Age of Viability

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Late last night...

Linda began bleeding, long before her due date. She was rushed to the hospital, where she was admitted to labor and delivery. You’re told her pregnancy is currently at 22 and 4/7 weeks and you are asked to speak with her.

You are Linda’s ______________
What will you say?
What should you say?

Periviability

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At the Threshold of Viability

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Disclosures

- None
- No specific manufacturers of products or providers of services will be discussed in this presentation

Outline

- Definitions
- Maternal Considerations
- Infant Resuscitation
- Infant Outcomes
- Ethical Considerations
- Communication and Counselling
- Guidelines and Recommendations
Definitions

Legal Definition

...viability marks the earliest point at which the State’s interest in fetal life is constitutionally adequate to justify a legislative ban on non-therapeutic abortions

The soundness or unsoundness of that judgment in no sense turns on whether viability occurs at approximately 28 weeks (as was usual at the time of Roe, at 23 to 24 weeks, as it sometimes does today, or at some moment even slightly earlier in pregnancy, as it may if fetal respiratory capacity can somehow be enhanced in the future.

Periviable Birth

[NICHD, AAP, ACOG joint workshop, 2014]

“Defined periviable birth as delivery occurring from 20 0/7 weeks to 25 6/7 weeks of gestation
Multiple Descriptors of birth near the limit of viability

Assessing Fetal Gestational Age

- Obstetrical team can estimate GA to within 7-10 days:
  - Last Menstrual Period
  - Bimanual Exam
  - Early Pregnancy Test
  - Ultrasound

- In addition, it is important to consider:
  - Maternal disease processes (DM, HTN, Preeclampsia)
  - Congenital abnormalities
  - Number of fetus(es)
  - Fetal Growth Restriction

- Most management algorithms begin decision-making process by GA assessment

- GA can be assessed to a window of 7-10 days; however there is no time in pregnancy when that window will have as much impact as it will in the periviable period

Obstetrical Care Consensus
Obstetrical Care Consensus

Table 2: Recommendations for Preivable Birth

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth or advanced neonatal or maternal complications, antenatal transport to a center with advanced levels of neonatal or maternal care is recommended when feasible and appropriate</td>
<td>Best practice</td>
</tr>
<tr>
<td>Perinatal and maternal counseling regarding anticipated birth or emergency neonatal resuscitation should be considered in consultation with stipulated perinatal staff, as well as other variables that impact the mother and the neonate.</td>
<td>Best practice</td>
</tr>
<tr>
<td>In the presence of suspected fetal malformations, antenatal consultation, administration, birth weight, and support to initial neonatal care.</td>
<td>Best practice</td>
</tr>
<tr>
<td>Early or cervical should be avoided by a multidisciplinary team that includes obstetrician– gynecologists and other obstetric providers, maternal fetal medicine specialists, if available, and neonatologists who can address the individual and shared considerations and perspectives. Maternal and neonatal outcomes should be considered. Follow-up counseling should be provided within seven days of delivery.</td>
<td>Best practice</td>
</tr>
<tr>
<td>A problem-solving plan made with the parents, family, or both, should be recognized as a general plan of approach, which may be modified as the neonatal condition is evaluated.</td>
<td>Best practice</td>
</tr>
</tbody>
</table>

Magnesium Sulfate Use in Obstetrics

ABSTRACT: The U.S. Food and Drug Administration advises against the use of magnesium sulfate in labors for more than 5-7 days to stop proteinuria in pregnant women. Based on this, the drug classification was changed from Category A to Category D, and the labeling was changed to include this new warning information. However, the U.S. Food and Drug Administration addresses this unbalanced and non-standard use of magnesium sulfate in obstetrics. The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine continue to recommend that the short-term benefit less than 48 hours of magnesium sulfate in obstetrics for appropriate indications is still defined. This includes the prevention and treatment of seizures in women with pre-eclampsia or eclampsia, fetal neuroprotection before viability, and women presenting less than 30 weeks of gestational delivery, and short-term prolongation of pregnancy up to 48 hours to allow for the administration of antenatal corticosteroids in pregnant women who are at risk of preterm delivery within 7 days.

Antenatal Steroids

Table 2: Hospital Outcomes of Surfactant 22 to 25 Weeks Gestation (by Antenatal Corticosteroid Treatment)
Periviable birth mode of delivery

- Randomized controlled studies are lacking
- Current data do not support routine cesarean delivery to improve perinatal mortality or neurologic outcomes
- Cesarean delivery may offer survival advantage to the periviable growth-restricted infant regardless of fetal presentation
- Cesarean delivery for breech-presenting early preterm fetuses does appear to offer newborn survival benefit
- Attempted vaginal delivery of the potentially viable preterm infant (after 24 weeks' gestation) is likely to be associated with outcomes comparable to or worse than those for breech presenting fetuses

Table 2: Actual delivery mode according to planned delivery mode among 1582 fetuses born at 24-27 weeks of gestation.

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Planned cesarean</th>
<th>Actual cesarean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ag agreement</td>
<td>351</td>
<td>363</td>
<td>0.0005</td>
</tr>
<tr>
<td>Normal delivery</td>
<td>125</td>
<td>165</td>
<td>0.0005</td>
</tr>
<tr>
<td>Targeted delivery</td>
<td>26</td>
<td>27</td>
<td>0.71</td>
</tr>
</tbody>
</table>

Adapted from Bailey et al.17

Obstetrical Care Consensus

Table 3. General Guidance Regarding Obstetric Interventions for Threatened and Inevitable Periviable Birth by gestational age.

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Planned cesarean</th>
<th>Actual cesarean</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal assessment for risk factors</td>
<td>Non-recommended</td>
<td>Consider 29</td>
<td>Consider 30</td>
</tr>
<tr>
<td>Advanced maternal age</td>
<td>Not recommended</td>
<td>Consider 20</td>
<td>Consider 21</td>
</tr>
<tr>
<td>Twin toxemia</td>
<td>Not recommended</td>
<td>Consider 20</td>
<td>Consider 21</td>
</tr>
<tr>
<td>Maternal effluent for amniotomy</td>
<td>Not recommended</td>
<td>Consider 20</td>
<td>Consider 21</td>
</tr>
<tr>
<td>Antenatal corticosteroids</td>
<td>Not recommended</td>
<td>Consider 20</td>
<td>Consider 21</td>
</tr>
<tr>
<td>Cesarean delivery for fetal indication</td>
<td>Not recommended</td>
<td>Consider 20</td>
<td>Consider 21</td>
</tr>
</tbody>
</table>

2015 “ILCOR” Guidelines
Multiple 2015 Resuscitation Documents

- 2015 European Resuscitation Council (ERC)
- 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendation (CoSTR)
- 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Published in *Circulation* as well as in *Pediatrics*)

2015 Resuscitation Statements

- Non-initiation of resuscitation and discontinuation of life-sustaining treatment during or after resuscitation are considered ethically equivalent
- No evidence to support prospective use of any “delivery room prognostic score” in extremely preterm infants (less than 25 weeks EGA)
- It is reasonable to consider variables such as perceived accuracy of EGA assignment, presence or absence of chorioamnionitis, and the level of care available
- Decisions about appropriateness of resuscitation below 25 weeks of gestation will be influenced by region-specific guidelines

Outcomes of Extremely Preterm Infants
Outcomes of Extremely Preterm Infants

- One perspective: resuscitation of more perinivable newborns (with intensive rather than comfort care) is justified if morbidity rates hold steady. Meaning, more survivors leads to increase in absolute number of survivors without morbidity.

- Alternate perspective: increase in absolute number of survivors leads to increase absolute number of severely impaired survivors.

Outcomes of Extremely Preterm Infants

- Eunice Kennedy Shriver NICHD:
  - 34,636 infants, 22-28 weeks, 1993-2012
  - 9,575 infants, 22-28 weeks, 2003-2007


- EPiCure 2: 2,460 infants, 22-26 weeks, 2006

- EPiCPAGE 2: 2,205 infants, 22-26 weeks, 2011
Outcomes—EPICure 1
EPIcure 2—2006

**Mortality and morbidity to discharge for babies of women transferred antenatally and for those who delivered in level 2 and level 3 services without transfer for births in England in 2006 between 22 and 26 weeks of gestation**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Level 1 (n=201)</th>
<th>Transfer (n=444)</th>
<th>Level 2 (n=500)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal death</td>
<td>174</td>
<td>51</td>
<td>122</td>
<td>0.044</td>
</tr>
<tr>
<td>Delivery room death</td>
<td>148</td>
<td>59</td>
<td>139</td>
<td>0.832</td>
</tr>
<tr>
<td>Neonatal unit death, ≤7 days</td>
<td>156</td>
<td>59</td>
<td>139</td>
<td>0.832</td>
</tr>
<tr>
<td>Non-neonatal death</td>
<td>22</td>
<td>13</td>
<td>9</td>
<td>0.009</td>
</tr>
<tr>
<td>Late neonatal death &lt;28 days</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0.009</td>
</tr>
<tr>
<td>Birth &gt;35 days to discharge</td>
<td>29</td>
<td>7</td>
<td>3</td>
<td>0.009</td>
</tr>
<tr>
<td>All deaths</td>
<td>124</td>
<td>41</td>
<td>132</td>
<td>0.848</td>
</tr>
<tr>
<td>Survivors without morbidity</td>
<td>75</td>
<td>23</td>
<td>57</td>
<td>0.009</td>
</tr>
<tr>
<td>Survivors only</td>
<td>75</td>
<td>23</td>
<td>57</td>
<td>0.009</td>
</tr>
</tbody>
</table>

**Perinatal factors**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Level 1 (n=201)</th>
<th>Transfer (n=444)</th>
<th>Level 2 (n=500)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal shared with NNT</td>
<td>39</td>
<td>34</td>
<td>44</td>
<td>0.223</td>
</tr>
<tr>
<td>Shared with Maternity Hospital</td>
<td>895</td>
<td>132</td>
<td>895</td>
<td>0.820</td>
</tr>
<tr>
<td>Shared with Fist Hospital</td>
<td>35</td>
<td>24</td>
<td>31</td>
<td>0.300</td>
</tr>
<tr>
<td>Admitted to NICU</td>
<td>15</td>
<td>12</td>
<td>13</td>
<td>0.630</td>
</tr>
</tbody>
</table>

*p Values for overall significance of trends adjusted for gestational age and birthweight for gestation.

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**EPIcure 2—2006**

**Table 3** Mortality and morbidity to discharge for neonatal unit admissions for babies who were transferred to a level 3 service after admission (NNT) compared with babies who remained in their hospital of birth, for births in England in 2006 between 22 and 26 weeks of gestation

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Level 2 (n=340)</th>
<th>Neonatal transfer (n=261)</th>
<th>Level 3 (n=100)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal unit deaths, ≤7 days</td>
<td>80</td>
<td>23</td>
<td>16</td>
<td>0.002</td>
</tr>
<tr>
<td>Late neonatal death (28–26 days)</td>
<td>24</td>
<td>10</td>
<td>14</td>
<td>0.005</td>
</tr>
<tr>
<td>Death &gt;35 days to discharge</td>
<td>22</td>
<td>6</td>
<td>8</td>
<td>0.031</td>
</tr>
<tr>
<td>All deaths</td>
<td>136</td>
<td>39</td>
<td>70</td>
<td>0.956</td>
</tr>
<tr>
<td>Survivors without morbidity</td>
<td>58</td>
<td>17</td>
<td>12</td>
<td>0.124</td>
</tr>
<tr>
<td>Survivors only</td>
<td>58</td>
<td>27</td>
<td>12</td>
<td>0.172</td>
</tr>
</tbody>
</table>

*p Values for overall significance of trends adjusted for gestational age and birthweight for gestation.
Percentage of survivors who survive “intact” is higher than the percentage of all births who survive intact

Percentage of intact survivors is relatively independent of gestational age

Factors influencing survival and outcome
Ethical Considerations

- Withdrawal of treatment is ethically equivalent to withholding of that treatment
- Best interest (of infant)
  - If resuscitation is stopped sooner, lower risk of survival with severe impairment, but higher chance death of possible intact survivor
  - Conversely, if resuscitation is continued, lower chance of death but higher chance of severely impaired survivor
- Consistency
- Decisions in consultation with parents

Ethical Considerations

- Gestational age estimation is imprecise, therefore basing decisions only on GA guidelines with rigid boundaries is illogical
- Categories often used
  - “Futile”
  - “Gray zone”
  - “Beneficial”
- When is a rate of survival to discharge so low that resuscitation should not be offered (quantitative vs qualitative futility)?
  - If a center
    - Does not intervene: no survivors, no impaired survivors
    - Intervenes on some: some survivors, some will be impaired
    - Intervenes on all: more survivors, more impaired survivors

CEASE—A framework for stopping

- Clinical factors predicting survival
- Effectiveness of resuscitation efforts
- Ask other clinicians for input
- Stop resuscitation efforts
- Explain what has happened
Suggestions

- Be okay with the gray
- Do not place too much emphasis on gestational age estimation
- Death without a proper chance at life is not usually in the best interest of an infant
- Impairment does not necessarily equal poor quality of life
- Just because a decision is made does not prohibit the opportunity to reconsider it

Suggestions

- Not all the burden should be on the parents
- Be aware of self-fulfilling prophecies
- Time lag often skews outcome data
- Statistics can be both confused and confusing
- Above all, never abandon parents

SOBPIE—Communication

- What is the Situation, how should communication take place
- Opinions and options: What are the alternatives?
- Basic human interactions, politeness; how not what
- Parents: their story, concerns, needs
- Information: personalized and balanced
- Emotions: addressing relational aspects of decision making
SOBPIE Mnemonic

International Perspective
- France: do not intervene ≤ 23 weeks, “grey zone” 23-25 weeks
- Israel: do not intervene ≤ 23 weeks, “grey zone” 23 weeks, intervene ≥ 24 weeks
- Netherlands: offer antenatal steroids > 23 5/7 weeks, intervene ≥ 24 weeks
- Norway: do not intervene ≤ 23 weeks, individualized treatment 23-25 weeks
- Sweden: do not intervene ≤ 23 weeks, intervene (for most) > 23 weeks
- Switzerland: do not intervene ≤ 24 weeks, “grey zone” 24 weeks, intervene ≥ 25 weeks
- Canada:
  - Do not intervene ≤ 22 weeks
  - Intervene (as appropriate) 22-24 weeks
  - Intervene ≥ 25 weeks

AAP Recommendations—2009
- Parents should be provided most accurate prognostic data available (which should not be based on gestational age alone)
- “Not possible” to develop specific criteria
- Guidelines:
  - If physicians believe there is no chance for survival, resuscitation should not be initiated and comfort care should be provided
  - If physicians consider good outcome unlikely, parents should be given choice as to resuscitation
  - If physicians believe good outcome is reasonably likely, clinicians should initiate resuscitation and continually re-evaluate whether intensive care should be continued
LLU Recommendations—Draft

- Recommend NICU consultation, palliative care consultation, ongoing dialog between MFM and NICU so that resuscitation efforts match prenatal measures
- Antenatal steroids starting at 22 5/7 weeks
- Resuscitation beginning at 23 weeks
- Considerations:
  - Discrepant weight
  - Fetal anomalies
  - Maternal health, maternal infection, steroid completion, accuracy of dating
  - If mother declines non-intervention prior to 25 weeks, support that decision; however counseling to reflect non-invasive support 24-25 weeks if infant is born and appears vigorous

Summary

- Survival rates are improving
- Outcomes for periviable infants will only improve if practice changes
- Morbidity appears to be mostly independent of gestational age for survivors
- Gestational age assessment is imprecise
- Avoid simple rules for complicated decisions
- Guidelines are guidelines, not rigid boundaries