

Neonatal organ donation – ethical and forensic considerations of the boundary between drama and hope

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Abstract

Background. Organ donation from newborns for transplantation is a relatively rare event, which requires proper knowledge of legal, ethical and medical issues. It implies the existence of a group of obstetricians, neonatologists, specialists in organ procurement, specialists in bioethics and lawyers. **Aim.** The purpose of this study was to highlight the need for adequate legislation to achieve organ donation in newborns and to give a chance to the lives of those children who require a transplant. **Materials and method.** We performed a comprehensive search on the following terms: (1) "neonatal organ donation"; (2) "ethics"; (3) "neonatal organs donors", for ten years, on two major databases, PubMed®/MEDLINE® and Web of Science, and we found 410 articles of which 27 were eligible for the study. **Conclusions.** The application of some recommendations will increase the number of donors and contribute as a model for realizing future practice guides, along with the need to create an infrastructure to manage these situations.

Keywords: neonatal organ donation, neonatal organ donors, ethics, neonatology

Submission date:
8.09.2022
Acceptance date:
16.09.2022

Donarea de organe neonatale – considerații etice și criminalistice la granița dintre dramă și speranță

Suggested citation for this article: Varlas V, Borș RG, Dima V, Velișcu A, Mehedințu C, Cirstoiu M, Vlădăreanu S. Neonatal organ donation – ethical and forensic considerations of the boundary between drama and hope. *Ginecologia.ro*. 2022;37(3):18-22.

Rezumat

Context. Donarea de organe de la nou-născuți pentru transplant este un eveniment relativ rar, care necesită cunoașterea corespunzătoare a problemelor legale, etice și medicale. Aceasta presupune existența unui grup de obstetricieni, neonatologi, specialiști în prelevarea de organe, specialiști în bioetică și avocați. **Scop.** Obiectivul acestui studiu a fost de a evidenția necesitatea unei legislații adecvate pentru a realiza donarea de organe la nou-născuți și pentru a oferi o șansă la viață acelor copii care necesită un transplant. **Materiale și metodă.** Am efectuat o căutare extensivă pentru următorii termeni: (1) „donare de organe neonatale”; (2) „etică”; (3) „donatori de organe neonatale”; timp de zece ani, în două baze de date majore, PubMed®/MEDLINE® și Web of Science. Am găsit 410 articole, dintre care 27 au fost eligibile pentru acest studiu. **Concluzii.** Aplicarea unor recomandări va crește numărul de donatori și va contribui ca model pentru realizarea viitoarelor ghiduri de practică, alături de necesitatea creării unei infrastructuri pentru gestionarea acestor situații. **Cuvinte-cheie:** donare de organe neonatale, donatori de organe neonatale, etică, neonatologie

1. Introduction

Although almost 37 years have passed since the first successful neonatal heart transplant, the concept of organ transplantation in children continues to arouse increased interest. This is because organ donation can save lives, especially in children with terminal organ failure. The origin of the donated organs can be made either from living donors or cadaveric donors. The first attempt at a heart transplant in children was performed in 1967 by Adrian Kantrowitz, using the heart of an anencephalic baby, three days after Christiaan Barnard's transplant in an adult⁽¹⁾.

Apart from the situations in which the donation is made for transplantation, in other cases the organs and tissues are donated for their use in medical research or educational purposes. Grant for medical research creates the premises for the emergence of new therapeutic options⁽²⁾.

The neonatal and pediatric intensive care unit staff does not consider the option of organ donation and is aware of the limited time for organ and tissue sampling. However, this implies on the part of the competent bodies the proper education and training of the medical staff. Thus, the concept of organ and tissue donation will need to be discussed and planned in cases where death is not sudden⁽³⁾.

Organ donation is still a sensitive issue, with growing awareness among adults and children as potential donors⁽⁴⁾. In addition, encouraging neonatal organ donation is important because newborn transplant recipients and young infants have fewer rejection episodes than older patients, especially in heart transplantation⁽⁵⁾.

According to the NICE guidelines, the organ donation recommendation should be part of the "end-of-life care" plan^(6,7). In addition, national guidelines must create the

legal framework for ethical reasons for organ donation, a complex public health issue.

The collection of organs and tissues from newborns from birth to 28 days for transplantation also encounters another problem related to the relatively small number of recipients corresponding to the size of the donor organs.

Caserío and Arnaez, in a survey for a cross-sectional national study on the eligibility of potential newborn donors, found that, out of 46,805 newborns admitted to the neonatal intensive care unit (NICU), 625 newborns died. Of these, 31 infants born at gestational ages ≥ 34 weeks and over 2000 g were eligible because the death occurred in less than 120 minutes due to diseases that did not contraindicate donation⁽⁸⁾. Another study by Vileito et al. revealed that 2% of newborns who died in the NICU were eligible for organ donation, and 12% for tissue donation⁽⁹⁾. Neonatal organ donation can be achieved by prolonged hypothermia in full-term infants with severe hypoxic-ischemic encephalopathy and multiorgan dysfunction after death has been declared according to neurological criteria⁽¹⁰⁾. Therefore, standardized eligibility criteria require establishing standardized criteria to identify potential donors after circulatory death or donors after brain death from the NICU for performing heart, liver and kidney transplants⁽¹¹⁾.

The purpose of this study was to highlight the need for adequate legislation to achieve organ donation in newborns, to give a chance to the lives of those children who require a transplant.

2. Neonatal organ transplantation

The donation of neonatal organs is an altruistic gesture on the part of the family, being at the same time a way to alleviate the suffering and to consider that the death of the newborn was not in vain⁽¹²⁾. An important desideratum is related to evaluating the organs for transplantation, the degree of compatibility, the moment and the type of donation. The organs that can be taken from newborns are the heart, lungs, kidneys, liver and bone marrow, and in older newborns, the pancreas and small intestine⁽¹³⁾. The donation can be considered from the gestational age of over 36 weeks of corrected gestational age. The number of organs taken is higher in the case of death on neurological criteria than on cardiorespiratory criteria.

In the case of unborn children, the donation is more difficult because it is necessary to advise parents during pregnancy on the impossibility of newborn survival (e.g., anencephalic). Then, if the parents accept, the organ can be carefully prepared. In parallel with family counseling, the organizational training of midwives and obstetricians takes place⁽¹⁴⁾.

According to a study by Labrecque et al., 8% of deaths after cardiac death in neonatal intensive care units may be possible candidates for donation⁽¹⁵⁾. The study by Stiers et al. highlighted that, out of 136 deaths in the NICU, 60 (44.1%) met the criteria eligible for donation after circulatory determination of death. However, only four cases were used for successful transplantation because they

were either not sent or were too late for evaluation⁽¹⁶⁾. Another important source of potential organ donors may be brain-dead neonatal patients undergoing extracorporeal membrane oxygenation⁽¹⁷⁾.

In 2014, Charles et al. revealed approximately 60 neonatal donors in the UK each year, representing significant transplant potential⁽¹⁸⁾. Furthermore, the Royal College of Pediatrics and Child Health (RCPCH) has developed a legal and ethical framework for organ donation entitled *Decisions to limit therapy*⁽¹⁹⁾. Following the RCPCH recommendations, cases of donors after circulatory death have been reported in infants where life support therapy has been discontinued⁽²⁰⁾.

Neonatal heart transplantation

According to the document, the number of donors is significantly lower than that of possible children receiving a heart transplant. The study highlights a contradiction between not using donated organs (approximately 40%) and increased mortality on the waiting list, postulating the need to streamline the process of organ donation⁽²¹⁾. To optimize the rate of heart transplantation and reduce the rate of unused organs, an optimal procedure must be performed regarding organ donation in pediatric patients. To perform the transplant, a team of specialists must take care of the heart donor by invasively monitoring the heart parameters (blood pressure, heart rate, oxygen saturation), liver and kidneys⁽²²⁾.

Neonatal lung transplantation

In newborns and young infants, performing a lung transplant or a heart-lung transplant involves surgical and intensive care treatments that are difficult to achieve and linked to severe terminal respiratory failure without any therapeutic alternative. Another problem is the small number of transplants performed, indicating insufficient surgical experience. However, North American centers have gained experience managing congenital lung diseases (surfactant protein-B deficiency, ABCA3 deficiency), severe pulmonary hypoplasia, and less so in those with a vascular component⁽²³⁾.

Although there is an extremely small number of patients to justify this transplant, it is important to create a European transplant program to manage these cases because there is currently no other therapeutic alternative (gene therapies are still being investigated for these diseases). In addition, neonatal lung transplantation is indicated for cases of congenital diaphragmatic hernia (CDH) with severe pulmonary hypoplasia, severe cases of congenital pulmonary cystic adenomatoid malformation, and irreversible primary pulmonary hypertension⁽²⁴⁾.

According to the Eldridge's study, the mortality after lung transplantation in children with surfactant metabolism genetic disorders continues to increase substantially despite improved immunosuppressive therapies and intensive care⁽²⁵⁾.

Neonatal liver transplantation

The therapeutic option for end-stage liver disease in infants is orthotopic liver transplantation (OLT). The survival rate currently in some centers specializing in OLT in infants is equivalent to that of adults. The extension of

OLT to newborns involves a series of technical difficulties as a pioneering transplantation area⁽²⁶⁾.

Liver transplantation from donors younger than 3 months old had a low rate of acute rejection and a slightly increased incidence of hepatic artery thrombosis⁽²⁷⁾.

Kasahara et al., in their study, showed that the total 10-year survival rate in recipients below 3 months of age was 90.9%. Early liver transplantation is accompanied by a lower incidence of acute cell rejection, while the rate of biliary complications is higher⁽²⁸⁾.

Neonatal kidney transplantation

Block kidney transplantation from donors younger than 10 months old to pediatric recipients older than 10 years old is feasible, with good postoperative results in the case of an experienced team and appropriate perioperative support⁽²⁹⁾. This transplant practice should be permanently encouraged so that these procedures are not sporadic^(30,31). Difficulties with kidney transplantation are represented by insufficient kidney volume, increased risk of thrombosis and hyperfiltration injury⁽²⁹⁾. Varley et al. performed a kidney transplant from newborn to adult, demonstrating that a single kidney can achieve renal function in adults⁽³²⁾.

To increase the number of kidneys from neonatal donors, a donation program for donors must be developed in the NICU after circulatory determination death⁽³³⁾.

3. Organ donation from anencephalic newborns

Newborns with anencephaly lack the anterior brain or the brain as a whole and the absence of a significant part of the skull, secondary to the closure defect of the neural tube⁽³⁴⁾. The incidence of births with anencephalic fetuses is continuously decreased by reducing neural tube defects due to the administration of folic acid and early ultrasound detection with the interruption of the pregnancy evolution⁽³⁵⁾.

Jivraj et al., in their study, showed that, through the anonymous online survey, 73% of respondents considered a donation to anencephalic infants acceptable, of which 64% advocated elective ventilation, 20% were neutral, and the remaining 16% disagreed. Furthermore, the maintenance of ventilation support to allow donation was supported by 53%, and 59% agreed that donation of anencephaly does not harm public opinion⁽³⁶⁾.

Walters et al. exposed the two schools of thought regarding using anencephalic newborns as possible organ donors: physicalism and personalism. Physicalism refers to all people being extremely valuable without exception, and personalism refers to a person's real mental abilities. The balance leans toward the personalist current, leading to important decision-making changes⁽³⁷⁾.

4. Ethical consideration for neonatal organ donation

A particular situation in the field of clinical ethics is the donation of neonatal organs that parents can consider when they have been advised about the terminal diagnosis and the death of the newborn. These difficult

cases that may arise during the care of newborns present a series of ethical considerations that must be considered when taking organs and tissues from newborns who die either intrapartum or immediately after birth⁽³⁸⁾.

The sampling of organs and tissues represents a valuable resource that must be exploited to save other lives, with the realization of transplants to patients who need them. Pediatric patients are the main beneficiaries of these organ samplings and donations. Currently, an attempt is being made to clarify the ethical aspects of this practice⁽³⁹⁾.

If in the past, organ donation was made with difficulty, now efforts are being made to facilitate the legislative levers in the field of perinatal and neonatal medicine. Nevertheless, the procurement, allocation and management of transplanted human organs leave room for many questions. A unique factor in perinatal medicine is the clinical possibility of having a stable fetus with a low probability of survival as a newborn. Therefore, counseling parents where the death of their children is anticipated is of particular importance in their mental preparation to consider the possibility that their babies are real candidates for organ donation⁽⁴⁰⁾.

Most neonatal deaths occur in intensive care units, mainly with or without treatment interruption. The donation of neonatal organs and their preparation for the transplantation of vital organs are carried out according to well-established protocols for severe acute or chronic organ failure. Like other types of transplantation, neonatal organ transplantation must respect the basic principles of medical ethics (legislation, autonomy, non-maleficence and charity) following the benefits of donation and transplantation. The allocation of resources regarding the ethics of transplantation requires transparency of a possible conflict of interest regarding the procedure of donating newborns in the terminal stage about the care of potential patients who are recipients of these organs. This requires better education in the medical community regarding the risks and benefits of obstetric management (caesarean section versus vaginal birth). Furthermore, the doctors dealing with the care of the critically ill patient do not have a decision-making role regarding the interruption of life-sustaining therapy, providing information on the potential optimization of the viability of the donor organs⁽⁴¹⁾.

a) Medical legislation represents all the laws that create the optimal conditions for the judicious allocation of resources to preserve people's health. The creation of the principles of law to define as correctly as possible the legislation regarding the removal of organs from dying newborns must be harmonized with the right to transplantation of people who die on the waiting lists.

A series of ethical considerations regarding organ donation may arise: the attitude of doctors regarding potential medical acts that may create a disservice to a newborn in the terminal phase, the parents' motivation to continue the pregnancy to donate organs or continue independently of this⁽⁴²⁾.

Attributing personality to a fetus during pregnancy or to a newborn at birth to donate organs must respect the inviolability of human dignity. Society and the medical

community encourage the participation of parents in the final acts of care for their children, therefore the time spent with them should not be sacrificed by the initiation of organ donation procedures. The removal of organs for donation after the death of the newborn is not an act that is always crowned with success, despite the express wishes of the family^(12,34).

This can be determined by several factors, such as associated comorbidities, gestational age, birth weight, Apgar score at birth, time spent in the neonatal intensive care unit, multiple organ failure, or infectious processes. For families who make this decision to donate their children's organs, the failure of the transplant – either through the death of the recipient in the meantime, or the rejection of the organs by the recipient –, the psychoemotional impact can be high, necessitating their psychological counseling⁽⁴⁰⁾.

Physicians must adhere to the best interest standard and allow parents responsibility for decisions to authorize donation procedures during the newborn's lifetime⁽⁴³⁾. Inadequate communication with the family and inappropriate language allow multiple interpretations that lead to the disruption of the use of curative/palliative interventions, affecting the care scheme of these children. Doctors, by ethical principles, must present truthful medical information for the benefit of the family, be sensitive and empathize with parents. Sometimes the exhaustive, direct presentation of a fetal malformation with lethal evolution, a condition incompatible with life or an inauspicious prognosis can be perceived by parents as disrespectful of their children's lives⁽⁴⁰⁾.

The removal of vital organs should be secondary to the organ donor's death, which is defined from the perspective of human existence as the cessation of respiratory and circulatory functions⁽⁴⁴⁾.

From an ethical and legal point of view, the determination and declaration of the death of the newborn are established based on neurological or circulatory criteria. Transplant societies have defined the *Dead Donor Rule*, which is the basis for collecting vital organs after the declaration of the death of the potential donor. This rule continues to be criticized mainly in the case of brain-dead patients in whom the removal of organs under consent would meet the criteria of medical ethics⁽⁴²⁾.

Currently, there is a continuous debate regarding the implementation of pre-mortem interventions to increase the efficiency of organ donation in order not to seriously harm the dying newborn^(45,46). The procedure for taking donor organs compatible for transplantation is initiated after establishing the absence of circulatory signs and brain activity (brain death or irreversible impairment of brain stem function) to increase the chance of transplantation, and without ethically prejudicing the donor, his parents, or the medical care team^(19,42).

The psychosocial and emotional implication of parents who have decided to donate their child's organs requires, in addition to the care techniques of the newborn, the special postpartum care of the mother who is facing the immense tragedy of losing her child.

Therefore, an important role is played by neonatologists specializing in pediatric palliative care, who are part of the multidisciplinary team.

In conclusion, we must offer the families of dying children a chance to donate vital organs without a conflict of interest between potential donors and beneficiaries. The autonomy of the donors should not be violated concerning the recipients' benefits; this desire is accepted as a basic principle regarding the donation and transplantation of neonatal organs⁽⁴¹⁾.

b) Although autonomy is defined as a person's right to self-determination, newborns do not have this capacity and, as a result, autonomy based on their superior interests represented by their parents must be respected. When parents discover that their child has diseases incompatible with life, their altruistic behavior regarding organ donation helps them face this tragedy, giving positive meaning to the loss through the possibility of the transplant⁽⁴⁰⁾.

c) Preserving the dignity of newborn donors correlated with the ethics of the procedures before their death is based on the concept of not harming a person, thus defining the principle of non-maleficence. For ethical reasons, taking the organs of newborns must respect the dignity of their death, not induce the death of the donors or cause pain to the donors. Preserving the dignity of the possible donor newborn means providing him with comfort and relieving his pain until the end of life, so that the parents can enjoy the last moments with their child during the life support disconnection procedure. The experience of pain in newborns is difficult to quantify, so intervention must be taken to alleviate any pain through analgesia and sedation.

Poor end-of-life care for donors can cause harm if we refer to procedures that can benefit transplant recipients before the donor's death is declared. Pre-mortem interventions carried out before the patient's death favor the removal of organs and increase the duration of their viability to considerably increase the chances of success regarding transplantation. However, these procedures must not be carried out at the donors' expense.

Parents' decisions regarding their children are considered to be addressed to a vulnerable population due to the absence of autonomy and the fragility of newborns. In newborns with diseases incompatible with life, organ donation requires the avoidance of life-sustaining interventions (anticoagulant therapy, intubation to ensure organ viability, assisted ventilation, vasopressor support) that are detrimental to that newborn, but which are necessary either for the parent who wishes to donate the child's organs, or for the benefit of the recipient of the transplant. In contrast to the characteristic non-maleficence defined as the avoidance of harm, the newborn donor is exposed to measures that may cause harm to him as a patient, which makes the sampling procedure unethical. As a result, careful consideration will be given to the acceptable harm to a newborn for a noble cause that may prove beneficial to the organ transplant recipient⁽⁴⁰⁾.

d) The act of charity defines the concept of beneficence. Thus, potential donors and their parents must be

supported by the health services to donate; this act will provide psychoemotional comfort by capitalizing on the death of their child, being a true act of charity, giving a new meaning to saving a patient with insufficiency of the end-stage organ⁽⁴¹⁾.

The involvement of specialists in maternal-fetal medicine and, respectively, in neonatal intensive care comes to complete the multidisciplinary approach regarding the unfavorable prognosis of the newborn. The role of neonatologists is the most important due to their experience, being able to address this sensitive topic regarding organ donation after birth. The cohesion of the neonatologist-obstetrician team will determine the increase of parents' confidence in intra- and postpartum management, as well as in the donation process⁽⁴³⁾.

5. Neonatal organ and tissue donation for research

Research on neonatal organs and tissues has led to important scientific discoveries. Neonatal organ donation is necessary for research into diabetes, neurological,

pulmonary, urological, gastrointestinal disorders, autism and psychiatric disorders⁽⁴⁷⁾. Other uses of neonatal organs and tissues are related to the study of cancer, fertility and regenerative medicine. Due to important scientific discoveries, the need to use neonatal organs and tissues has become more important in recent years. Thus, the act of family donation is a crucial option for future research.

6. Conclusions

Applying some recommendations will lead to an increase in the number of donors. It will contribute as a model for realizing future practice guides and creating an infrastructure meant to manage these situations.

The growing interest in organ donation has also been extrapolated to neonatal donors so that to support both organ donors and those who will benefit from transplantation; the medical community must consider the ethical and forensic considerations of this altruistic act. ■

Conflicts of interests: The authors declare no conflict of interests.

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