Periviable Gestation: New Data, New Ethics?

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Disclosures

- No financial disclosures
- I’m a maternal-fetal medicine specialist
- Former member of ACOG/ACOOG Ethics Committee
- I’m pro-choice
- I offer termination of pregnancy services
- I’m not a trained ethicist, but practice medical ethics every day
WARNING

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Case

- 24 y/o G2P1 presents at 24 weeks with preterm labor.
- Cervix is 3cm dilated.
- Patient given steroids, antibiotics, MgSO4.
- EFW 650g, female fetus
- Counseled by MFM and NICU
Case

- **Patient declines all further obstetrical interventions**
  - Does not want fetal monitoring
  - Does not want cesarean section for non-reassuring fetal testing

- **Patient requests non-resuscitation if baby born alive.**
A 42 y/o G₁P₀ comes in at 23w + 3d, IVF pregnancy, in labor 6cm dilated.
Fetus with known Trisomy 18.
She says she wants everything done.
Joint Workshop

Joint workshop
1. Society for Maternal–Fetal Medicine,
2. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
3. Section on Perinatal Pediatrics of the American Academy of Pediatrics,
4. American College of Obstetricians and Gynecologists

Definition- periviable birth from 20 0/7 weeks to 25 6/7 weeks of gestation
Are Physicians Biased?

- Do we give information that is based solely on the evidence?
  - Or is it influenced by our own values?

Precision and Bias of a Measurement System

- Precise but biased
- Unbiased but not precise
- Not precise and biased
- Precise and unbiased
The Ethical Question

- When (if ever) is it appropriate to override parental wishes in periviable gestations?
2 Cases

Patient #1
- Preterm labor at 24 weeks
- Wants nothing done

Patient #2
- Preterm labor at 23 weeks
- Trisomy 18
- Wants everything done
Descriptive Ethics

• What do people think?
At what gestational age should babies be routinely resuscitated? (even against parental wishes)

Resuscitation should be mandatory.
Survey Results

- N = 100
  - 18 OB Generalists
  - 20 MFM
  - 20 Other subspecialists, PEDS/NEO
  - 20 Residents (OB, PEDS)
  - 10 Fellows (MFM)
  - 12 Nurses
Resuscitation Should Be Mandatory (Even if Parents Don’t Want it)
Resuscitation Should NOT be Done (Even if Parents Wish It)
Normative Ethics

- What *should* we do?
- Is it permissible to overrule parents’ wishes?
- Under what circumstances?
- Why?
In order to determine *when* it is permissible to overrule the parents, we must determine *why* it is permissible.

- Parental authority, patient's best interest and refusal of resuscitation at borderline gestational age
- MR Mercurio, Department of Pediatrics, Yale University School of Medicine, Yale University Interdisciplinary Bioethics Center, New Haven, CT, USA
What makes something Ethical?

How important are ethics in today's society?
What makes something Ethical?

- **Frameworks**
  - Utilitarianism
  - Kantian (duty-based) Ethics
  - Communitarian Ethics
  - Feminist Ethics
  - Principlism
What makes something Ethical?

- **Principles of Bioethics**
  - Autonomy
  - Beneficence
  - Non-Maleficence
  - Justice
  - Veracity
  - Confidentiality
  - Respect for Persons
  - Quality of Life
  - Sanctity of Life
Autonomy

- Self Governance
- Self Determination

- Can a newborn be said to have these things?
Who Decides for Those Who Can’t Decide?

- Adults who once had decision-making capacity
  - Advance Directives
  - Substituted Judgment
Who Decides for Those Who Can’t Decide?

♦ What about children?

♦ Best Interests Standard
A balance of beneficence and non-maleficence based duties

- Overall benefit to the patient outweighs the overall burden

- Do as much good as you can, causing as little harm as is necessary
Best Interests Standard
Best Interests

- The Best Interests Standard tells us WHAT we can do

- But if there is more than one reasonable choice, someone has to make a choice
Who Decides?
Parental Choice

- Presumption that parents will make good choices for their children.

- They have their children’s best interests at heart.

- Not an absolute:
  - We don’t let parents make any decision they want
Bad Parental Choice
Not all parental choices are acceptable

- We let parents make choices for their children, but we draw the line when those choices are clearly not in the child’s best interest.

- Abuse, neglect
Our Job

- Help parents make good decisions for their children
What do Parents Need to Make Good Decisions for their Children?

- Good Ethics Require Good Facts

- In order for parents to make good decisions for their children, they need good information and counseling

- Informed Consent
Parents need accurate and adequate information about neonatal outcomes to make decisions that will be in their child’s best interest.
Periviability Counseling

- Survival Data
- Complication Data
- Effect of mode of delivery
- Effect on future pregnancies
- Prolonged NICU stay
- What intervention looks like
- What non-intervention looks like

- Prognosis for staying pregnant
- Risks of remaining pregnant
- Impact on family of prolonged NICU stay
- Pregnancy termination options
Counseling about Prematurity
Informed Consent
Difficulties in Informed Consent

- **Constraints of Time**
  - Often clinical decision-making under duress
    - Pain/Anxiety of labor
    - Abnormal fetal testing
    - Clinical emergencies (hemorrhage)

- **Constraints of Language**
  - Chance vs. risk
  - Death vs. survival
  - Intact vs. damaged
  - Disability vs. challenge
Watch Your Language!

- “No babies survive at our institution before 23 weeks.”

- “The chance of your baby being normal is quite low.”

- Most women in your situation do ____.
Demeanor
How do we know parents truly understand the information we’ve given them?
Ensuring Comprehension

Do you understand?

Does that make sense?

Tell me in your own words what I’ve said, just so I can be sure I’ve been clear.
Good Ethics Require Good Facts

- How do we know what the outcome will be?

- How sure are we that we know what we think we know?
Intensive Care for Extreme Prematurity — Moving Beyond Gestational Age

Jon E. Tyson, M.D., M.P.H., Nehal A. Parikh, D.O., John Langer, M.S., Charles Green, Ph.D., and Rosemary D. Higgins, M.D., for the National Institute of Child Health and Human Development Neonatal Research Network*
The estimated outcomes are probabilities derived from data obtained from 4,446 infants born at 400–1,000 g without major congenital anomalies who were admitted to a level III or IV Neonatal Research Network hospital between 1998 and 2003 and monitored until 18–22 months’ corrected age.

An Example

- 24 week Male
- 600g
- Twin
- No steroids
  - Survival: 27%
  - Survival without profound disability: 15%
NICHD Predictors

- Gestational Age
- Birth weight
- Sex
- Plurality
- Steroid Administration
Gestational Age is Precise

- X weeks and Y days
Is Gestational Age Accurate?
It’s hard to be accurate when...

The OB tells you the pregnancy is 24 weeks.

BUT:

It all depends on the dating!
It’s hard to be accurate when…

24 weeks equals:

…24 weeks if dating by IVF
…23-25 weeks if dating by early U/S
…22-26 weeks if dating only by LMP
Accuracy of Dating

IV
12 wk U/S
20 wk U/S

22wks  24wk  26wks  28wks  30wks
Estimated Fetal Weight

- Can be off by 10-15%
- 650g
  - +/- 15%
    - 552g - 747g
We Are Not Rocket Scientists
NICHD Parameters

- Individual parameters not important in and of themselves.
- But overall prognosis is.
The morally relevant question is not:

Do fetuses survive at this GA?

Or

Do fetuses survive at this weight?

But:

What is the prognosis for fetuses like this particular one?
The morally relevant question is not:

Do fetuses survive at this GA?

Or

Do fetuses survive at this weight?

But:

What is the prognosis for fetuses *like this particular one*?
## Imagine 2 More Babies

<table>
<thead>
<tr>
<th>Baby 1</th>
<th>Baby 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 24 wk female</td>
<td>- 25 wk male</td>
</tr>
<tr>
<td>- 680g</td>
<td>- 700g</td>
</tr>
<tr>
<td>- s/p steroids</td>
<td>- No steroids</td>
</tr>
<tr>
<td>- singleton</td>
<td>- singleton</td>
</tr>
</tbody>
</table>

Predicted Survival:  
- Baby 1: 70%  
- Baby 2: 60%
Gestational Age is Not Everything

- Making distinctions based on gestational age doesn’t seem morally justifiable.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factors Affecting Reliability of Estimates of Probability of Clinical Outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Data source</td>
<td>International, national, regional, and single-institution data reflect variations in regional and local practices.</td>
</tr>
<tr>
<td>Cohort selection</td>
<td>Exclusion of newborns not surviving to NICU admission results in inclusion of those with higher potential for survival and higher reported rates of survival. Inclusion of nonresuscitated infants or stillbirths reduces overall reported rates of survival. Inclusion of anomalous infants may decrease reported survival estimates.</td>
</tr>
<tr>
<td>Gestational age assignment</td>
<td>In vitro fertilization and ovulation induction provide accurate gestational age assignment. Dating by last menstrual period assumes accurate recollection of this date as well as conception on day 14. Ultrasonography initially performed at least 24 weeks of gestation estimates gestational age within 5–14 days.*</td>
</tr>
<tr>
<td><strong>Factors Potentially Affecting Clinical Outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Nonmodifiable risk factors</td>
<td>Race and ethnicity, plurality (singleton versus multiple gestation), infant sex, birth weight, gestational age</td>
</tr>
<tr>
<td>Modifiable obstetric practices</td>
<td>Antenatal interventions (eg, corticosteroids, tocolysis, antibiotics for preterm PROM, or magnesium for neuroprotection), site and mode of delivery</td>
</tr>
<tr>
<td>Modifiable neonatal practices</td>
<td>Initial resuscitation and subsequent care (eg, approaches to ventilation and oxygenation, nutritional support, and treatment of newborn infections)</td>
</tr>
<tr>
<td>Approaches to comfort care</td>
<td>Influenced by institutional and physician philosophies, parental wishes, and religious convictions</td>
</tr>
<tr>
<td>Regional/hospital legal and practice guidelines</td>
<td>Policies concerning neonatal resuscitation</td>
</tr>
</tbody>
</table>
Epistemology

- The study of how we know things
How do we know that what we think we know is true?

What is survival at 22 weeks?

• NICHD data: 6%
  – But resuscitation only attempted in 19%...

• Perhaps with more aggressive treatment, survival would be better?

• Do 22 week babies die because we don’t try to save them?
What do you do?

1. Stoll BJ, NICHD NRB Pediatrics, 2010
2. Costeloe KL, EPICure studies, BMJ, 2012
4. Rysay et al, NICHD NRB NEJM, 2015
2010 NICHD
Japanese Cohort

- Itabashi et al. Pediatrics 2009
- 97 infants
- Survival at 22 weeks…

34%!
Between-Hospital Variation in Treatment and Outcomes in Extremely Preterm Infants

Matthew A. Rysavy, B.S., Lei Li, Ph.D., Edward F. Bell, M.D., Abhik Das, Ph.D.,
Susan R. Hintz, M.D., Barbara J. Stoll, M.D., Betty R. Vohr, M.D.,
Waldemar A. Carlo, M.D., Seetha Shankaran, M.D., Michele C. Walsh, M.D.,
Jon E. Tyson, M.D., M.P.H., C. Michael Cotten, M.D., M.H.S.,
P. Brian Smith, M.D., M.P.H., M.H.S., Jeffrey C. Murray, M.D.,
Tarah T. Colaizy, M.D., M.P.H., Jane E. Brumbaugh, M.D., and
Rosemary D. Higgins, M.D., for the Eunice Kennedy Shriver National Institute
of Child Health and Human Development Neonatal Research Network
Infants born at 24 NICHD centers

4987 infants
  • Survival
  • Neurodevelopmental Impairment at 18-22 mos
Figure 1. Rates of Active Treatment by Gestational Age at Birth.
# Impact of Which Hospital You’re At

<table>
<thead>
<tr>
<th>GA</th>
<th>Impact Hospital of Delivery on Survival</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>22-23wk</td>
<td>78%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>24 wk</td>
<td>22%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>25 wk</td>
<td>1%</td>
<td>&lt;0.26</td>
</tr>
</tbody>
</table>
23 week survival

Hospital Rate of Intervention

% Survival

Rysavy et al. 2015
What impacts survival?

- **NICHD Parameters**
  - Sex
  - Birthweight
  - Gestational Age
  - Plurality
  - Steroid Exposure

- **Other Factors**
  - Which Hospital?
  - How aggressive are the OB/GYNs?
  - How aggressive are the Neonatologists?
  - What are the patterns of withdrawal of care in the NICU?
Survival: Survey Data

= NICHD Data

%
Survival Without Neuro Disability

20 weeks 21 weeks 22 weeks 23 weeks 24 weeks 25 weeks 26 weeks

% = NICHD Data

NICU

OB

= NICHD Data
Rysavy 2015 – Percentage survival with moderate or severe impairment among surviving newborns

Wood 2000 – Reflects 1995 data; percentage survival with severe disability at 30 months

Moore 2013 – Percentage survival with moderate to severe impairment at 4-8 years

Marlow 2005 – Reflects 1995 data; percentage survival with overall severe disability at 6 years

Ishii 2013 – Percentage survival with profound neurodevelopmental impairment
What about the Law?
Miller v HCA

- 23 week pregnancy in Texas in 2003
- Parents requested non-resuscitation
- DOC went against parents' wishes at the delivery

- Court ruled that DOC has this prerogative
  - Delivery is an emergency situation
  - Gave great discretion to physicians
  - Are the courts biased as some physicians? Of course!!!
If parents are to make good decisions for their children, they need good information.

We face difficulties providing that in a timely, unbiased, accurate and precise manner.

Difficulty assessing parents’ understanding.
Where We Are

- Parents need to know about prognosis
  - Gestational age is just one piece of the puzzle
Assuming Parents are well Informed…

- Can they make any choice they want?
Parental Standards

- Best Interests
- Family’s Interests
What are the Best interests?

- Survival?
- Survival free of severe disability?
- Survival free of any disability?
- A painless, brief NICU admission?
What are the Best Interests?

- How high does the chance of survival have to be to make resuscitation in the child’s best interests?

- How high does the chance of survival without profound disability have to be to make resuscitation in the child’s best interests?
Quality of Life
Quality of Life

- Sufficient functioning to engage in life tasks that bring enjoyment and satisfaction

- Capacity for symbolic interaction and communication

- Potential for cognitive development and interaction
Do we undervalue premature babies?
Anonymous Questionnaire
- 8 patients with potential poor neuro sequelae
  - Preterm infant
  - Newborns
  - Children
  - Adults
Premature infants compared to children or adults with similar chances of survival or similar prognoses

- Premature babies fared worse
  - Less likely to be resuscitated
  - More likely to be offered comfort care
Why Are Preemies Treated Differently?

- Reproductive choice colors decisions at periviability
- Diminished sense of duty to premature infant
- Lack of personhood
  - Or less personhood
Really?

![Graph showing a positive correlation between age and value.]
Children are not Preemies

When we treat a child with an illness, parents hope to return the child to a previous state of health.

Perhaps the older the child, the more willing parents are to attempt interventions to NOT LOSE that child.
Children are not Preemies

When we treat a child for prematurity, parents do not hope for a return to a child that already exists, but they hope for a different, older, healthier child.
Disability
Uncertainty

- Is it in the best interests of the child to face an uncertain future?

- If everything works out well, then we’re happy.

- But if outcomes are poor…
Does the child have a right to life?
  • So *any* chance of survival should be sought?

Or a right to a good life?

Or a right to merciful treatment?

Or a right to a decent existence on the path to survival?
Should Other Factors Matter?

- **The interests of others**
  - Parents’ interests
  - Other siblings
  - Society

- Do we include these in making decisions for 3 year-olds?
  - What is the moral distinction?
WHAT ABOUT THE MOTHER?

- 1. STEROIDS, MAG FOR NEUROPROTECTION - LITTLE RISKS
- 2. CLASSICAL CESAREAN SECTION
  - UTERINE RUPTURE IN FUTURE, ACCRETA, HEMORRHAGE
  - THROMBOSIS, DEATH
  - FUTURE REPRODUCTIVE RISKS
  - INFECTION
- EXPECTANT MANAGEMENT IN PPROM
  - MATERNAL SEPSIS, Hysterectomy, HEMORRHAGE,
- EXPECTANT MANAGEMENT IN PEC WITH SEVERE FEATURES
  - HELLP, DIC, PULMONARY EDEMA, DEATH, CVA
Cognitive Dissonance on the Labor Floor

- In one room: a 22 week laboring patient, wanting “everything done”

- In the next room: 23 week induction for PPROM; the parents want non-resuscitation
“Physicians should not be forced to undertreat or overtreat an infant when, in their best medical judgment, the treatment is not in compliance with the standard of care for that infant.”

- AAP Committee on Fetus and Newborn “The Initiation or Withdrawal of Treatment of High-Risk Newborns”
If physicians believe there is no chance of survival, resuscitation should not be initiated.

“"When the physicians’ judgment is that a good outcome is reasonably likely, clinicians should initiate resuscitation…”"
We have to draw lines

And even though GA is not a perfect predictor of outcome, it is an easy way to draw lines.
Resuscitation Should Be Mandatory (Even if Parents Don’t Want it)
I hear you're writing a book on medicine.

I hope you have a good title.

I have the perfect title...

"Has it ever occurred to you that you might be wrong?"
Clinicians should discuss with parents whether their goal is optimizing survival or minimizing suffering.

The approach to antenatal and post delivery care may differ dramatically depending on parental preferences regarding resuscitation.

A recommendation regarding assessment for resuscitation is not meant to indicate that resuscitation should always either be undertaken or deferred, or that every possible intervention need be offered.

A stepwise approach concordant with neonatal circumstances and condition and with parental wishes is appropriate.

Care should be reevaluated regularly and potentially redirected based on the evolution of the clinical situation. Assessment at birth, for example, may include confirmation that comfort measures are most appropriate.
A decision to proceed with resuscitation always should be informed by individual circumstances, including specific clinical issues

- estimated fetal weight **AND** most precise estimate of gestational age,
- family values and wishes,
- ongoing evaluation of fetal or neonatal condition.
- informed by local institutional policy and relevant laws
- guidelines offer recommendations with regard to the gestational ages at which **assessment for resuscitation rather than resuscitation itself** should be undertaken.
- Such assessment is meant in most cases to refer to that provided by neonatologists or other pediatric providers, separate from that offered by obstetrician–gynecologists and other obstetric providers.
Humility

- Admit when we don’t know things
- At best, we can only provide a range of prognoses based on incomplete information

Humility is not thinking less of yourself, but thinking of yourself less.

- C.S. Lewis
**Interdisciplinary Care**

- **Consensus**
  - Hospital policy
  - MFM and Neonatology

- **As much consistency as possible**
  - Plan should *not* change with every shift change

- **Counsel together**
  - MFM/OB and Neonatology together

- **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.**
Consensus
Deliberative Model of Care

- Exploration of patients’ goals and values
- Help patients understand options in terms of their goals and values
- May involve moral persuasion

- Emmanuel and Emmanuel, JAMA 1992
Informed Consent/Refusal

- Give patients the information they need to make good decisions for themselves and their children
- What is important is prognosis
  - Gestational age is often, but not always, a good proxy
Child Abuse Prevention and Treatment Act (CAPTA)

- Require treatment unless:
  - Chronically and irreversibly comatose
  - Treatment merely prolonging dying
  - Treatment not effective in ameliorating or correcting all the infant’s life-threatening conditions
  - Treatment would be virtually futile in terms of survival
<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Grade of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on anticipated neonatal or maternal complications, antepartum 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>Prenatal and postnatal counseling regarding anticipated short-term and long-term neonatal outcome should take into consideration anticipated gestational age at delivery, as well as other variables that may alter the likelihood of survival and adverse newborn outcomes (e.g., fetal sex, multiple gestation, the presence of suspected major fetal malformations, antenatal corticosteroid administration, birth weight, and response to initial newborn resuscitation).</td>
<td>Best practice</td>
</tr>
<tr>
<td>Family counseling should be provided by a multidisciplinary team that includes obstetrician–gynecologists and other obstetric providers, maternal–fetal medicine specialists, if available, and neonatologists who can address their individual and shared considerations and perspectives. Maternal and neonatal outcomes should be considered. Follow-up counseling should be provided when there is relevant new information about the maternal and fetal status or the newborn’s evolving condition.</td>
<td>Best practice</td>
</tr>
<tr>
<td>A predelivery plan, made with the parents, family, or both, should be recognized as a general plan of approach, which may be modified as the neonate’s condition and response is evaluated by the neonatal providers. A recommendation regarding assessment for resuscitation is not meant to indicate that resuscitation should always either be undertaken or deferred, or that every possible intervention need be offered. A stepwise approach concordant with neonatal circumstances and condition and with parental wishes is appropriate. Care should be reevaluated regularly and potentially redirected based on the evolution of the clinical situation.</td>
<td>Best practice</td>
</tr>
<tr>
<td>Recommendations regarding specific interventions, tailored to gestational age and other clinical data, and taking into account individual family preferences and values, are summarized in Table 3.</td>
<td>Best practice</td>
</tr>
</tbody>
</table>
One Model

<table>
<thead>
<tr>
<th></th>
<th>&lt;22 weeks</th>
<th>22 0/7-22 6/7</th>
<th>23 0/7-23 6/7</th>
<th>24 0/7-24 6/7</th>
<th>25 0/7-25 6/7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antenatal steroids</td>
<td>Not recommended</td>
<td>Consider</td>
<td>Consider</td>
<td>Recommend</td>
<td>Recommend</td>
</tr>
<tr>
<td>Tocolysis to allow ACS administration</td>
<td>Not recommended</td>
<td>Not recommended</td>
<td>Consider</td>
<td>Recommend</td>
<td>Recommend</td>
</tr>
<tr>
<td>Magnesium for neuroprotection</td>
<td>Not recommended</td>
<td>Not recommended</td>
<td>Consider</td>
<td>Recommend</td>
<td>Recommend</td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>Not recommended</td>
<td>Not recommended</td>
<td>Consider</td>
<td>Consider</td>
<td>Recommend</td>
</tr>
<tr>
<td>Antibiotics for latency in PPROM when delivery not imminent</td>
<td>Consider after counseling, if delivery is declined</td>
<td>Consider after counseling, if delivery is declined</td>
<td>Consider after counseling, if delivery is declined</td>
<td>Recommend</td>
<td>Recommend</td>
</tr>
<tr>
<td>Offer resuscitation/comfort care</td>
<td>Comfort care only</td>
<td>Comfort care encouraged; resuscitation considered if family desires</td>
<td>Resuscitation and comfort care offered</td>
<td>Resuscitation encouraged; comfort care considered if family desires</td>
<td>Resuscitation recommended unless other circumstances present</td>
</tr>
</tbody>
</table>
Role Modeling

- Fellows
- Residents
- Students
Take Home Message

- Do the right thing
- Good ethics require good facts

- All cut-offs are arbitrary
  - Distinctions should be morally relevant
Question Authority

❖ Socrates

“The unexamined life is not worth living.”

“Not life, but good life, is to be chiefly valued.”
THANK YOU!

I Believe...
That the people you care about most in life are taken from you much too soon.

I Believe...
That just because someone doesn’t love you the way you want them to, doesn’t mean they don’t love you with all they have.