Bioethical Considerations On Marginal Viability and Disability in Newborns

Ronald Lee Ariagno, M.D.
Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine

Prematurity in the USA

Birth Rate and Prematurity

<table>
<thead>
<tr>
<th>Premature Births by Gestational Age in U.S. 1998</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;28 weeks</td>
<td>29,037</td>
</tr>
<tr>
<td>28-31 weeks</td>
<td>47,486</td>
</tr>
<tr>
<td>32-35 weeks</td>
<td>212,210</td>
</tr>
<tr>
<td>Total &lt; 37 weeks</td>
<td>288,733</td>
</tr>
</tbody>
</table>


Distribution by Gestational Age

Births at the Threshold of Viability:

“Early preterm birth of an extremely low birth weight (ELBW) infant (less than 1000g), especially those weighing less than 750 g or less than 26 weeks of gestation, poses a variety of complex medical, social and ethical considerations. The effect of such births on the infants, their families, the health care system, and society is profound. Although the prevalence of such births is less than 1%, they account for nearly one half of all cases of perinatal mortality. Until recently, discussion of clinical management and ethical and economic considerations of extremely preterm births were hampered by conflicting and insufficiently detailed outcome data.”
Survival by Birth Weight 1997-2002

Mortality by Birth Wt, GA and Gender

No Significant Change in Morbidity over a Decade

Neurodevelopmental Outcome in Extremely Low Birth Weight Infants in USA

Table 1: Neurodevelopmental Outcome at 22Mo: Risk Levels at 19Mo Correlated by Age at 22Mo and Standard Age

Vohr BR et al. Pediatrics 2005

ABSTRACT. The Born-Alive Infants Protection Act (BAIPA), passed by Congress in 2002, has attracted little publicity. Its purpose was, in part, "to repudiate the flawed notion that a child's entitlement to the protections of the law is dependent on whether that child's mother or others want him or her." Understood as antiabortion rhetoric, the bill raised little concern among physicians at the time of legislative hearings and passed in both Houses by overwhelming majorities, hardly suggesting contentious legislation. After its signing into law, the Neonatal Resuscitation Program (NRP) Steering Committee issued an opinion stating that "[BAIPA] should not in any way affect the approach that physicians currently follow with respect to the extremely premature infant." This interpretation of the law, however, may have been short sighted.


In April 2005, the US Department of Health and Human Services (DHHS) brought life to the BAIPA, announcing: "As a matter of law and policy, [DHHS] will investigate all circumstances where individuals and entities are reported to be withholding medical care from an infant born alive in potential violation of federal statutes." The agency issued instructions to state officials on how the definitional provision within the BAIPA interacts with the Emergency Medical Treatment and Labor Act (EMTALA) and the Child Abuse Prevention and Treatment Act (CAPTA). Those interagency memos, potentially recur, dormant governmental oversight of newborn-treatment decisions and thus may have influence over normative neonatal practice.
**Guidelines for Neonatal Resuscitation**

Neonatal Resuscitation Program (NRP)
American Academy of Pediatrics (AAP)
American Heart Association (AHA)
International Liaison on Resuscitation (ILCOR)

Other refs.
Pediatrics 2006; 117: 978-988 and 1029-1038
Circulation 2005; 112; 188-195

---

**Update on Resuscitation of the Newborn 2006**

**Withholding or withdrawing Resuscitation**

- High rate of survival - resuscitation indicated
- Borderline survival - parental input essential
- When in doubt - resuscitate
- Discontinuation - after 10 minutes of effective resuscitation without signs of life

**What are some of the Biologic Issues?**

- Growth Restriction: short and long term
- Brain Growth
  - Development is linked with growth (viz., no growth = no developmental advance)
- Delay in regaining birth weight usually > 2-4 weeks
- Adverse Effects of Intensive Care
  - Morbidity of Prematurity (ROP, IVH, NEC, PDA, etc.)
  - Eutherian mammal and no substitute for placenta (viz., not marsupial like kangaroo)
  - “Barker Hypothesis” that low birth weight is a marker for adult diseases (viz., cardiovascular disease and diabetes mellitus)
Postnatal Growth Restriction in ELBW Infants: Effect on Brain Growth and Development

*Cooke RWI. 2005 Arch Dis Child Fetal Neonatal Ed; **Ehrenkranz RA et al Pediatrics 2006

What are Some of the Biologic Issues?

Chronic physiologic instability non-preventable in current neonatology practice (viz., repeated hypoxia and severe bradycardia) probably related to severe immaturity, insufficient development for metabolic demand, cardiopulmonary dysmaturity (e.g., arrest of lung development) and burden of intensive care.

Modern neonatal intensive care has limited developmental interventions beyond antenatal steroids.

At time of discharge infants are often growth restricted and although may be term corrected age are still fragile and not equivalent to full term infant in function or size.

Modern neonatal intensive care has limited developmental interventions beyond antenatal steroids.

At time of discharge infants are often growth restricted and although may be term corrected age are still fragile and not equivalent to full term infant in function or size.

Table 6.39: Summary of outcomes age in six years of age among children born after at different gestational ages in the 1995 EPICure study.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>22 weeks</th>
<th>23 weeks</th>
<th>24 weeks</th>
<th>25 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birthweight &lt; 1000 gr</td>
<td>90.2 (68)</td>
<td>90.2 (68)</td>
<td>90.2 (68)</td>
<td>90.2 (68)</td>
</tr>
<tr>
<td>Birthweight &lt; 1250 gr</td>
<td>82.1 (40)</td>
<td>82.1 (40)</td>
<td>82.1 (40)</td>
<td>82.1 (40)</td>
</tr>
<tr>
<td>Birthweight &lt; 1500 gr</td>
<td>77.0 (63)</td>
<td>77.0 (63)</td>
<td>77.0 (63)</td>
<td>77.0 (63)</td>
</tr>
<tr>
<td>Birthweight &lt; 1750 gr</td>
<td>69.9 (46)</td>
<td>69.9 (46)</td>
<td>69.9 (46)</td>
<td>69.9 (46)</td>
</tr>
<tr>
<td>Birthweight &lt; 2000 gr</td>
<td>64.0 (50)</td>
<td>64.0 (50)</td>
<td>64.0 (50)</td>
<td>64.0 (50)</td>
</tr>
<tr>
<td>Birthweight &lt; 2500 gr</td>
<td>57.1 (32)</td>
<td>57.1 (32)</td>
<td>57.1 (32)</td>
<td>57.1 (32)</td>
</tr>
<tr>
<td>Birthweight &lt; 3000 gr</td>
<td>49.5 (20)</td>
<td>49.5 (20)</td>
<td>49.5 (20)</td>
<td>49.5 (20)</td>
</tr>
<tr>
<td>Birthweight &lt; 3500 gr</td>
<td>45.6 (15)</td>
<td>45.6 (15)</td>
<td>45.6 (15)</td>
<td>45.6 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 4000 gr</td>
<td>41.9 (16)</td>
<td>41.9 (16)</td>
<td>41.9 (16)</td>
<td>41.9 (16)</td>
</tr>
<tr>
<td>Birthweight &lt; 4500 gr</td>
<td>39.0 (15)</td>
<td>39.0 (15)</td>
<td>39.0 (15)</td>
<td>39.0 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 5000 gr</td>
<td>36.3 (15)</td>
<td>36.3 (15)</td>
<td>36.3 (15)</td>
<td>36.3 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 5500 gr</td>
<td>33.6 (15)</td>
<td>33.6 (15)</td>
<td>33.6 (15)</td>
<td>33.6 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 6000 gr</td>
<td>31.0 (15)</td>
<td>31.0 (15)</td>
<td>31.0 (15)</td>
<td>31.0 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 6500 gr</td>
<td>28.5 (15)</td>
<td>28.5 (15)</td>
<td>28.5 (15)</td>
<td>28.5 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 7500 gr</td>
<td>23.7 (15)</td>
<td>23.7 (15)</td>
<td>23.7 (15)</td>
<td>23.7 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 8000 gr</td>
<td>21.3 (15)</td>
<td>21.3 (15)</td>
<td>21.3 (15)</td>
<td>21.3 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 8500 gr</td>
<td>19.0 (15)</td>
<td>19.0 (15)</td>
<td>19.0 (15)</td>
<td>19.0 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 9000 gr</td>
<td>16.7 (15)</td>
<td>16.7 (15)</td>
<td>16.7 (15)</td>
<td>16.7 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 10000 gr</td>
<td>12.1 (15)</td>
<td>12.1 (15)</td>
<td>12.1 (15)</td>
<td>12.1 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 10500 gr</td>
<td>9.8 (15)</td>
<td>9.8 (15)</td>
<td>9.8 (15)</td>
<td>9.8 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 11000 gr</td>
<td>7.5 (15)</td>
<td>7.5 (15)</td>
<td>7.5 (15)</td>
<td>7.5 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 11500 gr</td>
<td>5.2 (15)</td>
<td>5.2 (15)</td>
<td>5.2 (15)</td>
<td>5.2 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 12000 gr</td>
<td>2.9 (15)</td>
<td>2.9 (15)</td>
<td>2.9 (15)</td>
<td>2.9 (15)</td>
</tr>
<tr>
<td>Birthweight &lt; 12500 gr</td>
<td>0.6 (15)</td>
<td>0.6 (15)</td>
<td>0.6 (15)</td>
<td>0.6 (15)</td>
</tr>
</tbody>
</table>
Nuffield Council on Bioethics: regarding “previable” fetus 22 6/7 wk. GA or less

“While experimental studies are important to advance practice, it is our view that attempts to prolong life following birth before 22 weeks of gestation should be carried out only as part of a research study that has previously been assessed and approved by a research ethics committee. For such a study the parents would need to consent in advance to the resuscitation and active treatment of their baby.”

Effect of Physician’s Presentation on Parental Decisions

Objectives: To assess attitudes of neonatologists toward parental wishes in delivery room resuscitation decisions at the threshold of viability.

Study design: Cross-sectional survey of 153 practicing level III neonatologists in 8 New England states.

Results: Response rate was 86% (129/153). At 21-27 6/7 weeks’ gestation, 11% of neonatologists considered treatment short of death; 74% considered resuscitation short of death. When parents or neonatologists required resuscitation, 91% of neonatologists considered treatment short of death. Thirty-three percent reported that they would consider short-term treatment if parent consented. When neither parent nor physician wanted resuscitation, 74% of neonatologists would consider resuscitation. Parental non-consent and birth asphyxia reported that they would advise parents to consent to resuscitation.

Conclusion: Variation in neonatologists’ beliefs about the decisional limits of short-term resuscitation and surfactant use for preterms at the margin of viability is likely to impact the number of long-term survivors. This points to the importance of transparency in neonatal decision-making. (J Perinatol 2004; 24:589-92)

Peerzada JM, Richardson DK, Burns JP. Delivery room decision making at the threshold of viability. J Perinatol 2004; 24: 492-98

Nuffield Council on Bioethics: Borderline of viability

“The most important point to communicate at the borderline of viability is that between 23 and 25 weeks, six days of gestation, while survival is possible, the future for some children is bleak, yet for others it is not and doctors cannot reliably predict which group a surviving baby would fall into.”

23 Week GA Infant Resuscitated Against Parents’ Consent

In an English General Practitioner

LEGAL ISSUES IN MEDICINE

Extremely Preterm Birth and Parental Authority to Refuse Treatment — The Case of Sidney Miller

George L. Abraham, J.C., D.P.H.L.

September 13, 2012

Whether a consistent right to refuse treatment exists, it is clear that the issue of informed consent and the limits of parental authority to refuse treatment are complex and require further study. One approach is to consider the concept of consent as a form of delegated decision-making. This approach recognizes the importance of transparency in decision-making and emphasizes the role of the neonatologist in providing clear and comprehensive information to families. (J Perinatol 2004; 24:589-92)

In addition, although consent need not be absolute, the issue of informed consent in the NICU should not be considered as a simple matter of legal compliance.
Closing Remarks

Current approach to decision making is totally flexible and permissive thus same clinical scenario may have significantly different or opposite management in the same unit/hospital, the same state, the same country.

Intensive care for the extreme preterm infant is generously funded.

Parents’ wishes are more likely to be overruled if more intensive care or resuscitation is considered imperative by intensive care team or hospital. The trend over the last decade is intensive care for the most extreme fetal infants and nothing prohibits a neonatologist in this pursuit.

Closing Remarks

Closing Remarks

Use of Published Data to inform parents may be flawed if local data are not consistent.

Decisions should always be guided by “best interests of the child” which is often lost with so many other agendas (often parents are not sufficiently conscious about pain, suffering, current morbidity or risks or the distinction between possible and probable).

The outcome (i.e., to obtain the highest level of function) hinges on the intervention of parents, community services and development specialists.

Adult follow up studies will be need to address whether the Barker hypothesis is relevant to preterm child.

Closing Remarks

The rational for management may be difficult to understand particularly when the parents and neonatologist follow the maxim of “doing everything” and I would add “anything” perceived to be relevant to pursue survival.

Decisions made on what is “possible” (often parent perspective) rather than “probable” (research, evidence-based) may lead to opposite conclusion and management.
Recommendations for Your Consideration

Although the Fetus and Newborn Committee will be publishing an update on “Decision Making at the Threshold of Viability” later this year it is imperative that we have serious professional and community debate about the issues and concerns.

Ultimately, the voices that need to be heard are the adults who were extremely preterm to see if we acted in their best interests.