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Review Article :

Care at edge of viability: Legal and ethical issues

Tiwari S.,* Kuthe A.**

*Editor in Chief, New Indian Journal of Pediatrics. Founder President- Indian Medico- Legal and Ethics Association. **Practicing Obstetrician, Zonal Chairman, Indian Medico-Legal and Ethics Association.
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Abstract:

There has been changing face in child / neonatal care including the care of preterm babies. It is recommended that all hospitals that provide high-risk obstetric and neonatal intensive care should develop informative, rational, supportive, clear and practical guidelines to assist the women delivering extremely premature infants. One of the main problems after the survival of a preterm baby is impaired neuro-developmental outcome. The societal cost of saving the preterm babies will be enormous. When we are discussing the legal and ethical issues related to care at the edge of viability, almost everyone has a role to play. The multidisciplinary approach should involve team efforts in decision making. The team shall consist of pediatricians, legal or medico-legal expert, social worker, representative from judiciary, government and possibly policy makers. There are no clear cut "Do Not Resuscitate" (DNR) guidelines in India. Almost all NICUs have struggled with decisions about newborns at the threshold of viability and the question of "how small is too small". Relevant moral considerations include the primacy of the newborn's best interests, parental autonomy, physicians' duties of beneficence and non-maleficence, and distributive justice. Thus it is clear that care at the edge of viability is a challenging and responsible task for the perinatologists and the hospital staff attracting the attention of the concerned.

Key words:

Preterm, Low birth weight, age of viability, NICU, DNR, Euthanasia, Neuro-developmental outcome, ethical issues, Neonatal care,

Introduction:

The third millennium has seen many vibrations, flutters and turbulences in the health care facilities. There are many positive and negative changes in medical sciences in last few decades. The explosion of technical advances has drastically changed the outcome in many cases. Medicine is dynamic and medical ethics are much more dynamic.1 There has been changing face in child / neonatal care including the care of preterm babies. India is known to be land of low birth weight (Preterm as well as small for gestation age) babies. This nightmare continues because of the economical background, demographic conditions, community needs, lack of infrastructure, lack of political willingness and biased or unscientific approaches to various issues. Decision-making for extremely immature preterm infants at the margins of viability is ethically, legally, professionally and emotionally complicated. One may come across a critical situation when he may land up in a dilemma to decide whether to terminate pregnancy or not. Both humanitarian and human right issues need to be balanced with the proper application of physician's brain and mind. Beneficence and non-malfeasance are the first articulated ethical precepts that set the physician-patient framework.

Problems related to prematurity:

The outcome (morbidity or mortality) in a child born prematurely has most of the times created problems not only to the individual / family but also to the society / nation. The differently

enabled child may need special care in most of the situation and hence every one of us has a role to play in management of such children as far as their future life is concerned. It is recommended that all hospitals that provide high-risk obstetric and neonatal intensive care should develop informative, rational, supportive, clear and practical medical staff guidelines to assist in the counseling of women delivering extremely premature infants and implement them successfully. These include decision about instituting, withholding or withdrawing life support therapy, extreme prematurity, severe depression at birth, infants with multiple congenital anomalies and infants with severe chronic conditions such as ventilator dependency etc.

The Neuro-developmental outcome:

One of the main problems after the survival of a preterm baby is impaired neuro-developmental outcome. These children may have impaired physical, social, behavioral, emotional and cognitive functions or development. The resulting spastic, autistic and a child with compromised quality of life poses many obstacles to the optimal care and management of the future generation of any nation. Everybody knows that a child who has survived from an acute episode of severe birth asphyxia or a child who has developed cerebral palsy because of any reason are the potential risks as far as prognosis is concerned. Such children may land in "Permanent Vegetative state", "No chance" situation or even "No purpose" situation in their future life.[2]

The issues related to the cost:

As we have already seen that India is a developing country with restricted and mis-utilized or misappropriated resources. The societal cost of saving the preterm babies (who will in future also need lots of infrastructure for basic support in maintaining a dignified quality life) will be enormous. One has to decide whether this will be possible in debt ridden, multiple scam affected and financially deficient country like India. This is a common problem encountered in hospitals. Initially due to emotional upsurge and social pressures, many persons would consent for ventilation care or support. As the time passes and especially where response is not commensurate with expectations, distress sets in. Family members find themselves unable to take decisions on discontinuing life support and at the same time unable to bear the cost of treatment in a "Five star corporate facility".

The issues related to research:

As discussed earlier, we are in the era of technical advances, where we are trying to overcome the nature or the supernatural power that created the life on this earth. We are on the verge of identifying the "God particle" which will tell us how the life started in this universe. The advances in Gene therapy, Cloning, Stem cells researches are giving the impression that the time is not far away when a scientist will take the place of nature or god. The question is, Are we ethically or morally correct? Are we going in right direction? Is there need to discuss, rethink and introspect ourselves?

Everyone has a role to play:

When we are discussing the legal and ethical issues related to care at the edge of viability, almost everyone has a definite role to play. The multidisciplinary approach in such cases should involve team efforts in decision-making. The team shall consist of pediatricians, legal or medico-legal expert, social worker, representative from judiciary, government authority and possibly policy makers. The issues will involve the fundamental right to life (which includes right to quality of life and right to death) and what to do if this right is at stake. Right not to be born can also be legal right if the suffering itself is violation of Article 21; courts till now are unable to decide whether defective life is worse than non-existence? Therefore there has to be certain standard for prenatal consultation incorporating parental decision-making preferences, a communication process involving a reciprocal exchange of information allowing decisional deliberations.

The issue of Euthanasia:

The euthanasia has not been accepted in India either by policy makers or judiciary. There have been definitive decisions in the court of law that neither recommends "passive euthanasia" nor "active euthanasia". So, one can't accept the decision to terminate the life even if there are all the indications that the baby is going to have compromised life in the future. Professional caregivers providing perinatal consultations or end-of-life counseling for extremely preterm infants should be sensitive to these issues and be taught flexibility in counseling techniques adhering to consistent guidelines. Life support is continued as long as there is reasonable hope for survival and the infant's burden of intensive care is acceptable. If, on the other hand, the health care team and the parents have to recognize that in the light of a very poor prognosis the burden of the currently used therapies has become disproportionate, intensive care measures are no longer justified and other aspects of care (e.g., relief of pain and suffering) are the new priorities (i.e., redirection of care). If a decision is made to withhold or withdraw life-sustaining therapies, the health care team should focus on comfort care for the dying infant and support for the parents.[3]

Do Not Resuscitate:

In medical practice, occasionally, reality brings us to the shore of ethical dilemmas. Although a doctor is bound by the ancient Hippocratic oaths to heal the infirm, treating a person sometimes may appear more harmful than not treating them in certain situations.[4] Even if we feel that the babies born at the edge of viability are at risk of neuro-developmental deficit there are no clear cut "Do Not Resuscitate" (DNR) guidelines in India. In countries like ours, this poses a major difficulty in drawing up ethically sound guidelines, which can deal with this harsh reality while respecting the Human Rights and Child's Rights at the same time. One has to introspect oneself while continuing intensive resuscitation measures in a child having multiple congenital malformations which are not compatible as far as long term morbidity and mortality is concerned. As more reports emerge of improved mortality and morbidity rates in infants born at the edge of viability, there may be need to reassess protocols and recommendations that encourage only comfort care for infants who are born at less than 24 weeks' gestation. Extremely poor survival of these infants reveals that, all too often, the results reflect a predetermined non-aggressive global policy of no resuscitation and minimal investment in intensive care.

The rights of the fetus:

It's not only the right of the preterm babies; we are now in an era, where the discussions have started about the rights of the fetus. Many a times, prematurity could be iatrogenic. The pregnancy might have been terminated or the babies might be delivered for life saving medical indications (both for mother or the child in- utero). In today's era of consumerism, these risks cannot be just ignored. There can be situations in our day to day practice where fetal interests precede over maternal interests in order to avoid prematurity and the consequences arising there from, as well as the calculated risks of fetal anomalies if the pregnancy is allowed to continue. In, one case, Dr. Datar, Mr. X and Mrs. X v. Union of India, a 24 weeks pregnant patient was forced to carry a pregnancy to term that could end in fetal demise or result in the birth of a child with a seriously compromised quality of life. Since the pregnancy was beyond the legal limit, as per the Medical Termination of Pregnancy Act, 1971 the Bombay High Court denied the request made by patient, her husband, and Dr. Datar, failing to recognize the severe mental anguish suffered by patient. The fetal right of being born alive has to be matched with right of being born with mentally and physically healthy life.

Recently, in the first judicial sanction abortion beyond the permissible 20 weeks, the Supreme Court (SC) allowed a rape survivor to terminate her 24-week-old pregnancy after she appealed to the court saying there was an abnormal

growth in the fetus. The woman challenged the validity of Section 3(2) (b) of the Act, which imposes the 20-week restriction. She said she was informed about the abnormality of the fetus after 20 weeks. And because of the law, no hospital was ready to carry out an abortion, which has caused her extreme mental and physical trauma, she said.5 The petitioner had pleaded that the law should give equal weight to the abnormalities of fetus as well as health risk of women as ground for termination at any stage on the basis of expert medical opinion.

Delivered too soon:

One of the reasons for delivered too soon is induction of labor. Therefore before the induction, one must be sure about the proper indications, the contraindication, assess Bishop Score and ensure gestational age and the pulmonary maturity of the fetus. Otherwise apart from maternal complications there is a chance of iatrogenic prematurity which can prove detrimental to the life of newborn. Almost all NICUs have struggled with decisions about newborns at the threshold of viability and the question of "how small is too small".6

The Role of Judiciary:

The Supreme Court in, Aruna Shanbaug v. Union of India, WP (CRL) 115/ 2009 has commented that the issue is, "Is not keeping the women in this persistent vegetative state by force feeding violative of her right to live with dignity guaranteed by Article 21 (Right to life) of the constitution?"[7] The euthanasia is not accepted in our country. The Indian Medical Council (Professional Conduct, and Ethics) Regulations with regard to professional conduct, etiquette and ethics terms the practice of euthanasia as misconduct. The exception is withdrawal of supporting devices to sustain cardio-pulmonary function after brain death. In the rare circumstances where any significant disagreement about best interests cannot be resolved, legal advice should be sought on whether it is necessary to apply to the court for a ruling. Permission shall be sought from the jurisdictional District Court/ High Court (wherever the latter has original jurisdiction) where treatment is being given to the patient, where the patient is in a persistently vegetative state and chances of revival seem remote.

What to do: [8]

1) Counseling pregnant women/ parents regarding family choices, and neonatal outcomes.

2) Unless for a selective patient e.g. who has history of precipitate labor, the social or elective induction should not be accepted.

3) The fetal interest should get priority while deciding the termination unless continuation is dangerous to the life of mother or the fetus.

4) Prospective parents of extremely low birth weight infants should be advised of this substantial risk, to facilitate decision-making in the delivery room.

5) The efforts should focus on improving long-term outcome for survivors and on developing high quality palliative care for non-survivors.

6) Develop a written set of guidelines.

7) We should evolve a rational process and sound mechanism to make correct ethical decisions.

8) In case of decisions that have to be taken in haste, document everything later. Be objective and truthful.

9) Appropriate counseling by more than one consultant helps family members in taking this decision.

Despite ongoing progress in perinatal care over the past decade, mortality rates of infants born before 24 completed weeks of gestation have remained high, and the majority of survivors have at least some degree of neuro-sensory impairment. With increasing knowledge of long-term follow-up data, quality of life aspects have become more important in treatment decisions for infants born at

the limit of viability. Perinatal care of pregnant women at high risk for preterm infants born at the limit of viability (22-26 completed weeks of gestation) requires a multidisciplinary approach by an experienced perinatal team. Prenatally known factors which impact on prognosis can be helpful in the decision making process with the parents. However, if several prenatally known prognostic factors are unfavorable and the parents agree, primary non intervention and neonatal palliative care can be considered. Relevant moral considerations include the primacy of the newborn's best interests, parental autonomy, physicians' duties of beneficence and non-maleficence, and distributive justice. Sometimes there can be ethical dilemma faced by doctors who are unable to act in the best interest of their patients because their hands are tied by the law. Thus it is clear that care at the edge of viability is a challenging and responsible task for the perinatologists and the hospital staff attracting the attention of the concerned. The ethical and medical aspects need to be balanced in the context of benefit burden ratio. Ethical decisions in perinatal medicine are difficult and often complicated by profound medical uncertainty for making a correct diagnosis and prognosis in maternal, fetal and neonatal medicine. Ethical issues are indeed complex and often affected by economic and social realities, gender of the child and attitude of paternalism by the pediatricians in a developing country. The narrow principle of 'best interest' of the child should be replaced by global beneficence to the family, society and state.

(Note: The issues raised in this article were initially included in the booklet; Action report on Preterm Birth in India- "Delivered too soon" – published by IFPB – Indian Foundation for Premature Babies in November 2013).

References:

1) Tiwari S. Medical Ethics: Are we going in right direction? Mathur GP, Mathur Sarla editors; Current trend in Pediatrics Vol. 2, 1st edition Delhi, Academa Publishers 2006; 67-71

2) Bhattacharya A , Mishra S. DNR, Euthanasia and Life Support Systems; In: Tiwari S, Baldwa M, Tiwari M, Kuthe A editors; Text Book on medico-legal issues related to various medical specialties: 1st edition, Jaypee brothers medical Publishers, New Delhi 2012; 179-185

3) RCPCH, UK. Withholding and Withdrawing Life Prolonging Treatments: Good Practice in Decision-making. May 2004

4) Sanjib Das Adhikary, R Raviraj, Do Not Resuscitate orders. Indian J Med Ethics. 2006 Jul-Sep;3(3)

5) Abnormal' fetus: Supreme Court permits woman to terminate 24-week-old pregnancy. http://timesofindia.indiatimes.com/india/Abnormal-fetus-Supreme-Court-permits-woman-to-terminate-24-week-old-pregnancy/articleshow/53378678.cms Accessed on 28 July 2016

6) Birla M. Medicolegal and ethical issues in new born care; In: Tiwari S, Baldwa M, Tiwari M, Kuthe A editors; Text Book on medico-legal issues related to various medical specialties: 1st edition, Jaypee brothers medical Publishers, New Delhi 2012; 171-173

7) Mahapatra D. SC admits women's plea to end her life. The Times of India, 2009; 18th Dec. Nagpur page 1 (Col. 7-8).

8) Mani RK, Amin P, Chawla R, Divatia JV, Kapadia F, Khilnani P, et al. Limiting life-prolonging interventions and providing palliative care towards the end of life in Indian intensive care units. Indian J Crit Care Med 2005; 9: 96-107.