What Do We Do at the Threshold of Viability?

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REVERSAL: In the 1960s, when the first NICUs opened, premature infants had a 95% chance of dying.

Today, they have a 95% chance of survival.

NY Times, August 2012

Challenges remain. Survival at limits of viability, long-term morbidity in survivors.

“Fetal Pain” bills in many states have created a new sense of urgency to address these issue.

NY Times, August 2012

20 Week Abortion Bans and Fetal Pain Bills

- Alabama, Arizona, Arkansas, Georgia Idaho, Indiana, Kansas, Nebraska, North Carolina.
- No abortions after 20 weeks except for futility; Rape/Incest no exception
- Requirement to deliver baby alive and pain free after 20 weeks
- Up to 10 yr. criminal sentence for non compliance

Objectives

- Review medical treatment of potential deliveries between 20 and 24 weeks gestation and decisions that may change medical management
- Need for earlier diagnosis of futility
- Need of teamwork with our obstetrical colleagues
- Discuss the variability in care and factors that influence outcome
General Considerations

- Expected outcomes
- Reasonable treatment options
- Benefits and burdens of treatment/non-treatment
- Parental desire and need for data

GA Estimates

- Fetal pain bills often discuss pregnancy in terms of time since fertilization
- Normal obstetric nomenclature discusses dates based on LMP
- We need to now document GA two ways:
  - Based on LMP and Fertilization
  - ie: 20 weeks gestation is 18 weeks since fertilization
  - This will give families 2 additional weeks to make decision

Early Genetic Screening: Problems

- Second trimester testing brings us to 18 weeks in most instances before true work-up begins
- Patient usually referred to MFM for genetic sonogram and counseling
- Amniocentesis then offered
- 7-10 days for results to be obtained
- If normal great
- If abnormal then what?
Early Genetic Screening

- New paradigms
  - Push providers and patients to be screened for genetic diseases as early as possible
  - This will assist the patient in making better decisions regarding treatment
- Fortunately first trimester screening is readily available today
  - In fact a better testing method than midtrimester screening

Cell-free DNA in Maternal Blood

- Cell-free DNA (cfDNA): short DNA fragments (50-300 base pairs)
- Pregnancy: cfDNA from both the mom and fetus are in maternal blood
- Amount of fetal cfDNA present is a small fraction of the maternal cfDNA

Cell Free DNA Testing

- Noninvasive Prenatal Testing
- Can be accomplished after 10 weeks
- Intended for singleton pregnancies but one company now indicates that they can identify aneuploidy in twins
  - Not which twin however
- Simple blood test
- Very specific: low false positive rate

Obstetrical Decisions

- What to do with deliveries between 20 and 24 weeks
- Obstetrical complications
  - PPROM
  - Abruption
  - Chorioamnionitis
  - Preterm labor
  - Inevitable AB
  - Others

Limit of Fetal Viability

- Generally defined as the earliest GA with potential for survival
  - ACOG Practice Bulletin No. 38, 2002
  - NRP Guidelines
- In legal terms, there is no national definition
  - Minnesota: ≥ 22 weeks’ gestation
  - Massachusetts: ≥ 350g or ≥ 20 weeks
    - Allows abortion up to 23-6/7 weeks
  - Georgia: ≥ 22 weeks gestation or 20 weeks after fertilization
    - New definition in obstetrics

What do physicians think

- Majority of SMFM members place viability somewhere around 23rd week of gestation
- In 1980’s no one in that group thought viability began in the 23rd week: Only 18% felt a 24 week fetus to be viable
- Most OBs now counsel about viability beginning at 24 weeks if delivered in hospital with neonatal intensive care unit
  - This does not take into account morbidity
**Neonatal Considerations**

- **Treatment Decisions**
  - Based on best estimates of viability and outcomes, benefit from treatment, and parental wishes.
  - Comfort care, pain management is very important to families; should not be equated to "no treatment".

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**Extreme prematurity—Moving beyond gestational age**

- Prospectively studied a cohort of 4446 infants born at 22 to 25 weeks' gestation (determined on the basis of the best obstetrical estimate) between January 1, 1998, and December 31, 2003.
- Development to relate risk factors assessable at or before birth to the likelihood of survival, survival without neurodevelopmental impairment.


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**Maximal Potential Rate**

- Calculated with the assumption that the % of infants with a potentially favorable outcome among those who had died without undergoing mechanical ventilation would be the same as the percentage of infants in the same risk category who had a favorable outcome and who underwent mechanical ventilation.
- Because infants who did not undergo ventilation tended to be smaller, sicker, and less mature than infants in the same risk category who underwent ventilation (data not shown), this approach provides an optimistic estimate.


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**Survival**

- Observed vs. Maximum potential rate.

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**Survival Without Profound Impairment**

- Observed vs. Maximum potential rate.
Outcomes of 22-23 Weeks Japanese Infants

- Cohort of 1057 22-25 GA infants within the NICUs (2003-05)
- Death or NDI at 36-42 months
  - 80% at 22 weeks
  - 64% at 23 weeks
- Systemic Review (8 studies)
  - 99% at 22 weeks (90-100%)
  - 98% at 23 weeks (67%-100%)

Outcomes of 22-23 Weeks Japanese Infants

- Study included 3631 infants 22 to 24 wks GA and 5227 infants 25 to 27 weeks' gestation.
- Among the 22- to 24-wk infants:
  - Use of antenatal corticosteroids ranged from 28% to 100%.
  - CS from 13% to 65%.
  - Resuscitation from 30% to 100% by center.

Interventions in 22- to 24-week infants by center: Antenatal Steroid Use
Interventions in 22- to 24-week infants by center: Cesarean Section Rate

Interventions in 22- to 24-week infants by center: Resuscitation

Approach to Infants Born at 22 to 24 Weeks’ Gestation

- Not surprisingly, Centers with higher rates of antenatal corticosteroid use in 22- to 24-week infants had reduced rates of death, death or retinopathy of prematurity, death or late-onset sepsis, death or necrotizing enterocolitis, and death or neurodevelopmental impairment in 25- to 27-week infants.

Brian Smith et al. Pediatrics 2012;129;e1508

Association of Antenatal Corticosteroids With Mortality and Neurodevelopmental Outcomes Among Infants Born at 22 to 25 Weeks’ Gestation

- Physicians’ willingness to provide care to extremely low gestation infants as measured by frequency of use of antenatal corticosteroids is associated with improved outcomes for more mature infants.

- We learn from taking care of infants at the limits of viability how to provide better care to those that are beyond those limits.

Brian Smith et al. Pediatrics 2012;129;e1508
EGA 20 and 21 weeks

- In a data set of 803,430 infants cared for from 1997 and 2011 (14 years) there were very few inborn patients with no anomalies who had an EGA of 20 or 21 weeks.
  - At 20 weeks EGA, there were 15 neonates and all 15 died
  - At 21 weeks EGA, there were 30 neonates and all 30 died

Pediatric Data

- Courtesy Dr. Reese Clark

Pediatric Medical Group Clinical Data Warehouse: 2011 and 2012

- The outcomes of 110,640 non-anomalous neonates born at, cared for in, and discharged from 261 hospitals in 32 states from 2010 to 2011. PDX CDW

Number of Patients

- The outcomes of 110,640 non-anomalous neonates born at, cared for in, and discharged from 261 hospitals in 32 states from 2010 to 2011. PDX CDW

Focus on Infants <=26

- N=3514

Total Number of Patients

- Non-anomalous neonates born at, cared for in, and discharged from a single hospital (261) in 32 states from 2010 to 2011. PDX CDW
Antenatal Steroids Used

Tocolytics Used

Ventilated

Given Surfactant on Day of Birth

Dopamine, Dobutamine Or Epinephrine On Day Of Birth

Survival
Survival

Non-anomalous neonates born at, cared for in, and discharged from a single hospital (261) in 32 states from 2010 to 2011. PDX CDW

Survival Without Severe Morbidity (ROP 3 or 4, IVH 3 or 4, Or NEC Medical or Surgical)

Neurodevelopmental Outcome in Extremely Preterm Infants at 2.5 Years After Active Perinatal Care in Sweden


Available Models For Decision Making

Table. An Explicit Prognostic Strategy for Resuscitation Based on Commonly Used Gestational Thresholds

Group 1: 0-60% 0-25 wk
Group 2: 25-59% 25-26 wk
Group 3: 50-10% 26-27 wk

Gestational age equivalence refers to a gestation equivalent to an average infant born at the specified gestation.
Recent Resuscitation Guidelines for Extremely PT Gestations

- Resuscitation not recommended or not offered
- Resuscitation may be considered or provided
- Resuscitation depends on parents' wishes

- Gestation: 20, 25, 24, 25, 26

- UK: 2008 (BRAP) / AHA/ERC 2005
- US ACP 2002
- Australia 2006
- Netherlands 2005 (DPA)
- France 2010

Completed Weeks’ Gestation

Neonatal Resuscitation: 2010 AHA Guidelines for CPR

- When gestation, birth weight, or congenital anomalies are associated with almost certain early death and when unacceptably high morbidity is likely among the rare survivors, resuscitation is not indicated.

- Examples include:
  - extreme prematurity gestational age <23 weeks or birth weight 400 g),
  - anencephaly,
  - and some major chromosomal abnormalities,
  - such as trisomy 13 (Class IIb, LOE C)

Outcomes of 2 Hypothetical Infants with use of the National Institute of Child Health and Human Development Outcome Trajectory Estimator.

Summary

- Need for active participation of families in these decisions
- Address issues of pain/suffering in non-viable infants in a humane way, just like we do in any other situation
- Need for advance planning, informed decision making & thorough documentation
- Equally important to be prepared for precipitous births with limited/no time for counseling

Summary

- Moral/Ethical dilemma is a result of our separation of this issue from what we do everyday!
Thank you!! ljain@emory.edu

☐ No needless deaths
☐ No needless pain and suffering
☐ No unwanted waiting
☐ No helplessness
☐ No waste