Limits of Viability
What do the data tell us?

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Disclosure Statement

I have no relevant financial relationships to disclose or conflicts of interest to resolve.

I will not discuss any unapproved or off-label, experimental or investigational use of a product, drug or device.
One thing we know for sure:

Treatment of ELGANs varies widely between centers.
Portland St. Vincent Medical Center (PSVMC) approach to periviability counseling

- **NICU care**
  - Questionable
  - Investigational
  - Inadvisable

- **NICU care**
  - Individualized per clinical situation and family wishes

- **NICU care**
  - Reasonable
  - Highly advisable

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• We do not recommend NICU care for infants born at <25 weeks because
  (1) the chance of NICU death or significant neurologic injury is generally 50% or more, and
  (2) our providers believe it neither reasonable nor fair to insist on resuscitation of infants who may have enormous long-term health issues that we may not help the family cope with or resolve.”

  - Kaempf et al, Peds, 2009
Resuscitation and survival at various gestational ages - PSVMC

<table>
<thead>
<tr>
<th>Gestational age</th>
<th>% Vent</th>
<th>% survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 weeks</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>23 weeks</td>
<td>39%</td>
<td>0</td>
</tr>
<tr>
<td>24 weeks</td>
<td>62%</td>
<td>38</td>
</tr>
<tr>
<td>25 weeks</td>
<td>83%</td>
<td>74</td>
</tr>
<tr>
<td>26 weeks</td>
<td>100%</td>
<td>98</td>
</tr>
</tbody>
</table>

Survival by GA between 1986 and 2000, University of Minnesota


Copyright ©2004 American Academy of Pediatrics
Survival by GA, NICHD neonatal network, 2008

- 22 weeks – 5%
- 23 weeks - 26%
- 24 weeks - 56%
- 25 weeks - 76%

www.nichd.nih.gov/neonatalestimates
Reported survival rates - 23 weeks

- Portland St. Vincent – 0% survival
- University of Minnesota – 66%
- NICHD – 26%
International differences are even more striking
Survival rates at 11 European centers, EGA 24-27 weeks, 2003

Copyright ©2008 American Academy of Pediatrics
Canadian data, 11 centers, 1996

Lee SK et al, Pediatrics 11/ 2000, 1070-1079
GA-specific neonatal mortality, Japan, 2003

From 42 centers in Japan, 2003

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International differences in survival for babies at 24 weeks EGA

- Europe – 5-10%*
- Canada – 50%
- Minnesota – 81%
- Japan – 75%
- NICHD - 56%

*Netherlands has 0% survival
Are differences troublesome?

• Different doctors, hospitals, and countries clearly have different policies that lead to different outcomes.
• Should such differences bother us?
Ethical implications of practice variation

• Parents get very different facts, options, and recommendations.
• Leads to different outcomes.
• Would this be tolerated in any other area of medicine?

• (Imagine if survival rates for ALL or CF varied from 10% to 80% in different centers.)
Sometimes doctors recommend treatment when parents want comfort care.
This Lovely Life

- 23.5 week, 600g twins, parents request comfort care
- Mother: “We want the twins to be DNR. I was against resuscitation at birth and I’m not in favor of prolonging life support. These babies were born too early.”
- Doctor: “It is not typical for us to include this type of order in the chart.”
Sometimes parents think that important prognostic information was withheld.
Bitter parents

• “I think that the NICU staff members went out of their way to hide information from us about the likelihood that David would have neurologic damage. We weren’t given guidance about, for example, what a grade III brain bleed was. They said, ‘He may be a little behind.’”

• Gary Horn, about his son David, born at 24 weeks in 1993

Bitter parents

• “If doctors and nurses knew what our life was going to be like, why shouldn’t we have known? They need to be more honest with parents.”
  – Debby Barrett, mother of Michael, born at 1 lb, 15 oz and 24 5/7 weeks.

• Sometimes, doctors recommend comfort care and DNR when parents want more aggressive treatment.
Parents may choose NICU care when docs recommend against it

- 22 weeks: 11% → 0% wanted resuscitation
- 23 weeks: 17% → 39%
- 24 weeks: 44% → 62%
- 25 weeks: 71% → 83%
- 26 weeks: 74% → 100%

- “After discussion and informed consent, we will provide NICU care at <25 weeks' PMA if families so choose, but not below 23 weeks.”
  - Kaempf, et al, Peds, 2009
Percent of parents who chose resuscitation after counseled not to

- 22 weeks – none
- 23 weeks – 39%
- 24 weeks – 62%
- 25 weeks – 83%
- 26 weeks – 100%

- Kaempf et al, Peds, June 2009
A parent narrative – Trisomy 13

• Before Annie was diagnosed, we had never heard of Trisomy 13. Once her chromosomes came back, the doctors discussed with us the possibility of terminating the pregnancy. We chose not to terminate. Instead, we decided that we would treasure the time that we had with her.

Farlow, :”Misgivings” Hastings Ctr Report, Jan 2010
“Annie developed acute respiratory distress. She was admitted to the PICU. The intensivist seemed annoyed that we would not agree to a DNR order. We (later) learned that a DNR order had been entered without our knowledge or consent.”

Farlow, Misgivings. Hastings Ctr Report, 2010
What do parents want?
Most parents (but not all) say that they want everything done to try to save their baby
“I believe an attempt should be made to save all infants regardless of birth weight.”
Percentage of professionals and parents who thought attempts should be made to save every baby at all costs

P < .01

Percentage of the group who decided to save at all costs

0 20 40 60

HCWs MTs PPs


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A simple solution

• Shared Decision Making!
• Recommended by all professional societies.
• Warm and fuzzy, hard to argue with.
<table>
<thead>
<tr>
<th>Doctors views</th>
<th>Total</th>
<th>Neo</th>
<th>Parents</th>
<th>Neo and Parents</th>
<th>OB</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your opinion, who <strong>should</strong> make the final decision to withhold resuscitation in the delivery room?</td>
<td>149</td>
<td>19 (13)</td>
<td>16 (11)</td>
<td>114 (77)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>In your opinion, who <strong>does</strong> make the final decision to withhold resuscitation in the delivery room?</td>
<td>146</td>
<td>74 (50)</td>
<td>13 (9)</td>
<td>59 (40)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Bastek et al, Peds, August 2005
Proportion of physicians feeling that, in case of disagreement between parents and the staff, parents should be the ultimate decision-makers for their child.

So…

• Shared decision making sounds good in theory…
• Not always used in practice…
• Why?
Procedural reasons

- Information is complicated
- Sharing is hard
- Communication requires subtle attention to what we say and don’t say.
Moral reasons

- We need to decide how much moral variation we can tolerate
- For which babies do we offer parents choices?
- Where are the boundaries of the gray zone?
Upper and lower boundaries of the gray zone

• Somewhere between 22 and 25 weeks.
• What do we know about outcomes?
Overall Disability at 30 Months for 314 Children Born at 22 through 25 Weeks of Gestation

- No disability (49%)
- Severe disability (23%)
- Died (2%)
- No data (1%)
- Other disability (25%)

Disability rates among survivors, by gestational age

- 22 weeks - 1/2 (50%)
- 23 weeks - 14/26 (54%)
- 24 weeks - 52/100 (52%)
- 25 weeks - 84/186 (45%)

In each group, half of disability was “severe.”

Wood, NEJM, 2000
<table>
<thead>
<tr>
<th>Gestational age (wks)</th>
<th>&lt;23</th>
<th>24</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bayley scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mental</td>
<td>84</td>
<td>85</td>
<td>84</td>
</tr>
<tr>
<td>psychomotor</td>
<td>85</td>
<td>87</td>
<td>87</td>
</tr>
<tr>
<td>No developmental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>disability</td>
<td>42</td>
<td>30</td>
<td>39</td>
</tr>
<tr>
<td>Severe disability</td>
<td>27</td>
<td>19</td>
<td>17</td>
</tr>
<tr>
<td>No neuromotor disability</td>
<td>85</td>
<td>74</td>
<td>76</td>
</tr>
<tr>
<td>No sensory disability</td>
<td>58</td>
<td>64</td>
<td>69</td>
</tr>
</tbody>
</table>

• Wood, NEJM, 2000
Cognitive Scores

241 Extremely Preterm Children and 160 Age-Matched Classmates

Kaufman Assessment Battery for Children scores for the Mental Processing Composite or developmental scores according to the Griffiths Scales of Mental Development and NEPSY

(possible range, 39 -150)

Marlow et al. NEJM, 2005: 352 (1): 9
Babies <23wks, Edmonton; How many survivors are “intact”

40%

Intact (white), impairment (hatched), death (grey)

Robertson et al, Peds Neuro, March, 2009
24 weeks, Edmonton, How many survivors are “intact”

Robertson et al, Peds Neuro, March, 2009

Intact (white), impairment (hatched), death (grey)
25 weeks, Edmonton, How many “intact”

Intact (white), impairment (hatched), death (grey)
Robertson et al, Peds Neuro, March, 2009

75%
Things you could honestly say

- Survival for these babies has improved.
- 80% of these babies survive (last 3 years)
- 60% of these babies survive (last 9 years)
- >30% survive unimpaired (10y avg)
- 90% survive unimpaired (last 3 years)
- Most survivors are unimpaired. (last 20 yrs)
Similar data from NICHD neonatal network

How many 500g singleton babies survive without impairment?

- 23 week boys 16%
- 24 week boys 24%
- 25 week boys 33%
- 25 week girls 47%
  - Data from Tyson et al, NEJM 2008

If “grey zone” means “<50% survival without impairment,” then all these groups are in the “gray zone.”
How many 500g survivors are unimpaired?

<table>
<thead>
<tr>
<th></th>
<th>All Babies</th>
<th>Survivors</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 week boys</td>
<td>16%</td>
<td>57%</td>
</tr>
<tr>
<td>24 week boys</td>
<td>24%</td>
<td>61%</td>
</tr>
<tr>
<td>25 week boys</td>
<td>33%</td>
<td>64%</td>
</tr>
<tr>
<td>25 week girls</td>
<td>47%</td>
<td>76%</td>
</tr>
</tbody>
</table>

If “grey zone” means “Over 50% of survivors are unimpaired,” then nobody is in the grey zone.
Survival, <1000g, CWRU, 1982-2002


<50% babies <1000g survived unimpaired in each time period.
Percentage of unimpaired survivors <1000g, CWRU

> 50% of survivors were unimpaired.

How many are “intact?”

• In 2003:
  – 50% of all babies survive unimpaired
  – 76% of survivors are unimpaired

• Improved survival but no trend in impairment rates among survivors
  – % Survival: 32% → 40% → 50% 
  – % intact survivors: 72% → 65% → 75%

Shared decisions

• Given the data, what should we tell parents?
• What responses should we expect?
• Is “shared decision making” possible?
How we shape parents’ decisions
Message Framing and Perinatal Decisions

– Haward MF et al, Pediatrics July 2008
Methods

• Confidential internet survey,
• Adult volunteers.
• Hypothetical vignette: threatened delivery at 23 weeks
• Compared responses to “framing”
  – % survival with lack of disability
  – % death and likelihood of disability
Methods

- Participants were randomly assigned to receive either the positively or negatively framed vignette. (Survival or mortality frames.)
- Asked to choose whether they would prefer resuscitation or comfort care.
Positive frame

• At 23 weeks, which is how far along you are in your pregnancy:
  – 25 out of 100 babies will survive if given intensive care.
  – Of those who survive, 15 out of 25 will not have developmental disabilities.
  – With comfort care, all babies born this early will die, but their suffering will be minimized.
Negative frame

• At 23 weeks, which is how far along you are in your pregnancy,
  – 75 out of 100 babies will die even if given intensive care.
  – Of those who do not die, 10 out of 25 will have developmental disabilities.
  – With comfort care, all babies born this early will die, but their suffering will be minimized.
Results

• 24% overall chose comfort care
• Respondents who were given positive framing were more likely to elect resuscitation (OR: 1.7; 0.99–2.78; $P = .05$)
Religious people were less affected by framing.

Responses from non-religious subjects

Responses from religious subjects
Key question regarding parents

• Which is worse:
  A. To have tried to save a tiny baby, only to have that baby die?
  B. To not try to save the baby?

• Is it better to spare the baby the pain and suffering associated with unsuccessful NICU treatment, or to know that one tried and failed?
Key question regarding doctors

- How much discretion are you willing to give parents, and under what circumstances?
- Do known practice variations mean that:
  A. Reasonable people can disagree
  B. I am ethical, people who disagree with me are unethical
Conclusions

• Practice variation in the treatment of ELGANs is rampant, well-known, and apparently tolerated.

• “Shared decision making” sounds great in theory but is tough in practice,

• What we say to parents matters