral development in particular, improved medical management of pregnancy, innovative technology in neonatal resuscitation, and generally progress in medical and surgical therapy. During the same period, social welfare measures for mothers and children were instituted. Yet, such progress is mainly out of reach of most for the world's families.

Dans In industrialised countries, the risk of death is now small for mothers and they are not excessively anxious about pregnancy and delivery, although they may be a little apprehensive. Quality healthcare for children is provided so that a healthy development can be expected during gestation, at birth, and later at home.

Unfortunately, each year in France approximately 20000 children (1) are nevertheless born in a state of vital distress and need to stay in hospital neonatal resuscitation units, so that organ or vital function failures can be dealt with, in some cases for a certain length of time. Medical progress has greatly improved the chances of survival of the newly born, but some of those who survive suffer severe brain damage causing neurological sequelae so that lifelong intensive healthcare has to be provided. In spite of improvements, in particular in the care of preterm infants, the number of children suffering from cerebral palsy as a result of brain injury has not decreased whereas the number of surviving children has greatly increased.

The ethical problem of neonatal resuscitation has already been broached in a CCNE report, Ethics and Pediatrics, published in 1992. In December 1997, CCNE was asked for an opinion on a special case in which a medical team had to take a decision regarding an extremely premature infant in immediate vital distress due to respiratory failure. In the present report, CCNE has broadened the scope of its ethical reflection to encompass problems raised by the newly born in distress. The report considers in particular the subject of neonatal resuscitation circumstances and also preventive measures which should help to reduce the numbers of these dramatic cases.

MEDICAL AND EPIDEMIOLOGICAL DATA

Various circumstances may endanger the life of the newly born or represent a risk of irreversible damage, in particular brain injury.

1. Neonatal distress connected to extreme prematurity

In metropolitan France, approximately 9 000 extremely premature infants were born in 1995 (< 33 weeks of gestation) and 6500 - 7000 of these were live births (1). The national perinatal enquiry, the results of which have just been published, confirms that the proportion of premature births has again increased [2]. Extreme prematurity causes 50% of neonatal mortality and furthermore is associated with a high risk of serious sequelae.

Almost half of the severe infant motor disorders are related to this situation.

Since the early 90s, an increase in the frequency of prematurity has been observed in France. The perinatology programme instituted in 1971 was followed by a significant fall in premature birth and low birth weight occurrences which continued into the 80s, but there is a worrying increase in these figures, particularly because of modified obstetrical and neonatal practices. Delivery is induced ever earlier so that foetal or maternal disorders may be attended to and also to avoid the continuation of pregnancy when there is a risk of death in utero. Furthermore, progress in neonatal care increases chances of survival.

Amongst other risk factors, there is also the rising number of multiple births. The national perinatal enquiry of 1998 revealed that multiple births rose from 2.5% of all deliveries in 1995 to 3.5% in 1998, and represent 25% of premature deliveries. The proportion of births before 37 weeks of gestation has also increased since it was 5.9% in 1995 and has risen to 6.8% in 1998. The main causes are late pregnancies, faulty and poorly monitored medical prescription of ovulation induction drugs in some cases, and finally the transfer of several embryos during in vitro fertilisation (IVF). In spite of growing awareness on the part of IVF practitioners who are reducing the number of embryos transferred, the results of FIVNAT (2) for 1998 [3] do not show any reduction in the number of multiple pregnancies, mainly twins, which still represent 26% of births.

Preliminary results of an epidemiological study of low gestational age infants (EPIPAGE) [4] carried out in nine French regions for births in 1997, gave information on the survival rates of premature infants according to gestational age at birth. The table in Annex 1 provides information on birth between weeks 22 and 25. It shows that survival rates are very low when gestational age is less than 26 weeks. As regards live births, (therefore excluding still births before or during labour) there are no survivors at 22 and 23 weeks, whereas at 24 and 25 weeks respectively, 31% and 50% leave the hospital alive. The authors of this study intend to monitor surviving children up to the age of 5 years to gain information on sequelae-free survival rates.

Recent study grouping the results of transport from the place of birth to a specialist centre by paediatric emergency services in the Ile de France (greater Paris area), shows that out of 126 premature infants born before 26 weeks of gestation who are admitted to hospital, global mortality is 65%. There are no survivors at 22 and 23 weeks, 76% deaths at 24 weeks, and 60% for those born at 25 weeks [5, 6]. The risk is much greater for the very premature who are transported after their birth to a perinatal centre compared to those born in a hospital environment providing both obstetrical and neonatal intensive care.

Up to a fairly recent date, there were few studies describing the principal neurological complications of extreme prematurity leading to major medium or long term disability. A prospective British study of all births during 10 months in 1995 has been published recently (7). It reveals that at 30 months, half of the children born very prematurely (22 to 25 weeks gestation) still living after resuscitation, suffer from disabilities, half of which are described as severe " (Annexe 1).

One of the most severe disorders, periventricular leukomalacia, appears in 5 to 15% of premature infants depending on gestational age. Necrosis, mainly of motor fibres, is involved and this may generate irreversible cerebral palsy. However, systematic brain imagery is not able to reveal such injury and its extent in order to improve diagnostic precision, before 12 to 15 days after birth (8). Earlier imagery should soon be obtainable by systematic use in neonatology of high performance RMI equipment. .

2. Neonatal distress in full term infants

With full term infants, a great many totally unexpected problems may arise at birth. Distress may have many causes : developmental anomalies, coagulation disorders, auto-immune diseases, and infections (9). Severe hypotrophic disorders may be a result of various maternal or foetal conditions (e.g. multiple pregnancies). Finally, laborious birth may be the origin of prolonged neonatal anoxia leading to central nervous system injury, cerebral palsy in particular. Some distress is only temporary and with appropriate care, an early return to normal health will be achieved. In other and rarer cases, there may be long term sensomotor damage or learning problems (10).

Approximately 2.5% of the newly born suffer from congenital defects. Severe, and frequently multiple, defects are the cause of high infant mortality at an early stage (first week) (11).

Such neonatal distress may occur in remote areas so that emergency transport has to be arranged to the nearest NICU (neonatal intensive care unit). In 1997, the paediatric emergency services of the Ile de France (greater Paris area) transported 2307 full term infants out of a total of 6798 infants transported (5).

In conclusion, in the last few decades a spectacular reduction of infant mortality has been observed. It has decreased from a total of 17.4% in 1975 to 4.6% in 1997. Chances of survival have increased considerably and the percentage of neurological disability in surviving children has decreased. However, the significant increase in the number of survivors has not resulted in a reduction of the absolute figures of severe long-term impairment requiring prolonged medical attention in specialised institutions. This is a serious problem for children and their families as well as for the public health system and the facilities available to it.

MEDICAL PRACTICES

For many years, any severely compromised newly born infant invariably died, so that physicians could not do anything to remedy the situation and were resigned to the inevitable. Nowadays, there are a number of ways in which the initial vital distress of the newly born can be overcome. As a result, physicians and parents are undecided about whether such action is justified and to what extent. For some, whatever can be done should be done to save a distressed newly born infant ; others sometimes harbour fears of being too extreme. Successes in neonatal resuscitation have sometimes led to excessive optimism about outcomes. Several enquiries have shown that for fear of high risk of severe sequelae, after initiation of resuscitation, more than 50% of deaths in NICUs were due to decisions to cease resuscitation attempts or to end life (12). Because of the diversity of distress situations, there are a variety of attitudes taken by physicians confronted with such choices, which are all the more difficult and excruciating because frequently decisions need to be taken in an emergency and can never be supported by certainty.

In the circumstances, various situations need consideration :

The newly born infant has a low chance of survival

Two kinds of situation may arise. In the first case, the mother's pregnancy was properly monitored, and ultrasound examination and prenatal visits have revealed a congenital anomaly (about 4% of pregnancies). In a third of such cases, diagnosis of a disorder involving severe vital or functional prognosis moves parents to request termination. In other cases, that possibility is rejected for various reasons : parental opposition, risk to the mother because of tardy abortion, presence of an apparently healthy twin, or the hope that therapy at time of birth may have a better outcome because the condition was diagnosed before birth.

In such circumstances, as in the case of premature delivery, any decision not to take heroic measures to save the child would be taken in agreement with parents and with their informed consent. Decision not to resuscitate is based on an assessment of the immediate vital risk and of the risk of severe sequelae for the child, taking into account the parents' wishes after they have been as fully informed as possible.

When the newly born infant is in a critical condition, or in a state of apparent death in the delivery room, and the medical team has either no previous data of diagnostic or prognostic value (emergency arrival of patient with no available documentation of previous

examination), or has only non conclusive or inexact data at the time of birth, or when there is foetal insult or severe anoxia as a result of the intrapartum process, then the situation is very different (13). The decision has to be taken by the medical team alone in the delivery room because in an emergency it is not always possible to rely on carefully thought-out decisions by parents. Furthermore, in spite of progress in medical imagery technology, there is still no indication of immediate predictive value to assess cerebral status in the absence of obvious malformation.

Because such situations are so difficult, healthcare teams' practices and the way in which healthcare is organised have led to a diversity of attitudes based on various thresholds (gestational age, weight at birth, risk of disability) which are used to decide whether systematic resuscitation will or will not be initiated.

Determination of a lower gestational age limit as a guide for management of preterm infants is the subject of debate : should it be set at 26, 25, or even 24 weeks ?

Survival seems possible, but sequelae cannot be assessed

Most French neonatologists structure their response on the recognition of a "life a priori" for any newly born infant in distress, so that resuscitation on a "standby" basis is continued until all prognosis data has been collected. This attitude is founded on the understanding by the team that resuscitation will be discontinued if and when objective criteria make it possible to state that there is no hope of survival or that damage, in particular brain injury, will lead to extremely severe sequelae.

Based on a consensus, medical teams consider that they should withdraw resuscitative measures if they find that survival is impossible in spite of heroic technology. To continue resuscitation, and thereby delay death, is viewed as futile and aggressive therapy which should not be tolerated.

There are, however, differences of opinion between practitioners depending on the condition of the child at the time when brain injury with the possibility of severe and irreversible future impairment is diagnosed, leaving little hope of relational life but some hope of survival. If the vital functions of the neonate remain dependent on ventilatory and cardiovascular assistance, many doctors accept discontinuation of resuscitative efforts. Others, however, decide to end life when the infant is still in intensive care, but has acquired spontaneous respiration in spite of extremely serious brain injury which would have justified discontinuation of resuscitation if it had been discovered when the infant was still dependent on assisted respiration.

HEALTHCARE OPINIONS: EUROPEAN DATA

The difficulty of medical decision making in the various situations of neonatal resuscitation lead to divergent attitudes on the part of healthcare workers (physicians and nursing staff) in France and in Europe.

A European concerted action enquiry (Euronic) (14) involving 122 teams in neonatal intensive care units in eight European countries, was carried out in order to describe as exhaustively as possible the opinions and practices of a representative sample of neonatal resuscitation healthcare workers. One of the objectives of the enquiry was to describe how these people took decisions regarding the continuation or withdrawal of resuscitation.

In every country, the majority of doctors (two thirds or more) reported that "at least once in their career, alone or in agreement with other persons, they had decided to set a limit on their intensive interventions and to allow nature to take its course, even if that entailed the possibility of death" (Annex 2, Table 3).

There are, however, variations in attitudes regarding the various strategies for limiting care : take no new action, withdraw mechanical ventilation, and particularly administer drugs with the purpose of ending life (Annex 2, Table 6). The study shows that the decision not to provide intensive care is taken more frequently in Sweden, the Netherlands, the United Kingdom and in Spain than in France and Germany.

However, the table showing results for France (15) (Annex 2, Table 1) emphasises that 73% of physicians and 77% of nurses consider that it is acceptable in certain situations to discontinue intensive care and administer drugs with the purpose of ending life. This course of action is hardly even considered in other countries (Annex 2, Table 3) with the Netherlands as the only exception. In a European context, it would appear to be specific to

French neonatologists who prefer unconstrained access to systematic "standby" resuscitation, whilst accepting the possibility of later withdrawal of support. This raises problems.

THE LEGAL SITUATION

French law recognises that legal existence is acquired at birth by a child born live and able to sustain life, and is extinguished with death. Ability to sustain life at birth is defined as at least 22 weeks of gestation and minimum weight of 500 grammes (3). It is accepted that stillborn infants have no legal existence and that those born live but unable to sustain life are deemed to have never had legal existence (4).

The birth of a child born live and able to sustain life has to be notified to the Births Registry Office:

Article 55 of the "Code Civil" states "birth notifications shall be made within three days of delivery to the official in charge of the local Births Registry".

Act 93-22 dated January 8, 1993 supplements Article 79 concerning the death certificate by adding Article 79-1 which states that "when a child dies before birth has been notified to the Births Registry, the Official delivers both a birth certificate and a death certificate providing a medical certificate is supplied stating that the child was born alive and able to sustain life, giving dates and times of birth and death. If no such medical certificate is available, the Official establishes a document for a lifeless child".

Any assault on the physical or psychic integrity of a person is punishable by criminal law and the ending of the life of a child born live and able to sustain life is a violation of criminal law :

soit either by the fact of voluntarily inflicting death on a person, i.e. a crime as in Article 221-1 C. Criminal Code,

or by the fact of directly exposing a person to immediate risk of death, i.e. an offence as in Article 223-1 Criminal code.

In the past, complaints in connection with death through "failure to assist a newly born infant in danger" have been exceptional. However, prosecution - sometimes successful - has been made for malpractice leading to irreversible sequelae.

ETHICAL CONSIDERATIONS

The framework

The data described above raises obvious and particularly delicate ethical issues. Furthermore, it is part of a context - as recent studies have shown (5) - in which ideas regarding families and children have changed : the control of fertility and the drop in infant mortality have modified the degree of involvement of parents : a child is increasingly wanted and its birth is frequently planned. In addition, in today's society, the death of a child is all the more traumatic because some medical procedures, ultrasound prenatal examination in particular, give that child an identity well before birth and encourage early integration into the family.

When a newly born infant's life is threatened, several participants are thrown together : the child, its parents, and the medical team in charge of treatment and care. Society, whose values, laws and institutions are present in the background, is also an important participant. Therefore, one of the tasks incumbent on ethical reflection is to elaborate recommended relationships between persons and institutions concerned by an infant in distress, taking into account the human complexity of frequently tragic circumstances. The following points will be particularly emphasised :

- Should everything that possibly can be done to resuscitate a newly born infant, be done, regardless of medical status and consequences on future development ?
- Is it allowable to withdraw resuscitation, or even end the life of a neonate who has become competent as regards respiration but is seriously brain damaged ?
- Who may assess and decide in such circumstances ? On the basis of what expertise and criteria ? Where do parents, medical teams, and nursing staff stand in respect of each other ?

- The law stipulates that legal existence begins with birth, but is frequently broken. Therefore, should frank and precise conclusions be drawn from this factual situation ?
- The fundamental perspective through which these recurrent issues could be viewed might be the following : coping with unavoidable misfortune is an attitude which every civilisation encourages and which demands fortitude, dignity, and solidarity. But what of misfortune brought about by the consequences of technical progress, whereas its very object is theoretically to provide remedy when disaster threatens ? How, in such circumstances, should medical liability be viewed ?

CCNE's purpose is to throw light on these issues and their ethical consequences by offering avenues for thought and options for action - which may not be the best option, because that is frequently an impossibility - in as humane a manner as possible. Reflection is focused on the ethical implications of a double imperative which prescribes that vital distress at birth should be prevented to the greatest possible extent, and that one should act with compassion, correctness, and humanity if it does occur in spite of best attempts. These thoughts do not aim to set up rules or recommendations for medical teams who have to deal with these problems ; rather they aim to help them find solutions by highlighting the issues which need to be taken into account.

A. Prevention

Preventive policy aiming to reduce the presently large numbers of vital distress cases at birth is the first imperative.

The ethical value of prevention has already been emphasised by CCNE in its report on technical progress and collective choices (6): " Prevention of those ailments which can be prevented is an imperious ethical necessity and must be a health policy priority ". CCNE urges all practitioners concerned with pregnancy and birth to become aware of their own responsibilities in such an endeavour. Associating parents-to-be in a discussion on health risks for their child, as soon as plans to conceive come under medical management, and throughout pregnancy, would help them to also take on responsibility for preventive action. Scrupulous organisation of prevention would preclude or at least considerably attenuate some of the difficulties and quandaries of neonatal practice. This could be done in several ways but the aim must be to improve the organisation of healthcare so that in all cases management would be appropriate to the level of risk.

If existing regulations on the functioning of obstetric and neonatal units were applied, the number of preterm infants who are unsuitably managed could be further reduced (decrees on perinatal procedures : decrees 98-899 and 98-900 - Official publication October 10, 1998).

Implementation of decrees on hospital organisation and closing down ill-equipped maternity wards could reduce numbers of full term infants in distress.

A fundamental step is to include the prescription of ovulation inducers in medically assisted reproduction procedures when the bioethics laws are reviewed. In this way, thanks to programmed monitoring, the number of multiple births which are caused by these substances could be reduced. CCNE has formulated such recommendations on several occasions (7) in previous Opinions.

Efforts should be continued to define better strategy regarding the number of embryos to transfer in an IVF procedure (8).

Progress in the extension and application of preventive measures are still based on research programmes, either fundamental research on brain development and on the consequences of maternal or fetal disorders which may affect the development of the fetal brain, or applied research aiming to evaluate the medium and long term effects of medical activity. It would therefore be appropriate to continue and develop clinical and epidemiological studies on evolving health of all infants who have undergone resuscitative procedures or intensive care at birth. Systematic and prolonged cooperation between parents and doctors for such studies are an essential condition for their quality. This will be all the more acceptable if procedures and objectives are made clear during gestation and in the first days of the infant's life.

The results of such studies would help to set medical practices of the future on scientific foundations which should include

- long term outcomes of neonatal therapies, be they medical or surgical ,
- early management of resuscitated children of any gestational age,
- epidemiological monitoring of extreme prematurity and its consequences up to school age.

- Studies of such test cases over long prospective durations are essential not just to provide replies to queries, but also because they are a fundamental input for prevention and early management of the possible consequences of difficult deliveries. Medical and psychological monitoring over several years is an ethical necessity for all children who have had to be given special care at birth, either in the delivery room or in a neonatal resuscitation unit. Research programmes on the brain development of children could benefit from recent progress in the neurosciences. Such research should investigate the etiology of extreme prematurity, the mechanisms leading to brain damage, their diagnosis and identification, and the improvement of methods for early diagnosis, in particular imagery technology. Finally, further research on the reversible or non-reversible characteristics of these lesions is required, and also on the possibility of functional rehabilitation so as to prevent sequelae. All of the above research requires partnership with parents, irrespective of the health status of their child.

B. Coping

Background

Do no harm

- According to the Hippocratic oath, one of the foundations of medicine is encapsulated in the principle *Primum non nocere*. The principle of " not doing harm " is in fact viewed as one of the fundamental themes of bioethics. It is expressed by respecting four categorical prescriptions : do no harm, prevent a harmful effect, eliminate a harmful effect, provide a beneficial effect. However, one could observe that in order to have any operational value, such abstract precepts need to be related to what we consider to be desirable and what we wish to avoid. What is desirable is only defined in the light of a person's rights. What we wish to avoid is the onset of a major disability which would contradict the principle of beneficence.

- However, independently of age, state of health, and particularly handicaps which may afflict a person, human dignity and value must be recognised as worthy of respect. This is plainly supported by the 1990 Convention on the rights of children which defines an identical expectation and future for all children, disabled or not... " Member States, recognising that mentally or physically handicapped children must lead a full and seemly life, in circumstances which safeguard their dignity, enhance their autonomy, and facilitate their active participation in the life of the community " (Article 23). CCNE particularly underlined this point in its report on Ethics and Paediatrics : " A child is obviously to be considered in the same way as any other human being. Ethical principles applying to a person can and must apply to a child "

- But a person is not an island : individuals are all the more dependent when they are young and fragile. Therefore, they deserve more than any other person, consideration, help, and affection. To question or worry about the quality of life of a particular newly born infant or the child's future capacity for autonomy, and the kind of relationship which he or she may or may not be able to establish with loved ones and the surrounding world is perfectly legitimate (9). However, that is no justification for a process of dehumanisation which denies an endangered human child the right to dignity.

- Yet translating into fact this respect for dignity is no easy task. The sheer weight of difficulty and misfortune which highly dependent newly born infants are heirs to, not just at the time of birth, but also in the future when they may be increasingly isolated, can be a heavy burden on those who look after them. It is true that society should be encouraged to show as much solidarity as possible ; and those who bear this ordeal with fortitude are worth listening to, but should such trials be set as an example for all to follow ?

- There is a further and major difficulty : these severe disabilities are not always brought about by the decree of " nature " or " fate ". Sometimes they are the adverse result of deliberate human action, the fruits of increasingly sophisticated medical practice.

The "do no harm" principle is eminently applicable to rejecting any form of aggressive and futile therapy. The comments on this subject made by CCNE in Opinion N° 63 "End of life, ending life, euthanasia" are pertinent in this context and several points are worth repeating.

- CCNE defines aggressive and futile therapy as "irrational obstinacy," stubbornly refusing to recognise that a human being (in this case a newborn infant) is on the way to death and cannot be cured". It adds that there is now widespread agreement by representatives of all religious faiths and ethical authorities that it should be rejected.

In fact, some of the comments made at the time regarding mostly end of life situations apply also to issues which may arise at the beginning of life. For instance: "rejection of aggressive and futile therapy may also be the expression of rejection of inhumane situations, for instance in cases where the aims of therapy and the actual situation are out of proportion". An added difficulty, particular to neonatal resuscitation, is that there is not only uncertainty about neurological and cognitive long term consequences, that is regarding the child's future ability to manage his or her own life, but there is also the issue of responsibility for irreversible damage which may be attributed to the treatment delivered, and therefore to the actual process of neonatal resuscitation.

Implementing the principle of doing no harm in neonatal medical practice has several specific characteristics which must be integrated into the ethical consideration of each case. The appraisal of parents, who are the natural protectors of their child, is the sole criterion for evaluating the ethical demands of consent: therefore parents must participate in discussions and decisions even if they are not the originators of medical decisions. They must also be allowed, whenever possible, time sufficient to reason their own way through to a decision which can never be anything but agonising. Decisions by the medical team to undertake or withdraw treatment must be taken without shutting parents out, but in so doing, care must be taken not to place a burden of guilt on them. Nor should this process relieve professionals from their obligation to take full responsibility for professional decisions.

Urgency and uncertainty. Frequently, a decision which may have serious consequences has to be taken in spite of the difficulty or even the impossibility at the time of establishing any prognosis regarding the child's future condition. Difficulty in evaluating the limits of life and possible sequelae, even with the help of various scores for assessing the degree of compromise, complicate the gathering of objective criteria to decide that continuing treatment is futile.

Absence of consensus on reward to be gained or the ranking of priorities to guide action. For some people, the priority is preserving the child's life. Others are more concerned with future handicaps which could hamper the child's autonomous development and therefore impose a heavy burden on the family. Ethical conflict between these two views is exacerbated by the fact that, more often than not, the choice is not between life and death, but between certain death and uncertainty about the child's future condition.

Whatever courses of action are considered, moral issues arise.

The point has already been emphasised: in earlier times, any serious disorder afflicting a newborn child led to unavoidable death and, since there could be no remedy, doctors accepted the inevitable. Now, however, many possibilities are available to help a newly born infant in vital distress to survive, and this means that medical teams and parents need to consider whether they should be used and if so, until what limits are reached. Should everything possible be attempted, with the risk of attempting too much? Initiate resuscitation, or abstain; continue or withdraw support? How does one know if there is a "reasonable" certitude that such action will be beneficial? These are excellent examples of an ethical dilemma: conflict between several moral standards, all of which have a restricted degree of legitimacy. In this case, there is conflict between several benefits which may appear to be, or which may in fact be, contradictory. In any case, the action taken must always be justifiable and future consequences considered at the outset when an infant in distress is first taken into medical care. Keeping this in mind, the lure of performance for performance's sake and ensuring survival of ever younger infants, at the risk of severe future consequences for the child, is obviously non-ethical because it denies the notion of another's identity to satisfy either a narcissistic pursuit of personal satisfaction or a view of

medical progress which has become completely disconnected from its true object, that is the well being of patients.

All these possibilities, including extreme action, must be considered when discussing initiation of resuscitation, in spite of (or perhaps because of) uncertainty regarding consequences. At this point, several courses of action are possible and each one will have an impact on the subsequent number of options left open. Decision to undertake resuscitation to ensure survival leads to an acceptance of the risk of allowing a handicap to happen. If a child achieves respiratory autonomy while remaining dependent on highly intensive care, this situation is frequently the direct consequence of the initial decision to attempt rescue at any cost. Should one decide to refrain from systematic resuscitation of neonates in vital distress to avoid having later to decide on withdrawal of support ? It therefore does seem that all ethical considerations and responsibilities originate from the moment when the initial decision to resuscitate is taken.

Include parents

Respect for the dignity of the newborn implies respect for the family. What comes under the heading of free and informed consent when medical care for adults is in progress, in this case is the concern of those who conceived the child. Inclusion of the parents is therefore essential, because it signifies not only respect for the parents themselves, but also for the child, for the child within the family, and for the family itself. It is also the best course to prepare for the future or optimise future situations.

Information to parents should be imparted in a way which helps them see their way through a tragic ordeal and establishes a sense of partnership so that they are not left to deal unaided with questions and doubts. Support and counseling must start at the same time as therapy, and at the outset doctors must mention the possibility of adverse events.

Information must be as comprehensive as possible, and there need be no hesitation in mentioning points which are still uncertain. Information should be updated, re-evaluated and added-to on a continuing basis as and when the medical status of the infant in resuscitation evolves, regardless of any economic consideration. The duty to inform which is an essential component of the physician-patient relationship, has been recently restated in ANAES recommendations on information to be given to patients, encouraging doctors in particular to : define the information to be given; make sure that information is as objective and comprehensible as possible; think about how risks and healthcare should be explained (16). Respect for parents implies a joint quest for the most humane solution, committing both parents and carers. The strengths and weaknesses of parents who will have to look after the child once he or she leaves the intensive care unit must be included in the dialogue. Prospective medical data as well as their consequences as regards the child's capacity for autonomy and establishing a relationship with other people, must be explored without bias, and no attempt made to veil all the uncertainties which are inherent to medical prognosis in such cases.

However, although parental participation and talking with the medical team, the doctor and the carers are essentials, it is important to emphasise that in such a situation, communication has its limits. Even though prior objective information regarding risks may have been given repeatedly, there are situations in which one simply cannot take information on board. This is particularly true when there are major discrepancies between the reasoning and the expectations of the parties concerned. Dialogue and exchange can help to some extent; but there are situations in which willingness, information, and dialogue cannot close the gap between outlooks which are inevitably very far apart. In this event sufficient time for views to mature, the length of which may vary in situations which are always unique, and in different families where disagreement may emerge ; ambivalent behaviour and the expression of feelings of guilt which are so frequent should also be accepted willingly and taken into account. In this search for the most humane solution to the problem, it is not only useful but also necessary to associate several doctors and paramedical personnel, in particular nursing staff, and psychologists. They are best able to stay in touch with the way parents are progressing, their thoughts, fears, hopes, and evolving attitudes while their child is in intensive care. Teamwork, which is essential in any case, will be required to collect and compare the viewpoints of various actors regarding

medical considerations, and to be attentive to the expression of feelings of parents and family and their capacity to prepare for whatever the future has in store for them.

The extreme difficulty of making decisions in neonatal resuscitation situations is the reason why some medical teams may decide to invite other parties into the discussion. It can be useful to ask a physician who is not a member of the medical team in charge, who may or may not specialise in the management of handicapped children, to participate in discussions before a decision needs to be taken.

Should pre-decision discussions - when there is no urgent call for immediate action - include non-professionals, such as ethics committees or other ethical authorities, as is the custom in the English speaking world? According to certain opinions, one should not expect from those who are not directly responsible for actions and prescriptions a well-founded view and appreciation of the prognosis which is after all the very crux of the decision. If that is so, an outside view can only make procedures lengthier and more cumbersome, and there is also the risk of arriving at fairly stereotyped results depending on who is consulted. Nevertheless, CCNE notes with interest practices which include volunteers, particularly people trained by family and patient self-help groups. By providing a forum for an exchange of views, this could be a useful complement to the essential work done by psychologists and psychiatrists on the medical team to help parents and health providers - who may be under severe psychological and moral stress themselves, which also requires attention (10)

Coping with advancing neonatal distress

The points made above on the benefit of action in neonatal healthcare would be formulated differently depending on the child's progress since initiation of life support, action already taken, and updated medical data. Therefore, questions at different times will arise as follows :

Should resuscitation be initiated systematically for a newly born infant whose very early gestational age is combined with other risk factors such as very low birth weight, infection, and congenital anomalies ?

When it is known that there is no possibility of ultimate survival, should life-prolonging but futile resuscitation be continued ?

If medical work-ups demonstrate that a child is so severely damaged that extreme handicaps are inevitable, should the decision to withdraw support and avoid survival be taken ?

What should be done when infants are as severely damaged as in the previous case, but have regained respiratory autonomy while still needing intensive care ?

Emergencies

Emergencies in the delivery room pose a special kind of ethical problem. To act and inform are not necessarily compatible. The greater the risk for the newborn, the more urgent it is to take action. The ethical demand which calls for keeping parents informed and knowing their wishes may in such cases be difficult to satisfy. It is all the more difficult to pass on information because it can only be based on as precise a diagnosis as possible of the infant's condition so that an immediate and longer-term prognosis can be established. However, the time required to do so could delay initiation of resuscitation and other healthcare so that the infant's chances of survival and, more to the point, of handicap-free survival, are being lost. It is true that epidemiological studies contribute evidence on chances of survival according to various stages of gestation or various birth weights, and can help decision making, but this is always general information which is not sufficiently helpful in each individual case. As in other medical emergencies, the doctor's decision on whether resuscitation should reasonably be initiated can only be based on experience. Nevertheless, the doctor should try not to take a decision in isolation - which implies working in a medical team - and seek to inform parents as early as possible on existing situations and decisions pending, so that they may understand and participate, if a little tardily. CCNE also insists on the need for collegial discussion a posteriori which helps care providers, once the emergency and need to act is over, to analyse the events and decisions which have just taken place in the light of previously agreed ethical guidelines, so that

ethical criteria may be reinforced and guide action when new emergencies arise. Parents will also need ongoing attention and counseling, particularly in view of their bereavement, and this should help alleviate feelings of guilt which always emerge.

Initiate resuscitation or refrain ; continue or cease resuscitation

Although it is commonly considered that there is a difference in moral terms between action and omission (to provoke injury is worse than not doing anything to prevent it), as regards resuscitation there is very little difference between the two in real terms since both have the same outcome, death. As a result, a congruent ethical approach is difficult to achieve.

When at the time of delivery, the possibility of disability-free survival is nil or negligible, initiating systematic or standby resuscitation raises the issue of futile therapy. In this context, systematic resuscitation is only justified if survival chances are not zero but unfortunately, these chances cannot be precisely evaluated at the time when resuscitation is initiated. Resuscitation pending further evaluation is permissible if therapeutic obstinacy stops short of therapeutic obsession. In such a situation, discontinuation of resuscitation is the equivalent of discontinuing futile and aggressive therapy.

However, there may still be a conflict between the sanctity of life and principles of benevolence resting on a case by case evaluation of the benefits to be expected compared to possible consequences to be avoided. CCNE's Report n° 63 on the end of life - rather a far cry from the subject of neonatology - recognised the validity of such doubts and tried to give some indication of how to resolve them.

After standby resuscitation has been initiated, the question may arise of whether it ought to be discontinued if chances of short and medium term survival are thought to be non-existent or because of the exceptional gravity of lesions and extreme severity of long term consequences. Report n° 63 alluded to this phase when it stated inter alia that " Ceasing to provide respiratory or cardiac assistance simply means that the futility of such assistance – and thereby the imminence of death – is acknowledged... (...) these situations when therapeutic procedures are curtailed are consistent with a rejection of futile and aggressive therapy and should not be criticised on ethical grounds. "Other similar opinions state : " When a life survives only through pure technicality (i.e. resuscitation), and yet cannot offer the minimum vitality required for even limited existence,... putting a stop to technicality is not interrupting a life, it is simply interrupting the artificial suspension of death " (11).

In such cases, continuing resuscitation would simply become an intrusive travesty of therapy and furthermore mislead parents with illusory hopes that their child can be cured (12). A more humane approach with parents would be to acknowledge explicitly that medicine has its limitations. If an uncertain and ominous situation is clearly stated at the outset and explained step by step as it evolves, it will be easier to understand and to keep track of until all that can be done has been done. This can lessen the pain of travelling the path that leads from hope to accepting reality, and accompany the necessary process of mourning. Clearly, as long as the infant lives, palliative care is as mandatory as at any other age, and such care is the natural follow up of what up to that point aimed to cure.

Hope...and beyond

When the newly born infant has attained respiratory autonomy, and brain injuries which will lead to severe handicaps are discovered, neonatologists are placed in a situation where dramatic choices have to be made.

Such situations reveal earlier medical failures at various points : faulty and excessive medically assisted reproduction practices, defective monitoring during pregnancy, exaggeratedly early induction of delivery, prolonged anoxia during delivery... and technical heroics during resuscitation procedures as a result of obstinate attempts to remedy distress situations. Failure is aggravated by the fact that the community has devoted a great deal of effort to support reproduction and gestation but that those efforts have not been matched by sufficient human and financial resources to take care of disabled children. Everyone should feel concerned personally by this sequence of responsibilities. However, even if increasing awareness of such problems were to lead to preventive action which at some future time reduced the number of tragic situations, they will still occur, and they will have to be coped with.

The enquiry quoted in the first part of this report shows that a significant majority of French neonatologists consider that action with the overt aim of putting an end to the life of neonates whose condition is considered to be particularly "unbearable", particularly desperate, is "allowable" by their professional ethical standards. "This de facto acceptance raises a major ethical issue. Does it not encourage neglect of the factors which caused the situation in the first place and so neglect its prevention, whereas there is a real ethical need to limit to the fullest extent the advent of such situations ? This need is apparent at every phase of medical intervention in the process of reproduction and not just when neonatologists are involved. Physicians specialising in medically assisted reproduction, and obstetricians cannot just let neonatologists carry the burden of taking decisions when conditions they have helped to create arise. Developing research (imagery, neurosciences) and evaluation is an urgent requirement to reduce the number of situations where it is no longer clear whether resuscitation is necessary therapeutic obstinacy or unreasonable therapeutic obsession.

Nevertheless, unforeseen and extreme situations will always continue to occur. In particular, there are infants who attain respiratory autonomy but suffer from incurable and extreme long-term consequences of brain injury..

If ending life becomes an issue at this stage, it follows on the failure of earlier medical decisions to achieve survival with acceptable quality of life. Medical responsibility is directly involved at this point and adds a further deontological dimension to an already complex quest for the most humane of two courses : allow infants with grave infirmities to survive, or cause them to die.

The approach suggested by CCNE in its reflections on the end of life cannot be given here for identical reasons. It was based on notions of human solidarity and compassion in an end of life situation which the patient felt to be unbearable and beyond the reach of attenuation through palliative care. With newly born infants, to whom are their lives unbearable ? Does the child's suffering take second place behind the fact that brain-dead life lingers on and becomes "unbearable" for the family who will have to deal alone with the burden of caring, or for the medical team who view the outcome as one of their failures, or for the community which has to spend considerable sums to care for a life that will never develop or flourish ? Given that the attitude of medical teams when faced with the results of a decision for which they are accountable is a deontological issue, and that economic considerations cannot take precedence over ethical considerations in such cases, then parents' positions come to the forefront. It may be the perpetuation of brain-dead existence, devoid of any possibility of relationship, that parents find unbearable, rather than death itself. "In a situation where a child is obviously incapable of consenting to anything, and will always remain so, no one is more directly concerned by the child's fate than are the parents.

They see their child in a singular light : the birth, the trials and tribulations, the fragile survival, have left impressions which cannot be overestimated. In such dramatic situations, a human approach calls for the possibility of expressing parents' deep feelings but not allowing these to be totally distorted by unendurable feelings of guilt. It is precisely in such tragic moments that the issue of a medical ending of life sometimes arises.

It is clear that this would be an obvious transgression of the law which prohibits any assault on human life. However, when faced with tragedies for which no satisfactory solution can be found, there could perhaps be a measure of understanding for such transgression. Whatever outcome is chosen, whether or not it constitutes a transgression of texts of law as they are now applicable, there must be a guarantee that the decision is taken as a result of conscience-bound, humane, open and progressive processes, with due regard for the wishes of parents who alone are able to measure the burden of the life ahead of them.

A fitting ethical approach to these tragic and tormenting predicaments must therefore eschew dogmatic and harsh statements of certainty and instead seek a humanely tolerable solution in a spirit of humility, hesitancy, respect, and willingness to engage in thorough analysis. All aspects of the problem must then be examined and, in spite of their diversity, they all generally include two fundamental characteristics :

These situations are at the heart of diverse expectations, demands, and potentialities. The role of parents is paramount whenever the values of healthcarers and family are in conflict.

They bear the seeds of an ethical contradiction in time, since the immediate good intentions of resuscitation may be the cause of future transgression.

Key words to find a path in these situations appear to be : responsibility, discernment, and humanity. Responsibility is incumbent on the medical team whose difficult task it is to face up to each new difficulty with fortitude and do their best, give the child every chance of pulling through, knowing that they will be accountable for their decisions and will not have the option of simply spiriting away the consequences of their failures. The team's capacity for discernment will have already been put to the test when responsibility for initiating resuscitation was shouldered, or for deciding to discontinue futile resuscitative efforts, or on the contrary, prolong them. Finally, there are cases when functional prognosis is poor, but the child still lives. In these circumstances, the medical team should surely not be allowed to decide alone on ending life, since this would amount to giving them the possibility of cancelling out their failure. However, it is certainly the task of healthcareers in a continuing dialogue with parents, to help them understand what the fragile spark of life which persists, but will never be kindled by conscience, means for them. At this point, humanity with its characteristic values of compassion and solidarity, steps in. The medical team with the help of other disciplines, the human sciences in particular, and/or representatives of families, must try to ensure that an independent decision by parents, either way, is not constrained by guilt feelings.

At the last, it must be the physician in charge of the medical team who acts on the decision, which still remains a transgression of the unbreakable law that life must be preserved. Those concerned must accept the possible consequences and be ready to justify a collegial decision of "responsibility, discernment, and humanity" which to their minds, justified the action.

Ethical reflections as proposed here by CCNE call for a recognition that everything possible must be done so that :

- failings in the prevention of vital distress situations at birth,
- initial over-aggressive therapy decisions,
- striving to break medical performance records

are criticised to the extent that situations which sometimes lead to acts which will always be grave transgressions become increasingly rare in the near future.

These necessary efforts should not blind us to the lack of social investment in the management of disabled children. CCNE calls on society to accept the responsibility of correcting these shortcomings.

September 14, 2000

Bibliography

[1] Grande prématurité, dépistage et prévention du risque, Editions INSERM, 1997, 280 p.

[2] Blondel B., Norton J., Mazaubrun C. de, Bréart G. (2000), Enquête nationale périnatale 1998, Ministère de l'Emploi et de la solidarité, INSERM.

[3] Dossier FIVNAT 1999, Bilan de l'année 98. .

[4] Laroque B. (2000), Naissances avant 26 semaines : les premiers résultats d'Épipage, Actes des XXXèmes Journées Nationales de Néonatalogie, 8 et 9 juin 2000, Paris.

[5] Chabernaude J.L. et al. (2000), Devenir de 126 prématurés nés avant 26 SA pris en charge par les SMUR pédiatriques d'Ile de France de 1995 à 1999. Communication aux 11^{èmes} Journées de Néonatalogie de l'Hôpital St Antoine/Trousseau, 16 mars 2000.

[6] Truffert et al (1998), Outborn status with a medical neonatal transport service and survival without disability at two years. A population-based cohort survey of newborns of less than 33 weeks of gestation, European Journal of Obstetrics & Gynecology and Reproductive Biology 79, p. 13-18.

[7] Wood N.S. et al. (2000), Neurologic and developmental disability after extremely preterm birth, New England Journal of Medicine 343(6), p. 378-384.

[8] Baud O., d'Allest A.M., Lacaze-Masmonteil T. et al. (1998), The early diagnosis of periventricular leukomalacia in premature infants with positive rolandic sharp waves on serial electroencephalography, J. Pediatr 132, p. 813-817.

Fatal/terminal illness	61 (55-67)	76 (69-83)	85 (77-91)	86 (79-91)	81 (77-84)	77 (69-84)	96 (85-99)
Poor neurological prognosis	46 (39-54)	61 (50-70)	85 (77-90)	69 (56-79)	78 (71-83)	74 (60-85)	90 (82-95)

Table 3: Proportions of physicians who had ever decided (alone or with others) to set limits to intensive interventions

Decision	% of physicians (95%CI) who had made decision						
	Italy	Spain	France	Germany	Netherlands	UK	Sweden
To withhold intensive care*	45 (36-54)	75 (67-81)	63 (55-71)	69 (59-78)	85 (78-91)	81 (73-87)	88 (78-94)
To withhold emergency treatment/manoeuvres**	52 (46-59)	65 (59-71)	75 (68-81)	74 (62-83)	83 (78-87)	80 (71-86)	90 (80-95)
To continue current treatment without adding others	78 (74-81)	92 (86-95)	76 (65-84)	86 (78-92)	75 (66-83)	71 (62-79)	97 (90-99)
To withdraw life-saving drugs	34 (26-42)	48 (38-59)	50 (41-60)	79 (70-86)	71 (60-80)	64 (59-68)	53 (39-66)
To withdraw mechanical ventilation	28 (18-41)	36 (26-47)	66 (55-75)	61 (48-73)	89 (84-93)	83 (75-89)	90 (82-95)
To administer sedatives/analgesics to suppress pain even at risk of respiratory depression and death	32 (24-43)	64 (56-72)	87 (81-91)	67 (56-76)	89 (80-94)	70 (59-79)	86 (74-93)
To administer drugs with the purpose of ending life	2 (1-5)	2 (1-6)	73 (63-81)	4 (1-14)	47 (33-60)	4 (2-9)	2 (1-8)

* For example, resuscitation at birth, mechanical ventilation

** For example, resuscitation for cardiac arrest

Table 4 : Proportions of physicians who had made specific decisions

Decision	Adjusted % of physicians (95%CI)						
	Italy	Spain	France	Germany	Netherlands	UK	Sweden
To withhold intensive care	36 (25-48)	86 (79-91)	73 (63-81)	75 (63-84)	93 (88-95)	91 (84-95)	80 (66-90)
To withdraw mechanical ventilation	23 (15-33)	38 (24-54)	76 (64-84)	69 (56-80)	93 (86-96)	89 (80-94)	88 (76-95)
To administer sedatives/analgesics	26 (18-38)	67 (55-78)	92 (87-95)	74 (65-82)	92 (85-96)	78 (66-87)	82 (65-91)
To administer drugs with the purpose of ending life	86 (74-93)	..	45 (23-69)

Proportions are adjusted for all variables included in logistic regression analyses (except country).

**Table 6 : Adjusted proportions of physicians who had made specific decisions
Annex 2 (suite) EURONIC enquiry, French results (in [15])**

Tableau 1 : " Lesquelles de ces conduites considérez-vous comme acceptables pour limiter les soins intensifs dans les situations où l'on a choisi de le faire ?"

	"Acceptable"	
	Médecins % (IC 95%)	Infirmières % (IC 95%)
S'abstenir d'entreprendre des soins intensifs (par ex. réanimation à la naissance, ventilation artificielle)	67 (58-75)	56 (50-61)
S'abstenir de pratiquer des gestes ou des traitements d'urgence (par ex. réanimation d'un arrêt cardiaque)	82 (76-86)	66 (61-71)
S'abstenir d'entreprendre une intervention chirurgicale	85 (77-91)	66 (60-72)

Continuer le traitement courant mais ne pas ajouter de nouveaux traitements	83 (74-89)	78 (73-82)
Administrer des sédatifs et/ou analgésiques pour supprimer la douleur même si cela peut entraîner une dépression respiratoire et le décès	96 (91-98)	89 (86-92)
Administrer des drogues afin de mettre un terme à la vie du patient	73 (64-80)	77 (69-83)

NOTE DE M. HENRI CAILLAVET

Reflection focused on the consequences of two major imperatives - on the one hand prevent whenever possible vital distress situations at birth, and on the other, if they occur, to act with gentleness, humanity, and compassion - are in descriptive terms very seemly. However, to revert to basic values, I consider that what this document specifically omits to report, except to mention rare exceptions left to the appreciation of the medical team, is that resuscitation for gestational ages of less than 28 to 30 weeks, very frequently connected to malformation, should almost never be initiated. Nor should it for a very low birth weight.

A fortiori, when survival seems out of the question, the medical team should immediately discontinue resuscitation. In that case, if ill-advised resuscitation has been initiated, it is morally unacceptable to ensure survival of an infant whose massive brain injuries will also give rise to severe disability.

Finally, even if medical intervention has allowed an infant to regain respiratory autonomy, it is still not acceptable to continue intensive care in the presence of the massive injuries mentioned above.

I also believe that the report is rather weak on two counts. Firstly, it does not put sufficient stress on prevention (advanced imagery, systematic amniocentesis, etc.). If preventive measures became almost routine, parents would be less frequently subjected to such tragic ordeals, and major financial expenditure for doubtful results could be saved.

Secondly, while paying tribute to the noble and generous ideals of medical teams, in spite of some instances when a wish to excel underlies medical commitment, we must not forget that while we save or try to save a preterm infant whose future life is uncertain, many hundreds of thousands of perfectly normal children, even in Europe, are the pathetic victims of for example, malnutrition, poverty, and the ravages of pandemics, which threaten their very life expectancy. This obviously is an authentic cultural problem which goes beyond purely social or budgetary concerns.

HENRI CAILLAVET

September 22, 2000

Note By MICHEL BORNANCIN

By not voting for this report, I am not passing judgement on the decisions and actions of those who do as their conscience dictates in very painful and troublesome circumstances. I believe that in so doing I am part of the majority of people who, on an individual basis, refrain from blame and condemnation. However, if such individual positions became a form of collective, global and in a way anonymous, agreement by society as a whole, as the latter part of CCNE's report seems to advocate, I fear that it could be regarded as an invitation to shut our eyes and close the discussion. In agreement with the general tenor of the Committee's text, I prefer to urge society to remain vigilant and to reflect on the social and individual consequences of practices in which technology plays a major role and which lead adults to control and "rule" childhood and childbirth.

MICHEL BORNANCIN

September 26, 2000

Notes

(1) Out of 750 000 births.

(2) National results for in vitro fertilisation .

(3) Letter dated July 1993 signed by the Directeur Général de la Santé.

(4) G.Cornu, Droit civil, Introduction, les personnes, Montchrestien, 8e éd. 1997, p. 164.

(5) In this context, see Irène Théry's summary in Couple, filiation et parenté aujourd'hui, Ed. Odile Jacob, 1998.

(6) Technical progress, health and societal models : the ethical dimension of collective choices, n° 57, May 25, 1998.

(7) Opinion on embryonic and foetal reduction, Opinion n° 24, June 24, 1991; Opinion on the evolution of practices concerning medically assisted procreation, March 30, 1994; Re-examination of the laws on bioethics, Opinion n° 60, June 25, 1998.

(8) Ruling dated January 12 1999 (Official publication of 28-2-1999), concerning rules of good clinical and biological practices in medically assisted reproduction procedures. The ruling specifies that the number of embryos to be transferred should ideally be no more than two. If more are transferred, justification must be given in the patient's medical file.

(9) Cf. J.-F. Germain, Neontal resuscitation, ethics at the boundaries of life, (La réanimation néonatale, éthique aux limites de la vie), PUF, 1999.

(10) Cf. F. Molénat, Sur la souffrance des soignants, Mères vulnérables. Les maternités s'interrogent. Stock, 1992. 341p.

(11) D. Folscheid quoted by J.F. Germain, op.cit., p. 33-34

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