Periviable Birth – The Ethical Conundrum

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When delivery is anticipated near the limit of viability, both the family and the caregiver are faced with many complex and ethically challenging decisions. It must be remembered that the decisions that are made are going to impact the entire life of the baby and the family. Such decisions should be based on the best available evidence about the prognosis for the infant. If the chance of mortality and serious morbidity for an infant is high (but not too high), parental discretion around provision of life-sustaining treatment is appropriate. In this article, we discuss issues on survival and outcomes of extremely premature infants, and the available guidelines.

Keywords: *Ethics, Extreme prematurity, Survival, Viability*.

The World Association of Perinatal Medicine defines a fetus as viable when it is mature enough to survive into the neonatal period with the clinical support that is available. More objectively, Periviable birth is currently defined as delivery occurring from 20 0/7 weeks to 25 6/7 weeks of gestation [1]. The outcome of these babies ranges from certain or near-certain mortality to likely survival with a high chance of long-term morbidities. When delivery is anticipated near the limit of viability, both the family and caregiver are faced with many complex and ethically challenging decisions.

The clinical support available in India varies across the country and even within cities. The lack of widespread accreditation of neonatal units makes it difficult to determine the type of support available in a given unit. Currently, the focus is increasingly on the ethics of giving support to neonates that are born very preterm. Since most of India receives healthcare from out-of-pocket expenses, the debate around care of the extremely preterm neonates often attracts unfavorable media attention.

In this article, we discuss issues on survival and outcomes of extremely premature infants, available guidelines, and try to provide guidance on the need to develop a process locally that can address this issue.

SURVIVAL AND LONG-TERM OUTCOMES

Historically, neonatal mortality is considered an inevitability at or before 24 weeks of gestation [2,3]. While, we do not have any data on the outcomes of these babies from India, a review of studies from the past few decades do reveal an increase in the rate of survival of newborns born at 22-25weeks of gestation [4-7]. The rates of survival to discharge increase with increasing gestational age of periviable babies (23-27% for births at 23 weeks, 42-59% for births at 24 weeks, and 67-76% for births at 25 weeks) [4,5,7].

Data trends on long-term sequelae are the same, showing better outcomes at higher gestations. A follow-up study of a cohort of periviable babies in England, demonstrated a decrease in the proportion of children at age 30 months with severe or moderate impairment, with increasing gestational age at birth (45% at 22-23 weeks, 30% at 24 weeks, and 17% at 25 weeks of gestation) [8]. A review by Moore, *et al*. [9] also established that the incidence of moderate-to-severe neurodevelopmental impairment among survivors at 4-8 years improved with higher gestational age at birth: 43% at 22 weeks, 40% at 23 weeks, 28% at 24 weeks, and 24% at 25 weeks of gestation. However, even though the combined rate decreased, the rate of severe neuro-developmental impairment alone did not vary significantly with gestational age. A study from United States discussed survival and long-term neurologic outcomes in more than 4,000 births from 2001 to 2011 that were between 22 to 24 weeks of gestation [9]. The results demonstrated an actual increase in rate of survival without impairment in the study duration, whereas the rate of survival with impairment has remained constant. However, the lack of data from Indian settings makes us wary of drawing any such conclusions.

THE ETHICS OF DECISION-MAKING IN THE DELIVERY ROOM

The ethical principles, even in preterm infants, remain the same as applied to other areas of medicine. The guiding principles for the neonatologist are – beneficence (doing good), non-maleficence (doing no harm), autonomy (respecting individual preferences) and justice.

The principle of beneficence is a major force behind the efforts to rescue these newborns. Traditionally, medicine's ability to prolong life is taken as unqualified good. However, in case of these very premature babies, it needs to be decided whether use of medical technology is actually postponing death rather than prolonging life. Furthermore, life may not always be preferable to death, when continuing life means deep suffering, a common scenario for these very premature babies. The principle of non-maleficence is then taken into account as significant suffering must be justified by expected outcome, while inflicting such suffering may become unjustifiable when the likelihood of survival becomes extremely small.

The application of the principle of autonomy is complicated, as infants have no autonomy. Both parents and physicians have a moral right and a legal duty to make treatment decisions in the best interests of the baby. Parents and physicians may disagree regarding the course of action – pertaining to uncertain medical outcomes, different values, resources, tools and outlook [10]. For physicians, there is a greater focus on technical components, such as outcome data, evidence-based prognostic tools, and the clinical picture, such as the actual presentation of the baby at birth. Conversely, parents are generally more emotionally and psychologically invested in any decision made, lacking the technical expertise to assess complex clinical information.

Lastly, the principle of justice implies not only treating similar preterm babies similarly, but also effectively using resources (distributive justice). Aggressive care of extremely premature babies with a remote possibility of intact survival may be considered an inappropriate allocation of resources. Add to this a public-private co-operation health system with variation in availability of resources, inherently leading to unfairness.

Despite, such complexities in decision-making, it must be remembered that the decisions that are made are going to impact the entire life of the baby and the family; and many decisions such as stopping care are not reversible and can have long-term impact on the mental health of the parents. Hence, having a decision-making framework is beneficial for all stakeholders in the process.

President's Commission, 1983

This was a landmark decision-making framework, although not meant specifically for treatment dilemmas at the threshold of viability, the commission proposed ethically appropriate physician responses to parental requests for the provision or withholding of treatment in each of three treatment categories, *viz.*, clearly beneficial, of uncertain benefit, or futile [11] (***Table* I**).

As long as this choice does not cause substantial suffering for the child, providers should accept it. Although, individual health care professionals who find it personally offensive to engage in futile treatment may arrange to withdraw treatment.

The Grey Zone and Zone of Parental Discretion

Most of the periviable babies die, while majority of survivors have long-term morbidities. It is a difficult decision for doctors and parent – whether you decide to treat them with the knowledge that more often than not such efforts will be unsuccessful and result in huge discomfort to the baby. On the other hand, not giving treatment allows some of these babies to die who might have been saved? This is the Grey Zone [12].

The zone of parental discretion is the ethically protected space where parents may legitimately make decisions for their children, even if the decisions are sub-optimal for those children [13].

In the Grey Zone, the dictum is to follow parents' wishes. The major problem area for neonatologists is when the zone of parental discretion overlaps with area above the grey zone where treatment is considered mandatory, but there is difference of opinion between caregivers and parents (***Fig.* 1**). The major guiding principles in the Grey zone are detailed in ***Box* 1**.

TABLE I PRESIDENT'S COMMISSION, 1983 [11]

Physician assessment of treatment	*Parents prefer to accept treatment*	*Parents prefer to forego treatment*
Clearly beneficial to the infant	Provide treatment	Provide treatment (seek legal or other review)
Ambiguous or uncertain benefit to the infant	Provide treatment	Withhold/ withdraw treatment
Futile	Provide treatment unless provider declines to do so	Withhold/ withdraw treatment

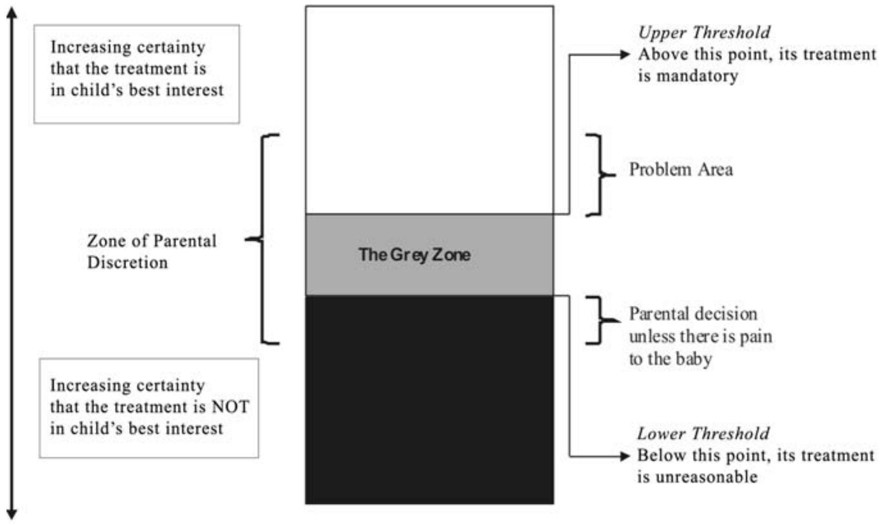

FIG. 1 *Conceptual framework for the grey zone in treatment decisions.*

Shared Decision-making

Under ordinary circumstances, parents are likely to be the best advocates for their infants. Therefore, parental wishes should generally be followed, and issues important to them should be considered in decision-making. In cases of borderline viability, clinicians may feel compelled to advocate for the neonate and provide treatment against parental wishes. Such decisions are not ethically justifiable if it is impossible to weigh up the potential harms to the child or to consider what is in the best interests of the child due to a lack of prognostic certainty.

BOX 1 GUIDING PRINCIPLES IN THE GREY ZONE

- Understand parents' view on optimizing survival or minimizing suffering beforehand during antenatal counselling and discussion sessions.
- Keep in mind the institutional policies and local laws.
- A stepwise approach based on newborn's condition and parental wishes is appropriate. Care should be regularly re-evaluated and redirected.
- Decision for continuing care or otherwise should be individualized – specific clinical issues, family values/wishes, and ongoing evaluation of fetal or neonatal condition.
- Multidisciplinary neonatal palliative care should be provided in babies with the decision to withdraw or withhold care.
- Healthy parent-clinician relationship with sharing of the decision-making responsibility.

NEONATAL PALLIATIVE CARE

In newborns affected by life-threatening or life-limiting conditions, when prolonging survival is no longer a goal, a plan of care focused on the infant's comfort is essential. These strategies identify and address the basic needs of the newborn such as bonding, maintenance of body temperature, relief of hunger/thirst, and alleviation of discomfort. It is a multidisciplinary care given the complex needs of infants and their families. Professionals like social workers, workers from non-governmental sector, psychologists, child life specialists, and spiritual representatives need to be actively involved in the care to address psychosocial, financial, emotional, practical, and spiritual needs of the family.

It is no surprise that parents of babies who have received palliative services are more likely to be satisfied with the care compared with parents whose infant did not receive it [14]. Thus, the authors feel that there is an urgent requirement to standardize neonatal palliative care practices and educate caregivers regarding palliative care.

Withdrawal and Withholding of Care

Both ethicists and clinicians generally accept that there is no significant ethical difference between withholding and withdrawing intensive care measures [15]. However, for some parents withdrawing is more difficult than withholding intensive care measures. This may be secondary to increased emotional attachment as time progresses. Proper understanding of this concept between parents and clinicians, can lead to initiation of resuscitation in uncertain cases with an option kept open to withdraw care if the situation warrants it. In fact, the authors feel that such a pathway should be preferred because with the passage of time a better clinical picture is formed to base the decision.

AVAILABLE GUIDELINES

The European Resuscitation Council 2015 guidelines mention a variation of opinions regarding aggressive therapies in such babies. Parents desire to participate in a larger manner in the decision to resuscitate and continue life support. Local survival and outcome data are essential to appropriately guide and counsel the parents [16]. The American Academy of Pediatrics/ American Health Academy's 2015 resuscitation guidelines takes 25 weeks' gestation as a cut-off point. It cautions into considering various factors that can affect survival, and using region-specific guidelines while counselling parents and constructing a prognosis [17].

The 2017 consensus of American College of Obstetricians and Gynecologists (ACOG) and Society of Maternal-Fetal Medicine on Pre-viable birth recommends resuscitation from 24 0/7 weeks onwards and considers resuscitation between 22 0/7 to 23 6/7 weeks gestational age. Below 22 weeks, resuscitation is not recommended [18]. The guidelines further state that a stepwise approach considering neonatal circumstances and parental wishes is appropriate. Care decisions should be re-evaluated regularly and potentially redirected based on the evolution of the clinical situation.

Clinicians also use certain tools to predict the outcome of babies especially those in the grey zone. One of the most commonly used models is the NICHD Neonatal Research Network tool that is based on prospectively collected large data of extremely premature infants [19]. There are some fallacies of such models. Most importantly, gestational age, generally a key component in these models may not be known accurately in all cases. The major problem by defining outcomes based on completed weeks is that it eliminates the differences between a fetus at 23 0/7 weeks and 23 6/7 weeks of gestation, as well as the similarities between a fetus at 23 6/7 weeks and 24 0/7 weeks of gestation. The inaccuracy of ultrasound-estimated fetal weight also introduces a degree of uncertainty to the prediction of newborn outcomes [18]. Lastly, the response of an individual neonate to resuscitation cannot be predicted.

Thus, when a specific estimated probability for an outcome is offered, it should be stated clearly that this is an estimate for a population and not a prediction of a certain outcome for a particular patient in a given institution.

Complexity of the Indian Scenario

In India, the scope and extent of medical services ranges across a spectrum from poor healthcare to the best in the world. In situations where appropriate care is not available, it would be ethically correct that the parents should be given a choice to seek care elsewhere.

The turmoil between ethics, logic and progress is deep-rooted and intense in India. In addition to expenses being out of pocket, we have cultural norms, which define who pays for first delivery or second delivery, decisions to treat or not to treat are taken by an extended family, the health care personnel are fewer in number and are poorly trained in ethics as well as communication. Even proper documented communication may be refuted by parents as we see in a recently published paper from India [20]. In addition, India is a cultural melting pot with multiple religions and sects with varying approaches to births and deaths and often with gender preferences. In such a scenario, making a blanket prescription for periviability is a prescription for disaster.

There is an urgent need for a national consensus for management of periviable babies and development of a database to collect outcomes in this group. Analyzing the facts of neonatal survival, morbidity and impact on families, we feel that each newborn should be treated individually. The predefined gestational age limits should be replaced with a more proactive approach. The neonatologist must develop a personal approach towards decision-making.

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