Decisions for Treatment of Neonates With Poor Prognosis: A Qualitative Study

Mamak Shariat[1], Fariba Asghari[2], Mahmoud Motevasel Arani[3], Nahid Farrokhzad[1], Yasamin Mohammadzadeh[4], Farahnaz Mohammadi Shahboulaghi[5], Ameneh Abroun[6], Sayeh Mirzatavoli[6], Zohreh Janani[6], Fatemeh Sadat Nayeri[4]

[1] Maternal, Fetal and Neonatal Health Research Center, Institute of Family Health, Tehran University of Medical Sciences, Tehran, Iran
[2] Medical Ethics and History of Medicine Research Center, Tehran University of Medical Sciences, Tehran, Iran
[3] Department of Islamic Maaref, School of Medicine, Tehran University of Medical Sciences, Tehran, Iran
[4] Breastfeeding Research Center, Institute of Family Health, Tehran University of Medical Sciences, Tehran, Iran
[5] Department of Nursing, Social Determinants of Health Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
[6] Neonatal Intensive Care Unit, Imam Khomeini Hospital Complex, Tehran University of Medical Sciences, Tehran, Iran

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Abstract- Advances in medicine and medical technology have presented new moral challenges in terms of the management of extremely preterm infants and newborns with severe anomalies and advanced asphyxia. The aim of the present study was to examine the attitudes of health care providers and parents regarding decisions about the treatment of these neonates. The attitude of the Shia clerics is assessed in this study as well. In this qualitative content analysis research, data were collected through semi-structured interviews and focus group discussions (FGDs) with 98 participants, including physicians, nurse practitioners, medical ethicists, Shia clerics, and parents. Purposive sampling was employed by selecting those members of the community whom we thought would provide us with the best information and were also eager to participate. Data collection continued until data saturation was reached. Data analysis was carried out using conventional content analysis. Analysis of the data resulted in the extraction of 332 codes along with the following four categories: the necessity for preparation of a national guideline for the management of neonates with poor prognosis, the establishment of hospital neonatal-management committees, decision-making regarding the limits of viability, and parental support. This study affirms that the responsibility in terms of decision-making for neonates with poor prognosis lies upon hospital neonatal-management committees based on approved national guidelines such that decisions are made according to the aforementioned guidelines, Islamic moral codes, and scope of services available in medical units. This study dismisses individual decision-making and underlines the responsibility of a hospital neonatal-management committee in making decisions based on approved guidelines that conform to the regulations of national law and Islamic moral codes that determine the continuation or withdrawal of medical care and treatment of infants with a poor prognosis while bearing in mind that regulations, hospital facilities, resources, and other conditions differ in various hospitals within the country and with developed countries.

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Introduction

With the improvement of medical knowledge and nursing practices, along with the dissemination of advanced medical equipment and the development of Neonatal Intensive Care Units (NICUs), the survival rate of extremely preterm infants and newborns with multiple congenital anomalies and advanced asphyxia has increased. As a result, neonatologists are facing new issues, such as decisions regarding the care of such infants. Despite all the efforts made by medical practitioners, the majority of these infants do not survive for long, and those who do survive experience serious disabilities. This usually signifies frequent returns to the

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Corresponding Author: F.S. Nayeri
Breastfeeding Research Center, Institute of Family Health, Tehran University of Medical Sciences, Tehran, Iran
Tel: +98 2166591316, Fax: +98 2166591315, E-mail address: nsnayeri@sina.tums.ac.ir

hospital or remaining in the hospital for long-term treatment and, as a result, experiencing poor quality of life. This also results in many financial, social, and emotional pressures on the family and society. In addition, due to the lack of NICU beds, allocating hospital beds to such neonates results in depriving a greater number of individuals of access to special care. Hence, infants with much better chances of survival might die waiting for a bed to be emptied.

According to the World Health Organization (WHO), around 30 million low-birth-weight infants are born annually, among which 15 million are premature (1). Prematurity is one of the major health problems today and the leading cause of neonatal death. Preterm infants may experience many medical complications and disorders. The limit of viability is referred to as the gestational age at which a prematurely born infant has a 50% chance of long-term survival after birth without major neurological disorders (2). Thanks to medical advances, the survival rate of preterm infants has increased. This rate, however, varies in different countries. According to Wilson-Costello et al., the survival rate of extremely low birth weight (ELBW) infants has increased from 49% to 67% (3). Based on another study, the survival rate of these neonates at a gestational age of fewer than 28 weeks is 77-82% (4). Currently, there is an agreement between most researchers in the United States about the limit of viability which is considered to be around 23 to 24 weeks of gestation, and birth weights of more than or equal to 500 g (5-7). In developed countries, consultation with parents usually takes place before the birth of a preterm infant to provide them with adequate information about the potential risks and consequences for the baby. Decisions about keeping an extremely preterm infant alive and continuation of treatment are usually made upon consultation with the related physicians, nurses, social workers, and at times with medical ethicists and parents. The opinion of the parents, however, is significant (8,9).

According to an Iranian study, ELBW neonates constitute 40% of total neonatal mortality but comprise only 2% of births (10). In our country, the threshold of viability has not yet been determined. Moreover, hospital facilities or resources and conditions differ in various parts of the country. There is also a lack of sufficient hospital facilities as well as a shortage of health care professionals. These factors have given rise to the moral and ethical questions and challenges that physicians encounter in terms of providing aggressive and advanced care to neonates with very poor prognoses. For example, how much effort should be made to keep a baby with a poor prognosis alive if there is a need for cardiopulmonary resuscitation at birth? Or, which baby should be given priority when there are insufficient medical facilities and/or staff? It should be noted that in our country, Islamic medical ethics play a fundamental role in decision-making in all such cases. As Islamic scholars have cited, physicians are responsible for doing everything they can to protect the life and health of the patient, and, in cases where advanced technology is used, treatment cannot be discontinued unless the practitioner is sure of the patient’s imminent death.

Considering the vital importance of this issue along with the dearth of research on the attitudes of neonatologists and other specialists regarding these critically ill neonates, this study was conducted with the aim of investigating the attitudes of neonatologists, obstetricians, gynecologists, forensic medicine specialists, medical ethicists, Shia clerics and parents towards decisions for treatment of infants with poor prognoses The attitude of the Shia clerics are assessed in this study as well.

Materials and Methods

The present research was a qualitative study using a content analysis approach. The study protocol was scientifically and ethically approved by the Research Committee of Tehran University of Medical Sciences (ID=27833). This study was performed at the Maternal, Neonatal, and Fetal Research Center (Vali-Asr Hospital) from 2014 to 2018. Purposive sampling was employed, selecting those members of the community whom we thought would provide us with the best information and were also eager to participate. Data collection continued until data saturation was reached. The study population involved 98 participants, including 27 neonatologists, 18 OB/GYN specialists, 15 NICU nurses, 8 forensic medicine specialists, 14 medical ethicists, 6 Shia clerics, and 10 parents who had critically ill neonates at the time of the interviews and FGD or during the past year. Before undertaking the study, the participants were briefed about the purpose of the study and provided their written consent to take part in the semi-structured interviews and the focus group discussion. In addition, an interview guide was prepared in advance to ensure that all of the important areas of concern were being considered.

The FGD sessions were conducted with regard to the privacy and confidentiality of the individuals. The interview setting was chosen by mutual agreement between the researcher and participant. Meetings with nurses and practitioners were convened at the hospital. Parents were interviewed in appropriate places near the NICU and others in their offices. The sequence of the FGDs was as follows:

1. Neonatologists
2. Obstetricians and Gynecologists
3. Nurses
4. Medical ethicists
5. Forensic medicine specialists
6. Shia clerics
7. Parents

The interview process began with some general questions followed up by exploratory questions. The interviews were conducted by four nurses with 10 to 15 years of professional experience in NICUs. The interviewers received two sessions of theoretical and practical training (8 hours) in advance. Subsequently, they gave a practical demonstration and received feedback from the researchers.

The neonatologists and gynecologists answered the following questions:

Have you ever encountered a situation in which you had to make a decision between two preterm infants, only one of which could receive priority for intensive care in the NICU? How did you make this decision? What factors did you consider in making this decision? What are the challenges you face in these cases? How do you decide when there is debate about the limit of viability?

The nurses answered the following questions:

Do you think every possible measure must be taken to preserve the lives of infants with extremely poor prognoses? To what extent is your decision in this regard affected by the wishes of your parents?

The medical ethicists answered the following question:

What medical codes of ethics influence decisions related to the gray zone of viability?

Forensic medicine specialists answered the following question:

What factors should be considered in the decisions of NICU physicians regarding infants with poor prognosis, especially those born in the gray zone of infant viability?

Others answered the following questions:

When there are insufficient hospital facilities or resources, which infants should receive priority for treatment? What do you advise when neonatologists or parents of a critically ill infant consult with you to make decisions and treatment plans for the baby?

Parents were also asked to describe their feelings along with the difficulties and complications of having such babies.

Additionally, different types of therapies and services were explained to the interviewees:

Aggressive Care: All necessary and practical measures that must be taken to preserve the life of the infant, including cardiopulmonary resuscitation, endotracheal tubing, mechanical ventilation, chest tube insertion, and surgery, as well as intravenous feeding and total parenteral nutrition.

Conservative or Supportive Care: Administration of oxygen through non-invasive methods and suctioning; feeding by way of a gastric tube and/or intravenous line through an umbilical artery catheter; use of a percutaneous intracardiac catheter; provision of antibiotics, inotropes, or blood products.

Palliative Care: Warming the infant and making it as comfortable as possible.

The main focus of the present study was on neonates with extremely poor prognosis. Such cases include severe prematurity, advanced asphyxia (according to textbooks), and anomalies incompatible with life.

Each interview session lasted for 60 to 90 minutes, and data collection continued until data saturation was reached. During the interviews, observations on participants’ behavior, their body language, or anything else of interest that could not be detected by tape recording were also recorded in the field notes.

The extracted material was reviewed by another researcher of the research team, then sent to the participants for approval. Confirmation was done in both stages, and no problem was found. Then the transcripts and field notes were reviewed several times. The recordings were fully transcribed at a later time.

The responses were examined by the research analyst, and the key points were marked with a series of codes. When the codes and concepts were identified, coding was carried out by one quantitative research expert (a researcher from the team with a doctorate in nursing and a qualitative study coaching certificate). These codes were then transformed into main and subcategories.

In this study, trustworthiness was measured through validity and reliability. Trustworthiness refers to standards for judging the quality and usefulness of qualitative research studies. Trustworthiness consists of the following components: (a) credibility, (b) transferability, (c) dependability, and (d) confirmability (3).

Credibility was enhanced by performing in-depth fieldwork using prolonged engagement and careful observation. In this study, data were gathered from the interviews and analyzed by the researchers. In order to demonstrate dependability, all interview sessions were recorded, fully transcribed, and documented. The utmost care and attention were taken in the preparation and collection of information and reports. Confirmability was established by maintaining precise data records and keeping all data for additional scrutiny. Transferability was demonstrated by thoroughly describing the research setting by stating a detailed, clear description of the participants, sampling, and data analysis that were central to the research. As a result, readers are able to form better judgments about the quality of data collection and analysis.

The study received the endorsement of the Ethics Committee of the research department of Tehran University of Medical Sciences. Informed consent was also obtained from all participants in addition to their consent to participate in electronically recorded interviews.

Results

Data analysis resulted in the extraction of 332 codes which were grouped into similar concepts. These concepts were then classified into main and subcategories. Four main categories were formed with subcategories as described below:

1. The necessity to prepare national guidelines for the management of preterm infants

According to this, there is a need for a national framework providing guidance and advice for appropriate decision- making at the borderline of viability. This requires the development of a national protocol by modifying international references. Therefore, the procedures and methods used to develop such guidance should be in line with the principles of authentic organizations such as the National Institute for Health and Care of Excellence (NICE). The related subcategories are as follows:

Determination of the limit of viability

The limit of viability is the gestational age at which a prematurely born infant has a 50% chance of long-term survival. However, decisions that are made in such conditions differ regarding available facilities and conditions in hospitals. Participants of the study generally believed that “Intensive care priority should be given to babies with greater chances of survival” and “the guideline should determine the legal limits of infant viability.”

Determination of gray zone

For infants born in the ‘gray zone’, the line between the limit of viability and medical futility is blurred, and death appears a certainty. This makes medical decision-making complex. As a result and according to the participants of the study, “the ‘gray zone’ should be clearly determined,” and “the threshold of infant viability along with the appropriate decisions in such cases should be included in the guidelines.”

Observing the principles of Islamic jurisprudence

Decision types in the developed guideline should clearly fall into two categories, mandatory and conditional, according to the Sharia ruling. As the Shia clerics of the present study stated, “There is a rule in the principles of Islamic jurisprudence stating, if two actions are obligatory for us while it is not possible to perform both of them at once, one must decide which action is more important to perform. Hence, in cases of resource constraints, the allocation of resources will be on the basis of prioritization”.

Observing the codes of medical ethics

The principles of medical ethics should also be taken into account, particularly for the management of infants in the grey zone of viability. The participating medical ethicists believed that “in addition to the opinion of physicians and infant’s parents, social norms should also be taken into account in decision-making” and “decisions about infants in the gray zone should be referred to the Hospital Ethics Committee”.

Dissemination and implementation

After receiving official approval, the guideline must be fully implemented. The participants also believed that “the guideline issued by the Ministry of Health and Medical Education is legally binding” and "basing decisions on the guideline is a reasonable line of defense against an accusation of malpractice".

Implementation challenges during guideline development

In order to prepare an accredited and updated guideline, it is of great importance to take implementation challenges into account. Included here is the lack of a relevant set of laws, reliable research studies, and team-based decision-making. The participants of the present study agreed that "guidelines should be updated every five years", and "the process of developing a guideline should involve establishing a guideline development group, introducing the guideline, and finally making the related policy".

2. Establishing hospital neonatal-management committees

Technical aspects of developing a national guideline should be observed. This includes forming neonatal-management committees to employ an organized approach to neonatal assessment. This category is regarded as the subcategory of forming a hospital decision-making committee:

The guideline should be introduced to healthcare providers dealing with neonates with poor prognosis. The supervision, however, falls in the jurisdiction of the committee. It is important that the committee be established in the hospital. The participants of the study also agreed with the statements, "I suggest that the hospital neonatal-management committees be established in hospitals with neonatal intensive care units" and "Committee members should vary according to the type of neonatal disease".

3. Decisions regarding limits of viability in extremely low gestational age newborns

A separate class was formed to emphasize the importance of care and decision for this group. This category includes the following subcategories:

Controversies surrounding the limits of viability

Although there are controversies surrounding the limits of viability, it is essential to determine the limit according to the guidelines and research studies. Participants of the present study suggested different limits based on their professional experience and hospital facilities. The limit of viability was considered to be from "25 to 26" completed weeks by participating gynecologists based on the facilities available in their hospitals and/or "25 to 26" completed weeks based on textbooks as well as "28" and/or "30" weeks. In contrast, nurse practitioners offered "27", "28", and "27 to 28" weeks of gestation. While the gestational age offered by neonatologists was "24", "25", and/or "26" weeks.

Explicitness of medical measures in the guideline

Any kind of decision regarding treatment for extremely-low-gestational-age newborns must be made on the basis of the approved guideline. Hence, the guideline should provide a clear pathway of care for the management of such babies (based on consensus views, best practices, and available evidence) to support clinicians faced with difficult decisions. The participants also agreed with the statement that "there should be a guideline to legally support decision-making".

Factors affecting treatment at the threshold of viability

The guideline should clearly state the treatment protocol for extremely preterm infants according to hospital facilities, hospital treatment protocol, consensus views, best practices, and available evidence. The participants shared the same opinion that "it is essential to determine the threshold of neonatal viability, which could also be generalized to the entire country".

Explicitness of Islamic jurisprudence

Due to the sanctity of life, every possible measure must be taken to preserve the life of the infant. However, Islamic jurisprudence allows the decision to discontinue treatment when the treatment only prolongs the process of death. The participating Shia clerics generally agreed that "it is not mandatory to continue treatment when the treatment is not effective and only prolongs the process of death" and "treatment can be discontinued when the infant is below the limit of viability".

Parents' wishes

The hospital neonatal-management committee is obligated to discuss the situation with the infant's parents and consider their wishes. The participants also agreed that “parental beliefs and wishes regarding the best interests of the child are significantly important” and “if parents of an extremely premature baby decide on non-initiation of resuscitation, there is no need to proceed”.

Hospital facilities and resources

In the process of guideline development, hospital facilities and all clinical aspects should be taken into consideration (in accordance with the levels of neonatal care). For instance, level III units are required to have neonatologists. Participants also agreed with the statement that “when resources are inadequate at the hospital level, withholding resuscitation or discontinuing life-preserving treatment for extremely premature babies is allowed.”

4. Parental support

This category underpins the fact that including parents in the discussion and process of decision-making will prepare them for the different possible outcomes. The related subcategories are as follows:

Providing emotional support for parents

This category underlines the importance of providing emotional comfort for parents of such babies. This significantly reduces parental stress and their concerns and helps them in the process of decision-making. The participating physicians also believed that “it is significantly important to offer understanding and help in order to alleviate the existing situation for parents”.

Offering real hope

The aim is to help parents in adopting an appropriate decision regarding their child by providing useful information and a comprehensive view of the situation that is necessary for decision-making and also to minimize decision-making driven by emotional bias. “A physician should be regarded as a representative of the healthcare team to provide parents with counseling and information about the process of treatment and possible outcomes”.

Providing parents with useful information

Parents have the right to obtain sufficient information in order to make a proper decision in the best interests of their child. It was also accepted by the participants of the study that “with respect to their social and cultural beliefs, parents should be provided with useful information and comprehensive view of the situation and expected outcomes for the infant”.

Support from close family and friends

Support from close friends and family can also facilitate decision-making for parents. The participants also agreed that “parents are encouraged to discuss the situation with close friends and family whom they feel more comfortable with or even other specialists to make their decisions”.

Direct observation

It is very important to make it possible for parents to be exposed to a real situation where they are able to closely observe other families dealing with premature babies. The primary goal of this observation is to assist parents in their decisions by providing a real-life situation that will help them manage what will likely be difficult aftermath. If the parents’ final decision is the discontinuation of advanced therapeutic measures for their baby, adverse emotional reactions are expected from parents. As a result, helping parents cope with their grief and fear following this decision is important. In this study, both parents and physicians believed that “parents should be given sufficient time and opportunity for calm and careful decision making” and “they should be given sufficient time and opportunity to see and embrace their child or even cry”.

Providing parents with support groups guided by a medical practitioner

Parents should be aware of the fact that their wish or decision is regarded as one of the key factors influencing decisions for continuation or withdrawal of advanced treatment. The participants of the study believed that “parental beliefs regarding the best interests of the child should play a significant role in decisions”.

Discussion

In this qualitative content analysis research, data were collected through semi-structured interviews and focus group discussions (FGDs), and this data collection continued until data saturation was reached.

In this study, it is clearly stated that the responsibility in terms of decision-making for neonates with poor prognosis is upon hospital neonatal-management committees and on the basis of an approved guideline such that decisions are made with regard to the aforementioned guideline, Islamic moral codes, and the scope of services available in the medical units.

This study was performed with the aim of investigating the challenges of decision-making for neonates with poor prognosis, particularly extremely preterm cases.

In a survey conducted in some European countries, two theories have been proposed regarding neonates with poor mental prognoses:

1. Theory of the sanctity of life: Sanctity of life is a priority. It is mandatory to employ any possible measures for every infant, except when death is inevitable.
2. Theory of quality of life: This theory supports the quality of life, allowing refusal of advanced treatment in cases of undesirably low levels of life quality (11).

These theories are in line with the findings of the present study in that every measure must be taken to preserve the life of the infant when there is evidence of the quality of life.

A study in Taiwan examined the attitudes of medical practitioners towards critically ill neonates in NICU’s. In their study, 86.5% of the NICU nurses agreed with “do-not-resuscitate,” and 70% agreed with the withdrawal of advanced treatment (12). Participants of the present study also agreed with palliative care for cases of severe anomalies or advanced asphyxia.

Practitioners from other parts of Iran also had the same attitude towards such infants. However, Huang *et al*., found that 70% of practitioners did not support the withdrawal of life-preserving treatment. According to them, religious beliefs play a significant role in the continuation or discontinuation of therapy in such cases. Other factors influencing practitioner decision included the number of children in the infant's family, pressure on hospital employees, requests by the infant's parents, infant sex, insufficient hospital facilities or resources, history of infertility, and financial status of the family (13).

The present study supports the use of palliative care for critically ill neonates in relation to the facilities and resources of the NICUs, country policies and regulations, and principles of Islamic moral codes mentioned in the guideline. The decision should also be under the supervision of a hospital neonatal-management committee. Similarly, according to the German Medical Association, decisions on the optimal care regarding these critically ill neonates are dependent on the situation and cannot be generalized for all cases (14).

Based on a guideline in Switzerland, neonatal care for preterm infants with gestational age between 22 completed weeks to 23+6/7 weeks should be limited to palliative care only, and midwifery interventions such as cesarean delivery at this age of pregnancy are not indicated. Midwifery interventions and the decision for aggressive care regarding preterm infants at 24 completed weeks to 24+6/7 weeks of gestation are dependent on factors like estimated fetal weight, single or multiple pregnancies, and administration of corticosteroid at the time of birth, along with the probability of success in treatment. The guideline also states that for preterm infants with a gestational age of 25 completed weeks to 25+6/7 weeks, aggressive care will be used whenever need be, while in cases with several predictive factors of poor prognosis and parental consent, palliative care will be employed (8).

In this study, participants believed that NICUs in Iran could provide extremely preterm neonates with special care on the basis of the aforementioned guideline. However, it is essential to determine the limit of viability in our country.

According to the American Academy of Pediatrics and the American Heart Association, resuscitation of newborns with a gestational age of fewer than 23 weeks has no indication due to the high probability of imminent death and the unacceptable consequences among surviving infants (15). This is also in line with the findings of the present study.

Attitudes toward infants who are born at the threshold of viability vary in this study, this is because the study’s participants were from different specialties and had different viewpoints. Considering the available facilities in Iranian hospitals, the neonatologists had the conviction that preterm infants with a gestational age of 25 weeks or more should receive advanced care, although a gestational age of 27 weeks or more was suggested by obstetricians gynecologists, and nurses.

A survey in Iran with the aim of investigating the attitudes of employed NICU pediatricians and neonatologists towards neonates with poor prognosis revealed that 80% of the NICU practitioners employ any necessary aggressive therapies for extremely preterm neonates (gestational age<26 weeks). Nevertheless, the majority of them showed no inclination to employ aggressive care in cases with severe anomalies, including genetic disorders and advanced asphyxia (16).

This study, however, dismisses individual decision-making and underlines the responsibility of hospital neonatal-management committees for making decisions based on an approved guidelines and Islamic moral codes.

Limitations

The sensitivity of this issue and the difficulty of conducting qualitative studies have led to a lack of similar surveys in Islamic and developing countries. As a result, we have not been able to make detailed comparisons with other studies in the discussion. In addition, the fear of legal actions in some cases has caused participants to not easily and unambiguously disclose their opinions.

This study dismisses individual decision-making and underlines the responsibility of a hospital neonatal-management committee. This committee has to make decisions based on an approved guideline that conforms to the regulations of national law and Islamic moral codes. The guideline determines cases that require limitation of treatment and the conditions for discontinuing such treatment for neonates with a poor prognosis. The said guideline should take into account different status of hospital facilities and resources and other conditions within the country.

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