Viability – and its Many Shades of Grey

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Faculty Disclosure of Commercial Relationships

- Provided full disclosure information which has been forwarded to the CME Office
- Have no significant financial relationship(s) to disclose

Objectives

1. Participant will be able to describe historical perspectives of viability.
2. Participant will be familiarized with the ACOG / SMFM Obstetric Care Consensus.
3. Participant will be able to use the NICHD Periviable calculator.
4. Participant will be able to describe ethical considerations of periviable care.
A Historical Look at Viability

- AJOG 1978
- 126 women < 34 weeks randomized to steroids or placebo
Injection of corticosteroids into mother to prevent neonatal respiratory distress syndrome.

- Significant decrease in RDS and improved neonatal survival
- "It would appear from these data that the injection of steroids is beneficial in mothers at risk of being delivered of premature infants."

Fetal Growth and Perinatal Viability in California

- Green Journal, 1982
- Reviewed 2,288,806 births
- Mortality more strongly related to birthweight over gestational age

The variability of viability: The effect of physicians' perceptions of viability on the survival of very low-birth weight infants

- AJOG 1982
- Survey of delivering physicians in Alabama
“...physicians who perform deliveries tended to underestimate the potential for neonatal survival in premature infants... In the hypothetical cases, management decisions often appeared to be based on incorrect information about neonatal survival.”

“...These decisions, including not electronically monitoring fetuses, not performing a cesarean section for fetal distress, and not transferring women in premature labor to a perinatal center, if made in actual cases, would result in potentially viable fetuses receiving less than optimal management.”

- Green Journal, 1985
- Determine the association between mode of delivery and in-hospital mortality and morbidity and mortality at 2 years
Cesarean section or vaginal delivery at 24 to 28 weeks' gestation

- 172 of 326 infants survived to home
- Factors associated with improved survival
  - Increasing gestational age ($p < 0.0001$)
  - Absence of maternal hypertension ($p = 0.007$)
  - Singleton pregnancy ($p = 0.007$)
  - Antenatal steroids ($p = 0.018$)

Of the 172 initial survivors, five died at home
162 / 167 were followed:
- 18 (11.1%) had cerebral palsy
- 2 (1.2%) were deaf

Of 111 children fully assessed:
- 13.5% had major handicaps
- 23.4% were “suspect”
- 63.1% were free of handicap at two years' corrected age
Fast forward 17 years ...

Contemporary Trends in the Management of Delivery at 23 Weeks’ Gestation

- 2000: surveys sent to members of SMFM
- (Mail or fax!)
- 462 / 1,244 surveys returned (37%)
Significant portion of those who believe viability ≤ 23 weeks practicing ≥ 10 years (30% vs 70%, p = 0.05)
Is neonatal intensive care justified in all preterm infants? Yu et al., 2005

“If doctors believe that such infants have little prospect for intact survival, their management would be suboptimal or delayed, thus creating a self-fulfilling prophecy...”

<table>
<thead>
<tr>
<th>Week</th>
<th>Survival</th>
<th>Intact Survival</th>
</tr>
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<tbody>
<tr>
<td>&lt;23 weeks</td>
<td>5 - 6%</td>
<td>0 – 2 %</td>
</tr>
<tr>
<td>23 weeks</td>
<td>25%</td>
<td>*</td>
</tr>
<tr>
<td>24 weeks</td>
<td>50%</td>
<td>*</td>
</tr>
<tr>
<td>25 weeks</td>
<td>75%</td>
<td>*</td>
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ACOG / SMFM Consensus

Generally speaking, at UAB we:

• Offer obstetric intervention at 24 weeks gestation
• Offer, but not encourage, obstetric interventions at 23 weeks
• Offer BTMS at 22 weeks with post-delivery NICU assessment
• For growth restricted fetuses, ~ 450 grams is another threshold for offering obstetric intervention
“A decision not to undertake resuscitation of a liveborn infant should not be seen as a decision to provide no care, but rather a decision to redirect care to comfort measures.”

Counseling

Shared Decision Making
Periviable Counseling

• Discuss outcomes
  • Survival
  • Survival without handicaps
    • Handicaps may range from difficulty with math in school to the baby being blind, deaf, and unable to walk requiring 24/7 nursing care.
  • "We support whatever decision you make."
Extremely Preterm Birth Outcomes Calculator

- Prospectively collected information
- 1998 and 2003, 22 to 25 weeks
- 401 - 1,000 grams at birth, non-anomalous
- 19 academic centers
- Based on assessments of outcomes at 18 - 22 months corrected age
- Column 1: includes all 4,446 infants in the study
- Column 2: based on 3,702 infants who received intensive care

The combination of five variables—1) gestational age, 2) birth weight, 3) exposure to antenatal corticosteroids, 4) sex, and 5) plurality—was found to be more predictive of outcomes than gestational age and birth weight alone.

NICU Counseling
Face to face time with the family

Infants of borderline viability: The ethics of delivery room care

• They propose 10 suggestions for physicians who deal with ‘viability’.
• 1. Be ok with the grey.
  • Variation in management in inevitable and that’s ok.

• 2. Do not place too much emphasis on gestational age.
  • Dating is imprecise. Infants of the same known gestational age may behave very differently.
Infants of borderline viability: The ethics of delivery room care

3. Dying is usually not in an infant’s best interest.
   • Long term outcomes, QOL, burden of care are all important.
   • If an infant is not allowed a “trial of life” s/he will never have the opportunity to confront these battles.
   • It is hard to argue that death without a proper chance of life is ever in an infant’s best interest.

Infants of borderline viability: The ethics of delivery room care

4. Impairment does not necessarily equal poor quality of life.
   • Self-reported QOL scores from former preemies are equal to their normal birth weight counterparts.
   • We cannot judge someone else’s QOL.

Infants of borderline viability: The ethics of delivery room care

5. Just because the train has left the station does not mean that you can’t get off.
“Just because the decision was made to attempt resuscitation at 23 weeks in the delivery room, it does not mean that the baby is automatically committed to a tracheostomy, g-tube, and home ventilator at the age 6 months. Discussions about the care of extremely preterm infants must be ongoing. Parents and the medical team are welcome to alter the course of treatment at anytime, should complications arise. It must be remembered that withdrawal of care is ethically equivalent to the withholding of care.”

Infants of borderline viability: The ethics of delivery room care
• 6. Respect powerful emotions. They reveal moral truths.
  • Emotion and feelings of parental duty will overrule logic without direction and guidance from the medical team.

Infants of borderline viability: The ethics of delivery room care
• 7. Be aware of the self-fulfilling prophecy.
  • “If resuscitation is never attempted at 22 weeks, then of course no infants will survive at 22 weeks...”
  • May contribute to the increased survival rates seen in the Japanese population.
  • In the 1950's the survival rate at 26 weeks was close to 0% because resuscitation was not attempted.
Infants of borderline viability: The ethics of delivery room care

• 8. Time lag likely skews all outcome data.
  • "An infant admitted to a NICU today does not receive the same care as an infant born in 1995 or in 2013."
  • "By the time data can be collected, analyzed and published, advances undoubtedly will have occurred."
  • "Long-term follow up data must be interpreted cautiously when applied to an infant born today."

• 9. Statistics can be both confused and confusing.
  • "For parents … statistics are an all or non retrospective phenomenon. If their child lives, survival is 100%. If their child dies, survival is zero. There is no such thing as 26% survival for an individual baby."

• 10. Above all, never abandon parents.
  • "Parents of babies in the NICU are on an emotional roller-coaster. They may behave badly. Some get angry. Some don’t visit their babies. Others can be intrusive or critical of staff. Parents need the support and guidance of doctors and nurses. The parents who are the most difficult to get along with are often the ones who need support the most."
What’s on the horizon?

ClinicalTrials.gov

- 31 trials currently recruiting for surfactant
  - Various methods of administration
    - Aerosolized
    - LMA
    - Topical
Additional Disclosures

• Today’s presentation may not fully represent my partners’ views
• Questions? Call us on the MIST line

Thank you!
Neonatal Research Network: Antenatal Corticosteroids

• “Sought to determine if antenatal corticosteroids are associated with improvement in major outcomes in infants born at 22 and 23 weeks.”

• “Prospectively collected data on 401–1000 gram inborn infants (N=10,541) of 22–25 weeks gestation born between 1993–2009 at 23 academic perinatal centers in the United States.”

• “Certified examiners unaware of exposure to antenatal corticosteroids performed follow-up examinations on 4,924 (86.5%) of the infants born in 1993–2008 who survived to 18–22 months. Logistic regression models generated adjusted odds ratios, controlling for maternal and neonatal variables.”

Results

“Death by 18–22 months, hospital death, death/intraventricular hemorrhage/periventricular leukomalacia, and death/necrotizing enterocolitis were significantly lower for infants born at 23, 24, and 25 weeks gestational age if the mothers had received antenatal corticosteroids but the only outcome significantly lower at 22 weeks was death/necrotizing enterocolitis (antenatal corticosteroids, 73.5% vs no antenatal corticosteroids, 84.5%; adjusted odds ratio 0.54; 95% CI, 0.30–0.97).”
Between hospital variation ...

- Multi-centered, 2006 – 2011
- 4,987 infants < 27 weeks without congenital anomalies
- Survival and neurodevelopmental impairment at 18 – 22 months corrected age assessed in 4,704 children (94.3%)
• Focused from birth (not ob interventions)
• Active treatment: surfactant therapy, tracheal intubation, ventilatory support, parenteral nutrition, epinephrine, or chest compressions.
• Neurodevelopment assessments: Bayley-III, Gross Motor Function Classification System (GMFCS), degree of CP, blindness, deafness
Cost of Periviable Care
In 2011, total healthcare expenditures exceeded $2.7 trillion dollars, 17.9% GDP.

Can our society afford this?

Neonatal care is costly, it is also cost effective as it produces both life-years and quality-adjusted life-years (QALYs).

As GA ↓, costs ↑, cost-effectiveness threshold is harder to achieve.

Is periviable care (22-24 weeks) cost effective? Depends on the perspective.

Resuscitation of neonates at 23 weeks’ gestational age: a cost-effectiveness analysis.

Partridge (Caughey) et al., 2015 JFM

Investigated cost effectiveness of resuscitation of infants born 23+0 to 23+6

Modeling compare universal and selective resuscitation to non-resuscitation for 5,176 live births at 23 weeks in a theoreic U.S. cohort
Resuscitation of neonates at 23 weeks' gestational age: a cost-effectiveness analysis.

- Death (77%), disability (64-86%)
- Universal resuscitation - save 1,059 infants
  - 138 severely disabled
  - 413 moderately impaired
  - 508 without significant sequelae
- Selective resuscitation would save 717 infants: 93 severely disabled, 279 moderately impaired and 343 without significant sequelae.

Resuscitation of neonates at 23 weeks' gestational age: a cost-effectiveness analysis.

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Resuscitation of neonates at 23 weeks' gestational age: a cost-effectiveness analysis.

- Universal and selective resuscitation strategies were not cost-effective from a maternal perspective.
- Both strategies were cost-effective from a maternal-neonatal perspective.
- Results could support a more permissive response to parental requests for aggressive intervention at 23 weeks' gestation.