Evolution, impact and application of bioethics in the newborn

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Abstract
We describe the application of bioethics with a practical approach in the newborn. We discuss ethical dilemmas such as in vitro fertilization, umbilical cord blood banks, neonatal screening, gene therapy, anencephalic children as organ donors, circumcision, the newborn as a subject of clinical research and types of representative bioethical diseases. Bioethical aspects are discussed in those children born preterm at 24 weeks of gestation or less and its quantitative impact on society as well as the initiation and evolution of bioethics in these children. We also describe four paradigmatic cases related to Baby Doe and the impact leading the world to change the design of bioethics.

We discuss the Netherlands Groningen Protocol and we later describe the evolution and importance of clinical bioethics committees (CBC) focused on the newborn, which relates to an actual case methodology at the Children’s Hospital of Mexico Federico Gómez. We conclude with a set of bioethical reflections relating to its application in the newborn.

Key words: bioethics; neonate; bioethics committee, Groningen Protocol, prematurity, Baby Doe.

Introduction
In order to apply the principles of bioethics in ethical dilemmas that present themselves in the newborn, it is necessary to understand its evolution and the specific times that require certain actions for its application, as well as the changes that have taken place through actual examples that have impacted the medical and scientific conscience and the way in which the analysis of each particular case should be focused by the clinical bioethics committee (CBC).

Bioethics, day to day, acquires greater importance in regard to its application to humans. An example of this is that in November 24, 2009, U.S. President Obama signed an executive order to create a presidential commission for the study of the different aspects that science has before the emergence of bioscience advances, as well as the area related to science and technology. That commission will work with the objective of confirming that the norms and practices of scientific investigation in health care and technological innovation will be conducted in an ethically responsible manner.¹

Grounds on which bioethics is applied in the neonate
The application of bioethics focused on the neonate is usually performed in the neonatal intensive care unit (NICU) where the majority of ethical dilemmas are most often present and can be grouped into three major categories:
1) extremely premature infants  
2) infants born at term or post-term and who are seriously ill  
3) infants born with congenital malformations

However, there are more than those three groups that present themselves in clinical practice. A common aspect in all these groups is the need to perform frequent cardiopulmonary resuscitation where the ethical principles of dignity, integrity, responsibility, virtue, and vulnerability should always be taken into consideration, which guides the work of the profession.\textsuperscript{2,3} It is said that dignity in life has no price, particularly for humans. Integrity refers to an entity considered as a whole, which is in order according to its nature, that is a free and rational human being. The principle of responsibility points to our commitment to the exercise of freedom with the future. Cardiopulmonary resuscitation is intended to overcome cardiopulmonary collapse, trying to avoid irreversible consequences that would affect the quality of life. It is not sufficient to want to do good, one must learn to do good and to do it well and as perfectly as possible where the possibility of adverse events are not ruled out. It is a common error in medicine to make demigods among its practitioners. Beyond the three major categories of groups mentioned is the fact that the list of bioethical dilemmas is extensive. In this paper we discuss at length the bioethical dilemma that corresponds to premature birth at 24 weeks or less gestation. With the exception of the latter, the most transcendental and common causes will be enunciated, of which a brief commentary will be made related to bioethics and for each at least one recent citation that amplifies the information is complete.

**Neonatal screening**

Regarding this topic, it is worth mentioning that there is a report of more than 178 pages prepared by the U.S. President’s Council on Bioethics in 2008 which questioned the relevance of bioethics to continue or not to expand the number of conditions that can be identified by neonatal screening or to only be restricted to those that meet some of the following conditions that in general continue to support the Wilson and Jungner criteria:\textsuperscript{4}

- The disease should be an important problem in public health
- There should exist an accepted treatment for the disease
- There should be specific diagnostic procedures and adequate treatment available.
- It is required to know precisely the natural history of the disease, including from a possible latent state up to declared disease.
- It is recommended to not include in the screening other illnesses that do not meet the prior conditions and only perform screening study requested by the parents with the understanding that it would only be used for research.
- The cost of the identification of the cases, including diagnostic confirmation and treatment, should be in balance with total cost of the medical care.
- The simple approach of studying a multitude of ailments in a single sample under the same laboratory team only because it is possible, even when not justified, the disease is not known with certainty, and there is no defined treatment should be rejected.

In Mexico there is great variability in the determination of the number of screening tests performed on the neonate. It goes from performing the obligatory screening for congenital hypothyroidism and extends past that noted in the NOM-034-SSA2-2002 (which although not obligatory recommends that phenylketonuria, congenital adrenal hyperplasia, galactosemia, cystic fibrosis, maple syrup disease, and homocystineuria be
performed\textsuperscript{5}) up to the extent that some private institutions perform screening for 64 diseases.

**Cord blood and other tissue banks**

Biological banks including blood banks are typically considered matters of investigation; however, under the topic of genomic medicine, it is probable that in the future they will become a necessary tool for the physician.\textsuperscript{4} With these tissue banks, among other matters these topics can be studied: family history, genotype of a great number of patients, and the ability to ratify these facts with the precise recorded medical history over many years. However, in cases where a carrier of a rare genetic alteration is identified by a defective and harmful gene, devastating effects are produced for the family. In addition to the fact that other persons stigmatize and discriminate against them, it also causes anxiety and depression among its family members. This is the reason why it is so important that informed consent be obtained for this type of study.\textsuperscript{6}

**“Test Tube” babies and in vitro fertilization**

There are conservative and liberal positions in this regard, from those who defend only natural reproduction and who are opposed to even have gametes provided by the couple, up to those who accept in vitro fertilization of a donor, having as a condition that the gamete come from one of the partners, and that the use of the donor be due to necessity because one partner cannot produce a gamete or is a carrier of a sexually transmitted disease or a disease of inborn error of metabolism.\textsuperscript{7}

**Gene therapy**

This can be done during fetal development, replacing the defective gene for another. However, the consequences that their introduction would have on other organs, devices or systems of the fetus is not known with certainty. In the case of the newborn there are therapies that replace a missing or defective enzyme of metabolism such as some variants of mucopolysaccharidosis.\textsuperscript{7,8} It is noteworthy that these therapies currently only improve the quality of life. In the end, in most cases the individual dies and, depending on the variety of the disorder, this happens during school age or adolescence. Some ethical questions raised concerning gene therapy are “Which gene therapy should be initiated first? Cystic fibrosis first and then phenylketonuria, or vice versa?” Or “Why was this type of therapy started for mucopolysaccharidosis?”

**Anencephaly and organ donations**

Some transplant surgeons, parents of children with anencephaly, medical ethicists and legislators have proposed that children with anencephaly may be used as organ donors. However, due to the analysis of medical, bioethical, and legal issues surrounding these children, the general tendency is to reject that position. It is considered that there are insufficient and convincing arguments to modify the behavior of not using these children as organ donors and, if they do, this should be analyzed by the Ethics Committees for Human Research so that they should be subject to the regulations and standards that exist from the ethical point of view for these purposes.\textsuperscript{7,9,10}

**The neonate as subject of investigation**

When the history is reviewed and development of the investigation is applied to the newborn, it is observed that during the years 1940-1980 in many countries, treatments with new medications or with certain equipment and substances was carried out without investigation protocols done that included bioethical aspects. This caused considerable consequences, irreversible damage and even the death of many neonates.\textsuperscript{11} In the following decades, with the establishment of Research
Bioethics Committees in a number of countries, including Mexico, this has improved. However, several bioethical issues remain to be considered, such as medication administration in the newborn. Although the use of these medications has been approved in children, they are not approved for use in the neonate or, indeed, are used in the newborn without even being approved for children.

Circumcision

Some agree that the arguments to perform circumcision in the neonate have, in very specific cases, sufficient medical support, while others consider the practice is not synonymous with good medical practice in which justice is applied, maintaining bodily integrity, autonomy and analogy with the mutilation of female genitalia.12-14

Diseases with ethical problems

Ethical dilemmas often present “pro and con” positions where the discrepancies are fundamentally focused on the assumption that in a period of days or months the baby will die and, by keeping the infant alive causes greater suffering.7,15-19 Examples include the following:

- Extensive myelomeningocele and hydrocephalus
- Grade IV intraventricular hemorrhage and extensive brain damage
- Hypoplastic left ventricle
- Extensive hydranencephaly
- Short bowel dependent on total parenteral nutrition
- Trisomy 13
- Trisomy 18

The latter are the most common autosomal trisomies in newborns; on average, 75% of children with trisomy 13 die on the first day of life and 80% die with trisomy 18; however, at the end of first year 11% of patients with trisomy 13 and 10% with trisomy 18 survive. This is the reason for the importance of prenatal diagnosis. The earlier it occurs, the greater possibilities that exist for treatment.

Quantitative dimension of prematurity

To measure the impact of prematurity, we have the example of the U.S. On average, four million babies are born annually, of which 500,000 are <37 completed weeks of gestation and of the live births, 12-14% are admitted to a NICU. In the U.S., if the baby is born after 30 weeks, the chances of being discharged alive from the NICU is 90%. However, it is also true that the frequency of cerebral palsy, developmental delays and problems with vision or hearing is about 20%, a percentage that increases to 50 or 60% in those born at 24 weeks of gestation. Of those infants, and depending on the publications, the mortality rate is 60-70%. It increases to 75-80% in those infants at 23 weeks and in the case of those born at 22 completed weeks of gestation, it is usually 95% or higher.20 In Mexico, neonatal mortality rates have declined from 15.2/1,000 in 1980, to 10.3 x 1,000 live births registered in 2005. The leading causes of death were multiple organ immaturity and congenital structural defects.21 In 2006, in the Mexican Social Security Institute (IMSS), 75% of the mortality cases (first 7 days of postnatal age) were associated with prematurity and in the case of neonatal mortality (first 28 days), prematurity accounted for 40% of those deaths.22 In addition to the impact on mortality and sequelae from prematurity, it is clear that every time there is greater survival at lower gestational ages, other ethical problems are generated. In Mexico, the Health Act indicates that a birth weight of <501 g or <22 weeks, the product of that pregnancy is considered to be an abortion, and although this concept as such does not apply in France, in this country no resuscitation or other treatment
is done for any infant weighing <500 g or <24 weeks of gestation. This is in contrast with other experiences where even at 22 weeks of gestation, some groups of neonatologists opt to administer resuscitation at birth and continue life-sustaining treatment.20,23-25

Beginnings of bioethics in neonatology
With neonatology being one of the most successful disciplines in modern medicine in the second half of the 20th century, it is considered “an innovation that is not an innovation”, a term meaning that there was no “eureka” moment to place the key of a momentous innovation in this subspecialty of pediatrics. Nor was there a particular individual who can be considered the “founder of the field” or a moment that can define the first success. It is more difficult to identify the beginning of bioethics in this discipline. However, considering the impact, it arbitrarily had its beginnings in the use of incubators in premature infants. A good example in which bioethics should have been applied for the newborn was when, without informed consent of parents, live preterm infants in incubators were presented in several exhibitions in the U.S. exprofeso in an exhibition instead of a hospital. Here preterm infants were visited by the general public. This exhibition was so successful that participants repeatedly returned to watch the babies, as occurred with the Pan-American Exhibition in 1901 or 1907 in Jamestown exhibition (Current Virginia Norfolk Naval Base) to commemorate the 300th anniversary of the arrival of the English to “America.”26,27 Perhaps one of the first examples of evidence in this respect was when, in 1968, Jerold Lucey, a well-known neonatologist of those years, said “in order to reduce infant mortality and with the firm hope to increase the number surviving intellectually intact … . It can be considered too early to judge the overall effectiveness of these efforts.”28 Another important moment came in 1972 when Dr. Mildred Stahlman, also a neonatologist, hosted a meeting entitled “Ethical Dilemmas in Obstetrics and Newborn Care.” One participant, Dr. Wolf Zuelzer, posed the following questions related to ethical dilemmas:

“Who should make the decision that would deprive a human being, even if defective, the possibility of life?”

“What criteria should we use in these cases, in medical, genetic, sociological and psychological terms?”

“What guarantees will be necessary for our protection against a Hitler non-eugenics type of destruction?”28

At the same meeting, Joseph Fletcher, medical ethicist and theologian, argued that the utilitarian principle that the end justifies the means allows the inference of four options for those “babies born abnormal”:

1. Kill them
2. Starve them
3. Do not help them
4. Treat them and protect them

With regard to the above, he said:

“Are the first three not different degrees of the same? Morally speaking is there any difference between them? I say, he said, that among them there is no difference and that their goal is the same: death of the newborn.”28

It is important to consider in a neonate, as during other ages, the definition of terminal illness as described in the Manual of Ethics of the American College of Physicians is an inexorable condition that no matter whether treatment is received or not, the patient will probably die soon.29 On the assumption that the main goal of medicine, during the initial stages of any illness, is to control or cure the patient even if this means in many cases aggressive treatment, it is also true that the
ideal from the medical point of view is to manage any patient “with the principle of therapeutic proportionality.” This principle holds that there is a moral obligation to implement all therapeutic measures proportional between the means used and the predictable result. In this way, those measures in which the relationship of proportion are not met are considered disproportionate and would not be morally binding. It is important to note that the judgment regarding the proportionality of a particular medical intervention should be done in reference to the overall benefit of therapy and not only in relation to possible physiological effects that it is capable of inducing.

Bioethics of the newborn: paradigmatic cases in premature infants <24 weeks gestation
During the evolution of bioethics in neonatology there have been a variety of examples of babies who, for various reasons, have been the subject of deep reflection, not only medical but also ethical, whose reasoning and rationale expressed by physicians, ethicists and philosophers are generally divergent among them.

However, these examples have given rise to changes in prevailing thoughts and decision-making. For this reason they can be considered as paradigms on the basis of the definition that the scientist philosopher Thomas Kuhn wrote: “In science, a paradigm is a set of exemplary experiments that should be copied or imitated because they change what up to this moment was considered to be definitive...the paradigms are immeasurable, which means that two paradigms, simultaneously, cannot be reconciled one with the other because they cannot be subject to a common measurement or standard of comparison...that is, that no comparison between them is possible unless fundamental modifications are made in the concepts that are part of the paradigm with what is being compared.” Although it is strictly not the case of examples to be mentioned, the concept of the paradigm applied here is founded on the adoption that social researchers have made of the Kuhn concept (“change paradigm”) to highlight a change in the way in which a society organizes and interprets reality. A “dominant paradigm” refers to the values and systems of thought in a stable society at a given time. These are shared by the community’s cultural background and historical context at the moment. The latter concept is the one selected for use of the word paradigm.

The case of Vera Cáslavská
When Dr. Luis Jasso Gutiérrez (one of the authors of this paper) was a graduate intern on call (which is no longer required for preparation of specialists in Mexico), in 1968 he delivered on October 2 a baby weighing 520 g and with confirmed gestational age of 25.6 weeks (since the mother had undergone curettage and the baby who was born October 1 of that year had that gestational age). He was admitted to the then-named Hospital of Pediatrics, Centro Medico Nacional, Instituto Mexicano del Seguro Social (CMN, IMSS) with signs of respiratory failure and with Silverman scores ranging from 5-6. At that time, preventive treatments were not incorporated such as steroid administration prior to the onset of preterm labor or therapeutic measures such as total parenteral nutrition or negative or positive pressure ventilation, which were initiated several years later, only to name a few therapeutic measures implemented during those years. The female infant developed an idiopathic respiratory distress syndrome or hyaline membrane disease (as the current respiratory distress syndrome of the newborn was then called). She remained in the incubator with intermediate moisture, oxygen concentration 60%, 5% dextrose intravenous solution, accompanied by sodium bicarbonate (important success of Robert Usher at McGill University in 1963), as well as oral administration of etilefrine (Effortil) used as a circulatory stimulant for the frequent periods of apnea. In addition to this, “careful bagging” was carried out when the apnea was prolonged. This
was identified through constant visual surveillance because no monitors were available at that time. The infant survived, breaking the paradigm of the time (for those of us as interns and residents and physicians of the neonatal intensive care unit) that children born ≤28 weeks of gestation had no chance of survival due to anatomic characteristics of the respiratory tract and almost no production of alveolar surfactant. Although it was not published in any national or international journal, according to the ethical standards of its time, it is a case that at the time was paradigmatic. In conclusion, “Vera” (as she was called by Dr. Jasso in honor of the great Czech gymnast and Olympic medalist of the Olympics held in Mexico, 1968) was released from the hospital and evaluated periodically during follow-up consultations initiated since 1963 by the attending physician Dr. Ernesto Diaz del Castillo. She was followed up until 6 years of age during which time her growth and development were within normal limits.

The case of Baby Doe

On April 2, 1982 baby Jane Doe (Baby Doe) was born in Bloomington, Indiana, with Down’s syndrome and esophageal atresia. She died from deliberate starvation on April 16 of that year as a result of not receiving any medical treatment. This was because the parents decided that this was best for her, a situation that had the consent of physicians and judges. This led to conscientious objection throughout American society and, in 1984, an amendment to “The Child Abuse and Treatment Act” was published, which in 1985 became the Baby Doe law. It specified that “all children with deficits and in conditions of imminent danger to life will receive proper nutrition, hydration and medications that the physician must provide ...with reasonable therapeutic judgment, which are likely to be effective to alleviate or correct the situation.” Despite the existence of the Baby Doe law, 3 years later the results of a questionnaire administered to members of the perinatal section of the American Academy of Pediatrics (AAP) were published in which the strong disagreement with it became very clear, based on the following results: 76% considered that the law of that time was not essential to protect the rights of children, 66% thought that it interfered with the rights of parents to determine what course of action was in the best interest of their child, and 60% of respondents said that legislation does not allow adequate consideration of the suffering of children in response to three hypothetical cases of severely affected infants. Also related to the Baby Doe case, former President Ronald Reagan, who from the beginning disagreed with the decision made on that case, wrote the following a few years later: “What more dramatic confirmation could we have of the real problems of Baby Doe? Her death has broken the hearts of the American people on having denied life to a child who, undoubtedly, was a human being who laid impotent before the eyes of physicians and the nation...

The issue for the court was not if the baby was a human being but if it should protect her life, which would probably have been one of mental disabilities and who only needed a routine surgical procedure to correct her esophageal defect. It concluded by stating: “A physician testified before the judge that in spite of the surgery, the baby would not have a minimal and adequate quality of life. In other words, her mental retardation was the equivalent of a death sentence for a criminal.” As a result of this, there was an amendment to “The Child Abuse and Treatment Act of 2002”, which specified that public hospitals could only be federally funded when, in the event of death due to futile treatment provided in the death of a baby, one of the following conditions had to be met:

1) The child was in an irreversible coma.
2) The establishment of treatment prolonged the time to death and was not effective in improving or correcting all life-threatening conditions.
3) The initiation of treatment was virtually in vain and, if applied, by itself is harmful to the child.

Despite the above and to the poor response from the community of neonatologists, in April 2005 the Department of Health and Human Services (DHHS), reinforcing the statement in the amendment of 2002, said: \(3^{35}\) “As a matter of law and regulations, the DHHS routinely investigates all cases in which individuals or entities report the suspension of medical care of a live newborn where there is a potential violation of federal statutes and will investigate any evidence in which a systematic review was not done in the presence of a ‘prudent observer of the law’ so that he may make conclusions about the appearance or relevant behavior that the infant is suffering from an ‘emergency medical condition’.” Despite these rulings, there were public actions against this amendment because on the judgement of those who were against it, there was no specification in the amendment to what was called a ‘prudent observer of the law’ or what was meant by an infant that was suffering from ‘an emergency medical condition’. \(3^{36}\)

The case of Amillia Taylor

This female infant is considered, so far, as one of the paradigmatic cases of extreme prematurity to have survived. “Amillia” was born at Baptist Children’s Hospital in Miami, Florida on October 24, 2006 after just 21 weeks and 6 days of gestation and with a weight of 283 g and length of 23 cm. She celebrated her second birthday in 2008. The child received medical treatment including everything related to life support because physicians believed her gestational age was longer than 21.6 weeks. They even acknowledged that if they had realized the true gestational age from the beginning, no treatment would have been provided. At the same time as the case of “Amillia” was being discussed, there was a debate in the English Parliament. Taking this case as the basis, it was proposed to reduce the limit of viability to 22 weeks of gestation because it was possible to survive at this gestational age. This argument was not accepted by the English Parliament in spite of the fact that they themselves, in 1990, had reduced from 28 to 24 weeks the limit of viability. They argued that cases like “Amillia” are rare or exceptional, so that by agreeing to reduce the threshold of viability false expectations regarding survival may be raised. \(3^{38}\)

The case of Violeta

Annie Janvier wrote about her experience on the birth of Violeta, her daughter of 24 weeks gestation. She and her husband were neonatologists at McGill University in Montreal, Canada. Her knowledge and experience on the consequences regarding the mortality and neurological sequelae of infants born at gestational ages at the limits of viability led Annie, on more than one occasion, to suggest that physicians discontinue Violeta’s treatment. Moreover, her husband, with the same professional knowledge as Annie, ignored the above and clung to the human desire and hope of the chances of his daughter’s survival, as she showed significant signs of life. Violeta improved and, judging by her parents, has had good growth and development. \(3^{39}\) With this experience, the married couple dedicated themselves to publishing various considerations and experiences on the subject. In a survey performed on 290 residents and nurses involved in perinatal care, the following were asked:

“Would you resuscitate a depressed infant at birth with a gestational age of 24 weeks?” The answer, in only 21% of respondents, was that they would have performed resuscitation at the time of birth. The next question was:

“Would you resuscitate a depressed infant born with 50% chance of survival knowing that for those who survive, 50% would develop within the normal range, 20-25% will have significant
consequences, and 40% will have behavioral and/or learning disorders?”

In this scenario, 51% answered yes they would have resuscitated ($p <0.05$). Their conclusions were that the decision to not resuscitate an infant of 24 weeks was surprising, given that the prognosis for such children is the same or better than the one described according to the other scenario in which only statistical data were provided without including gestational age.40

Case of Layden Capewell
Sarah Capewell gave birth to her infant daughter Layden in the James Paget Hospital in Gorleston, Norfolk, England on October 2008 at 23 weeks gestation. The physicians stated that she refused to see her infant and she died within hours of birth without any medical support. Sarah states that she did see the baby and saw her breathing without assistance, with an intense heart beat, and that she moved her arms and legs, and that in reality what happened was that the physicians did not admit her to the NICU due to the current guidelines (of the British Association of Perinatal Medicine, written by the Nuffield Council on Bioethics in 2008).41,42 The guidelines state that if the gestational age is precise and is <23 weeks + 0 days, for the best interest of the child and according to standard practice, no process of resuscitation should be performed. However, it also points out that if the newborn had a gestational age of 22-23 weeks of gestation, and the parents request that life support continues, it should be continued, if and when the short- and long-term consequences of what to expect were clearly explained to them. Currently, Sarah is an activist in England, working so that the guidelines for management of the very premature child can be changed. These stories as others43 illustrate the different aspects that should be taken into consideration in the care of extremely premature infants of short gestational age, such as the right to life and the concept of parental autonomy. These should be balanced with other essential principles such as distributive justice, the best interest of the child and the autonomy of the physician. Its applications in practice will certainly offer better results in decision making.

Groningen protocol
Eduard Verhagen and Pieter Sauer, pediatricians at the University Medical Center of Groningen, The Netherlands, published in two prestigious medical journals in the U.S. the protocol.44,45 The purpose of the protocol is to standardize medical practice for physicians to end the life of a seriously ill newborn in a responsible manner. It is supported in well-defined legal procedures. The report should be sent, prior to the decision, to the medicolegal authority, which should arrive at the place where the newborn is and, in case of the infants absence, should report to a district judge. The judge should send the report for a final decision to a Central Review Committee.46 The protocol identified three groups of neonates for whom withdrawal of life support was indicated. Group I included those neonates without chance of survival as a consequence of a fatal illness, those under life support while the extent of damage is being quantified: “in some cases they are maintained alive for a short period of time...and, when the futility of the treatment is evident, ventilatory support is removed so that the baby can expire in the arms of the mother or the father.” In general this decision is accepted by the physicians in Europe and in the U.S. One thing is clear in this regard, and it is that the neonate has no chance of survival so that continuing or even initiating a new treatment would be medically irresponsible.46

Group 2 included neonates who could survive after a period of intensive treatment, although the future prognosis would be somber. The dilemma in these cases is how to quantify the degree of damage present to withdraw support. In countries such as Holland and in the majority of European countries there is consensus in this regard and include quality of life when making the decision.
In England, the Nuffield Council on Bioethics recently wrote: “For the best interest of the child one should not insist on imposing or continuing treatments to maintain the life of the infant, causing something that is intolerable and harmful to him.” In the U.S. there is also consensus regarding the permissibility of withdrawing or not initiating other measures of life support for neonates in this category. Group 3 neonates are those who have a very poor prognosis. “They do not depend on technology for their physiological stability but have intense and sustained suffering that cannot be alleviated. They may survive for many years and even reach adulthood but will experience major problems that cannot be treated and may also cause insufferable consequences.” In Holland, to maintain or withdraw intensive treatment is less relevant than the suffering the infant may be experiencing, which is why the physician proposes from a compassionate point of view, termination of life. In England, “active termination of the life of an infant is intolerable and should be rejected.”

After its publication in the U.S., various critiques to the Groningen protocol have been made by different authors where some have even been considered as “criminal actions.” The basic points of the comments are summarized below:

- It focuses primarily on children with spina bifida, many of whom could have a satisfactory life.
- It fails to distinguish with clinical precision among children whose prognosis is certain and those who should continue to live.
- It allows the parents to commit infanticide as a means of escape from the heavy load implied by care and attention of the child.
- It allows physicians to decide what is an acceptable quality of life.
- Physicians determine the morality of their own actions.
- It provides a procedural proposal in the subjective measurement of suffering.
- It approves infanticide instead of prevention of spina bifida or the promotion of its early detection through fetal ultrasound, followed by abortion.
- It offers an incoherent criteria for deciding when to terminate life when neonates are unable to express their wishes and hopes for the future.

Clinical bioethics committees

In general, one of the problems of bioethics is to be able to practice those concepts which are described in theory, and therefore are mentioned in academic ethical discussions. For this reason, the evolution of the clinical bioethics committees (CBC) has been different from the committees on bioethical investigation (CBI) applied to humans. In the latter case, creation of these committees in hospitals dates back many years, in the Mexican pediatric environment for at least 45-50 years. However, establishment of CBC applied to seriously ill newborns dates back <10-15 years. According to these committees, and with certain frequency, concrete deeds are proposed on the possibility of continuing or not continuing the life of an infant who has special conditions and where death is inevitable in a matter of days or, in case of surviving the critical stage, future quality of life may remain very compromised. The first mention of the CBC without applying it to the neonatal environment is variable depending on the country involved. For example, in the U.S. in 1975 an article was published that was widely disseminated and written by an interdisciplinary group at Johns Hopkins Hospital, which recommended no treatment for children born with Down’s syndrome. In that country, the Hastings Center in 1977 communicated its recommendations on the characteristics
of the CBC, noting that they should be multidisciplinary with members versed in medical ethics in order to be able to provide adequate counseling to physicians and family members when confronting complex cases that represent ethical decisions. In 1983, also in the U.S., the Presidential Commission for the Study of Ethical Issues in Medicine and Biomedical and Behavioral Research published a report on the ethical, medical and legal aspects that should be taken into consideration for the CBC.48,49 It highlighted that the committees should serve to do the following:

a) Confirm patient diagnosis and prognosis
b) Be a forum for social and ethical discussion of a particular case
c) Educate health personnel on the identification and resolution of ethical problems
d) Formulate institutional policies and procedures for decision-making
e) Mediate conflicts regarding treatment of patients among health professionals, members of the family and the institution

An important aspect of the functioning of the CBC in the hospitals is that on being analyzed by external observers and by consensus, its actions performed or by the treating physician and judgments made regarding whether the actions undertaken are or are not ethically adequate have greater validity.50 This allows for identification if there is a lack of hierarchy of values: relativism where each one chooses the guidelines that they agree upon according to the case. From the medical point of view, it is easier to be in agreement among colleagues, but from the bioethical point of view this is more difficult. The CBC should include physicians, nurses, social workers, health professionals, philosophers and religious persons representing different religions, as well as some community representative, lawyers and administrators.50

The most common errors that the CBC should avoid on searching for consensus are as follows:

1) Not clearly defining the central thesis of the argument
2) Adopting a hypothetical attitude
3) Not presenting sufficient information
4) Not examining or considering each possibility
5) That the analysis of the basis or reasoning is incomplete
6) Disorganized ideas
7) Not analyzing with evidences the causes of the problems
8) Not having an epistemological rationale or guarantee
9) Not using with efficiency the back-up and tests that the guarantee provides
10) Not proposing a solution
11) That the solution is not viable or possible
12) Inappropriate vocabulary

After all have presented their positions, the first thing to do is to find areas in which all agree. Once this is achieved, efforts can be concentrated on the objectives and interests that are not recurring.51

The reports of 1977 and 1983 were each reinforced with the regulations or guidelines issued as a result of the Baby Doe case.48,49 Still, without defining or completing the creation of the CBC in neonatology, it was implicit that in order to meet the regulations, it was necessary to constitute them.

Although the U.S. federal government did not mandate the creation of the CBC, the Joint Commission on the Accreditation of Healthcare Organizations in 1992 included it among the points of indispensable evaluation in order to obtain accreditation for a hospital center. That decision
caused a substantial increase in the number of CBCs as compared to the number present in prior years in that country. However, although new CBCs have been incorporated or installed, it is also true that there is no assurance that those from the previous decade, once accreditation is achieved, will continue to function as originally planned.48

What happens when a physician thinks that life support for a neonate should be withdrawn, but the parents demand that the treatment be continued? The group of neonatologists have concluded that the treatment beyond providing comfort measures for the baby is futile because it only prolongs the time of death or because a poor quality of life is expected if the infant does not die. The AAP has generally maintained “silence” about a futile treatment scenario, perhaps because it is an uncertain landscape not only because of the medical and ethical uncertainty but also because of the legal aspects. Therefore, the following describes an actual case where in the state of Texas a physician believed that he should withdraw all life support in a neonate whose treatment was considered futile. It should be noted that because of this case, a legal precedent was established in Texas and explained the path to be followed, not only medically but also legally. The following is described:52

1. In the first case, parents of a child whose treatment is considered futile should have written information provided relating to the policies that exist in the hospital regarding the ethical aspects in those cases, inviting them to participate in the process of ethical analysis of the neonate. This should be provided to the parents 48 hours in advance.

2. Those involved in the process of consultation of the ethical aspects should offer the written report to the family, detailing the ethical findings of the review process.

3. If the consultation process fails in resolution of the dispute, the hospital, in close contact with the family, should promote transfer of the baby to another physician or to another medical center where the treatment desired by the family can be carried out, which was rejected by the original hospital.

4. If after 10 days from the time the parents were provided with the written report as noted in #2, no other facility accepts transfer of the baby, then the attending hospital and the attending physician could unilaterally maintain or withdraw the therapy, which is considered to be futile.

5. The parents can request from the state courts a time extension before treatment is withdrawn. The judge will decide on the reasonable probability of finding another hospital or physician that can provide treatment.

6. If the family is not granted the time extension or if the judge does not locate another facility to provide the treatment, it will be suspended and protection will be provided for the attending physicians without the consequence of legal criminal proceedings. This document is considered to be the first of its type in the U.S.

Bioethics Committee for the Care of Clinical Cases at Hospital Infantil de México Federico Gómez

As noted previously in Mexico, there are established CBCs that are functioning; however, their number, location in pediatric hospitals, experiences, and how they function apparently has not been quantified. Despite this, some formal and active experiences in pediatric hospitals are found in the Hospital de Pediatría, CMN Siglo XXI, IMSS7 as well as in the Hospital Infantil de México Federico Gómez. The latter demonstrates with the description of an actual case, general methodology used, and a holistic approach to ethics, which involves the use of different models based on ethical codes of conduct, cultures, lectures in different groups and the existential search for knowledge and en-
Case Report
Clinical history reports a 16-year-old apparently healthy mother with secondary education and employed as a domestic worker. The father is 16 years of age with secondary schooling and works as a farmer. He lives outside the family nucleus.

This was a normal first pregnancy with adequate prenatal care with a total of seven consultations. There were two prenatal ultrasounds at 30 weeks of gestation, which were reported as normal. Vaginal delivery took place at 39 weeks. The infant cried and breathed at birth, weight 2,600 g, height 44 cm, and chest circumference 28 cm. Apgar score is unknown.

Clinical examination revealed microcephaly, normotensive anterior fontanel, dysmorphic facies, hypotelorism, flattened nasal bridge, small nostrils, central cleft lip, and droop neck. Lung fields and cardiac sounds were normal. Extremities showed restricted flexion and extension and normal pulse for all four limbs with good capillary refill. The hypoactive infant responded to tactile stimulation with mid-tone crying. Fundus and cranial nerves were reported as normal.

Motor examination demonstrated slightly increased muscle tone, decreased tropism, with overall strength IV-V. Muscle extension reflexes showed upper extremities (++/+ + + +) and lower extremities (++/+ + + + +) with indifferent plantar response. During the examination, myoclonus in the right upper extremity and left lower extremity was noted. Primitive reflexes were absent. There was a sacral pit and Mongolian spot. Transfontanel ultrasound revealed agenesis of the corpus callosum splenium. Corpus callosum was present. EEG was irregular with delta activity with no neonatal pattern and severe generalized dysfunction without epileptic activity. At 19 days of age the infant presented multiple generalized tonic seizures lasting approximately 10 sec. Laboratory tests were conducted and the following diagnoses were made:

1. Lobar holoprosencephaly with secondary microcephaly
2. Difficult-to-control epilepsy secondary to lobar holoprosencephaly
3. Panhypopituitarism secondary to lobar holoprosencephaly
4. Diabetes insipidus secondary to panhypopituitarism
5. Central cleft lip
6. Patau syndrome (trisomy 13 according to karyotype)

Circumstances, external or internal influencing factors
External factors included very young parents, altered family dynamics (poor relationship between mother and maternal grandmother), and insufficient economic income for their basic needs.

- Principal actors: Patient, mother and grandmothers
- Secondary actors: Father and institutional health team

Discovery and identification of problems
Scientific and technical problems included “Is the diagnostic and therapeutic approach complete, is it adequate and has it resolved all the problems?”

This case has been adequately approached on the basis of clinical history, complete physical examination, detection of secondary medical alterations or those associated with baseline pathology plus performance of laboratory and imaging tests for determination of internal alterations and karyotypic confirmation to determine genetic alterations.
Ethical problems include “What is the good that is sought?” The child has a lethal disease and management should be geared toward avoiding unnecessary and futile actions that include extraordinary management in the case of cardiopulmonary arrest and palliative care for preservation of an adequate quality of life.

- Legal problems. Is it legal if I do it? Yes.
- Am I within the professional, institutional or national guidelines?

At the professional level, all medical and socio-economic studies for support of the infant and the family has been done. At the institutional level, it is within the ethical guidelines for the hospital and also according to the Health Law of the Federal District of Mexico, which determines that the user will have humanitarian terminal assistance and will receive all the available care in order to have a dignified and painless death.

Hierarchy of ethical problems
Is there therapeutic proportionality among the means employed and the foreseen results? The infant was in intensive therapy, which indicates extraordinary support and that extreme measures for daily management such as clinical deterioration are not being avoided. In this case it is indispensable, as well as genetic counseling for the parents because the majority of the pathologies with holoprosencephaly have a dominant autosomic inheritance with a 50% risk for each pregnancy.

- What is the good being sought? The good being sought is quality of life added to the dignity of the patient.
- Who is the recipient of the good? The patient
- Who is the main character? The patient
- Who are the secondary characters? The mother, maternal and paternal grandmothers, as well as the father
- What are the circumstances? There was family dysfunction due to the absence of the father and the relationship between the mother and maternal grandmother deteriorated at the time the pregnancy was known, which is why communication was not able to be adequately established and the distancing between them has not allowed for reaching agreements. The patient was taken to the hospital by the paternal grandmother who had power of attorney in case the mother was considered incompetent to care for the infant.

What decisions should be taken?
1. Confirm that the patient is in terminal condition.
2. Transfer the baby from an intensive care area to another area where interaction between infant and family can take place and where personnel will be trained in patient care to be able to maintain the patient in the best possible condition.
3. Avoid extraordinary measures as well as aggressive therapy.
4. Consider that palliative care does not exclude other necessary measures for quality of life such as hormone replacement therapy.
5. Psychological and thanatological support for the family.
6. Home visits by a social worker to evaluate home conditions in case the patient is discharged to home.
7. Find subsidy for hormone replacement therapy.
8. Identify caregivers.
9. Informed consent for parents. Who is responsible for giving informed consent? The health team.
10. What are the preferences of the health team? To be able to manage the diagnosis of terminally ill patient and carry out ambulatory palliative care.
Recommendations through discernment

1. Diagnosis of the terminally ill patient on the basis of a lethal condition
2. Use of palliative care during the hospital stay as well as postdischarge
3. Use of substitute therapy as long as necessary through subsidy because this should not be a determinant factor for remaining in the institution
4. Integral support of the family for training to provide care as well as medication administration and improvement of family dynamics through thanatological and psychological support.53

For all these reasons, it is recommended that in all NICUs there be a CBC, independent or dependent upon a CBC in a pediatric hospital or a General Bioethics Committee in general hospitals or specialty hospitals (e.g., an obstetrics and gynecology hospital) where there is a NICU.

Reflections on bioethics in the newborn

A selection of bioethical considerations focused on the newborn is summarized. Although these are not very precise as to when to apply them in decision-making, they allow us to reflect on each of them and use them as topics for discussion when participating in the CBC in different hospitals with a NICU. “Decisions taken in the NICU are influenced by the liberal era in which we live, what happens to human dignity and the principle of the sanctity of life, which are at risk of losing the humanitarian focus. Neonatology is an unpredictable process that never intends to do harm but is accompanied by potentially devastating consequences that may lead to benevolent injustice. Parents, as autonomous surrogate agents for the baby, must be involved in the course of treatment decisions and promote their family values. In modern medicine, patients want to be involved in medical decisions, which are increasingly against the paternalism of the past.54

Is preventive care morally preferable rather than the NICU because it is less costly and more effective? Are the benefits of increased survival of children in the NICU greater than the damage caused by the increase in survivors with brain damage and neurological deficit? Are the parents the only ones who should have the final decision about treating their child? Does respect for the sanctity of life demand that we never consider the “quality of life” to decide to withdraw a vital therapy?28

What would be the best time for prognostic testing of brain damage and to continue or not with life-sustaining treatment? It is known that there is an early phase in the seriously ill neonate when the outcome is uncertain, followed by a physiological recovery during which the magnitude of future harm can be predicted with greater certainty. This creates a window of opportunity before the early withdrawal of medical support. When this stage passes, there is a risk if the baby survives of even more extensive neurological sequelae compared to the initial ones. The sensitivity of tests used to make early or late predictions that help to improve the uncertainty should be analyzed.55

“The golden rule: Do not do to others what you do not want them to do to you, forces humans to preserve fairness among its members including those most vulnerable as in the case of infants, which is the very basis of morals. Medical ethics for an individual should not be used to decide when a human being should die. If there is sufficient evidence that death is imminent and curative treatment is futile, it is the duty of the physician to ensure that death occurs in situations of dignity and comfort.56

“The principle of sanctity of life does not justify preserving it until death occurs. A treatment that is not useful generates a lack of respect for the patient and irreverence for life and death. Respect for the sanctity of life of the patient does not require decision makers to decide between life...
and death but to only provide a treatment that is beneficial to the sick and comfort care in death. The decision to initiate, maintain or withdraw treatment under difficult circumstances can be guided by taking into consideration the intent to always achieve a good effect during any act.56

Because of the difficulty of predicting with certainty what the future of the newborn will be in the first minutes after birth, some recommend resuscitation maneuvers in all those born after 22 weeks of gestation. But what if survival is <50%, 20%, 5% or 1%, despite there being complete functional capacity of the neonate? And what are the circumstances in which treatment should be withdrawn?17

Proper understanding and application of the basic concepts of bioethics in the newborn are among the most beautiful feelings and expressions of a human being, comparable or superior to others such as creating a painting, a poem, a symphony, or a law of the universe. For its exercise, it is required to be in perfect harmony with the existing principles of life, science, art, suffering and human happiness (L. Jasso-Gutiérrez, author).

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