Infant outcomes at marginally viable gestational ages; clinical and ethical considerations in counseling

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Objectives

- Review published guidelines on resuscitation at limits of viability
- Review outcomes at limits of viability
- Discuss counseling and resuscitation strategies at the limits of viability
- Review legal cases that may influence
- Explore ethical concepts that help guide decision making at the limits of viability

The Scenario

- You are the obstetrician who's patient presents to L&D at 22 weeks gestation and in early labor. You start magnesium sulfate to try to slow things down and get steroids on board.
- Does your NICU have guidelines?
- How should you counsel her?

Dilemma of Uncertainty

"If it is hard to justify creating blind paraplegics to obtain a number of healthy survivors, it is equally hard to explain to the ghosts of the potentially healthy that they had to die in order to avoid creating blind paraplegics."

Jeff Lyon – "Playing God in the Nursery"

Newly Suggested Guidelines

JOINT WORKSHOP EXECUTIVE SUMMARY

Periviable birth: executive summary of a joint workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Academy of Pediatrics, and American College of Obstetricians and Gynecologists

Tonse N. K. Raju, MD; Brian M. Mercer, MD; David J. Burchfield, MD; Gerald F. Joseph Jr, MD

American Journal of Obstetrics & Gynecology MAY 2014

Newly Suggested Guidelines

STATE-OF-THE-ART

Periviable birth: executive summary of a Joint Workshop by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, American Academy of Pediatrics, and American College of Obstetricians and Gynecologists

TNK Raju1, BM Mercer2, DJ Burchfield3 and GF Joseph4

Journal of Perinatology (2014) 34, 333–342; doi:10.1038/jp.2014.70; published online 10 April 2014

NICHD Executive Summary

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Table 1. Survival-to-discharge after birth at 22-25 weeks of gestation in studies published that include infants born since 2000

Authors	Time frame	Study setting	Inclusions	Exclusions	Sample size	Survival (%)			
						22 Weeks	23 Weeks	24 Weeks	25 Weeks
Donohue et al.[24]	1993-2001	Retrospective cohort, single center	Women admitted with a live fetus	None	104 (2001-2003)	31			
Petrova et al.[24]	1998-2001	Retrospective cohort, single center	NICU admissions	Congenital malformations	114	40			
Tyson et al.[25]	1998-2003	Retrospective cohort, multicenter	Live births	Birth weight <401 g, <1000g, or >97th percentile; ambiguous genitalia; major anomalies; survival without mechanical ventilation	4446	51			
Mehler et al.[27]	2000-2007	Prospective cohort, single center	Live births	None	208	41	76	82	80
Kyser et al.[28]	2000-2009	Retrospective cohort, single center	NICU admissions	Major anomalies; birth weight <401g or >1000g	134	33	58	87	
Stoll et al.[5]	2003-2007	Retrospective cohort, multicenter	Live births	None	4160	6	26	55	72
Lee et al.[29]	2005-2008	Prospective cohort, multicenter state-level	Live births	Birth weight <401 g or >1000g, or >97th percentile; major anomalies; survival without mechanical ventilation	3048	5	28	60	

NICHD Executive Summary

TABLE 2
General guidance regarding obstetric interventions for threatened and imminent periviable birth[2]

Variable	Weeks of gestation[3]		
	<22 0/7	22 0/7-22 6/7	≥23 0/7
Antenatal corticosteroids	Not recommended	Consider if delivery at ≥23 0/7 is anticipated	Recommended
Tocolytics to enhance latency for potential steroid benefit	Not recommended	Not recommended unless concurrent with antenatal steroids	Consider
Magnesium sulfate for neuroprotection	Not recommended	Not recommended	Recommended
Antibiotics for preterm premature rupture of membranes to enhance latency	Consider if delivery not imminent	Consider if delivery not imminent	Recommended if delivery not imminent
Intrapartum antibiotics for group B streptococcus prophylaxis[4]	Not recommended	Not recommended	Recommended
Continuous intrapartum electronic fetal monitoring	Not recommended	Not recommended	Recommended
Cesarean delivery for fetal indication[5]	Not recommended	Not recommended	Recommended
Aggressive newborn infant resuscitation	Not recommended, comfort care only	Not recommended unless considered potentially viable based on individual circumstance	Recommended unless considered nonviable based on individual circumstances

[1] Survival of infants born in the periviable period is dependent on resuscitation and support. Between 22 weeks and 25 weeks of gestation, there may be mitigating factors (eg, intrauterine growth restriction, small fetal size, the presence of fetal malformations or aneuploidy, and pulmonary hypoplasia due to prolonged membrane rupture) that will affect the potential for survival and the determination of viability (Table 2). The majority of survivors born at 25 6/7 weeks of gestation or less will incur major morbidities, regardless of gestational age at birth. [2] Infants born before 22 0/7 weeks of gestation are generally considered nonviable. Data from recent large studies suggest survival with delivery at 22 0/7 weeks through 22 6/7 weeks to be 5-8%.[26,27] With survival rates of ~26-28% and higher, infants born at 23 0/7 weeks through 25 6/7 weeks of gestation are generally considered potentially viable (Tables 1 and 2). [3] GBS carrier or carrier status is unknown. [4] For example, persistently abnormal fetal heart rate patterns or biophysical testing (category II–III).

Raju. Periviable birth: executive summary of a joint workshop. Am J Obstet Gynecol 2014.

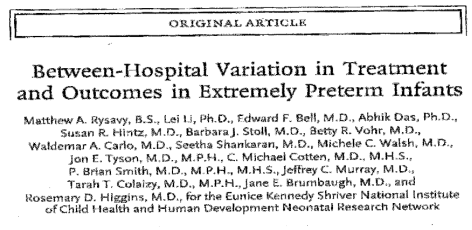
NICHD Executive Summary

Table 3. General guidance regarding obstetric interventions for threatened and imminent periviable birth, ***according to whether the fetus is considered potentially viable, and the parents' wishes for aggressive intervention[3]***

	*Weeks of gestation**		
	< 22 0/7 Weeks	*22 0/7 Weeks to 22 6/7 Weeks*	*23 0/7 Weeks or more*
Antenatal corticosteroids	Not Recommended	Consider if delivery at or later than 23 0/7 weeks is anticipated	Recommended
Tocolytics to enhance latency for potential steroid benefit	Not recommended	Not recommended unless concurrent with antenatal steroids	Consider
Magnesium sulfate for neuroprotection	Not recommended	Not recommended	Recommended
Antibiotics for PROM to enhance latency	Consider if delivery is not imminent	Consider if delivery is not imminent	Recommended if delivery is not imminent
Intrapartum antibiotics for GBS prophylaxis[c]	Not recommended	Not recommended	Recommended
Continuous intrapartum electronic fetal monitoring	Not recommended	Not recommended	Recommended
Cesarean delivery for fetal indication[21]	Not recommended	Not recommended	Recommended
Aggressive newborn resuscitation	Not recommended, comfort care only	Not recommended unless considered potentially viable based on individual circumstances	Recommended unless considered nonviable based on individual circumstances

Abbreviations: PROM, preterm rupture of membranes; GBS, group B streptococcus.
*Survival of infants born in the periviable period is dependent on resuscitation and support. Between 22 and 25 weeks of gestation, there may be mitigating factors (for example, intrauterine growth restriction, small fetal size, the presence of fetal malformations or aneuploidy and pulmonary hypoplasia due to prolonged membrane rupture) that will affect the potential for survival and the determination of viability (Table 2). The majority of survivors born at 25 6/7 weeks of gestation or less will incur major morbidities, regardless of gestational age at birth. [b]Infants born before 22 0/7 weeks of gestation are generally considered nonviable. Data from recent large studies suggest survival with delivery at 22 0/7 weeks through 22 6/7 weeks to be 5-8%.[26,27] With survival rates of ~26-28% and higher, infants born at 23 0/7 weeks through 25 6/7 weeks of gestation are generally considered potentially viable (Tables 1 and 2). [c]GBS carrier or carrier status is unknown. [d]For example, persistently abnormal fetal heart rate patterns or biophysical testing (category II-III).

NICHD Outcomes - NEJM


THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

NEJM 372;19. May 2015

NICHD Outcomes - NEJM

- 24 Hospitals in the NICHD
- 4987 infants born
- Percent active treatment at 22, 23, 24, 25, 26 weeks gestation
- Survival
- Neurodevelopmental outcome at 18-22 months

NICHD Outcomes - NEJM

- Neurodevelopmental outcomes
  - Severe Impairment
    - Cognitive or motor score on Bayley Scales of Infant and Toddler Development < 70 (>2 SD below the mean)
    - Severe CP – Gross Motor Function Classification System of 4 or 5 (0=normal, 5= most impaired)
    - Bilateral blindness (<20/200)
    - Severe hearing impaired (not correctable by amplification)
  - Moderate Impairment
    - Bayley 70-84 (Cognitive or motor)
    - CP – GMFCS 2-3

NICHD Outcomes - NEJM

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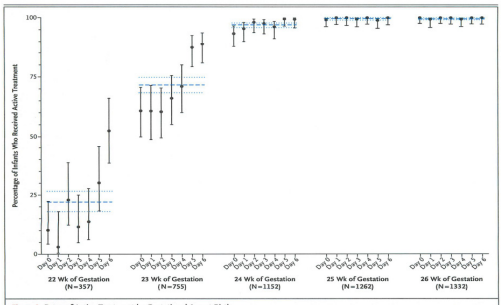


Figure 1. Rates of Active Treatment by Gestational Age at Birth.
Point values represent the mean percentage, across all hospitals, of infants born at a given gestational age (in weeks and days) who received active treatment. Vertical bars represent 95% confidence intervals. Blue dashed lines indicate the mean rate of active treatment among infants born during a given week of gestation, and blue dotted lines indicate 95% confidence intervals.

NICHD Outcomes - NEJM

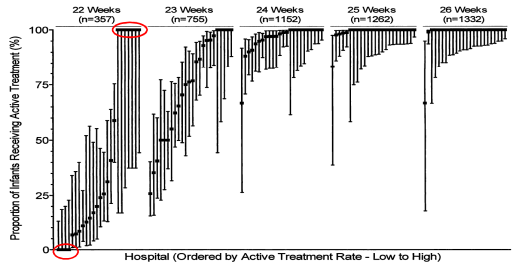
VARIATION IN TREATMENT AND OUTCOMES IN PRETERM INFANTS

Table 2. Crude Outcomes by Gestational Age at Birth.*

Outcome	All Infants		Infants Who Received Active Treatment		Intact Survival
	Overall Rate† mean (95% CI)	Hospital Rate‡ median (interquartile range)	Overall Rate† mean (95% CI)	Hospital Rate‡ median (interquartile range)	
22 Wk of gestation					
Survival	5.1 (3.2–7.9)	3.4 (0.0–10.6)	23.1 (14.9–34.0)	21.1 (0.0–50.0)§	
Survival without severe impairment	3.4 (1.9–5.9)	0.0 (0.0–6.9)	15.4 (8.8–25.4)	5.0 (0.0–33.3)§	39%
Survival without moderate or severe impairment	2.0 (0.9–4.1)	0.0 (0.0–0.7)	9.0 (4.3–17.9)	0.0 (0.0–14.6)§	
23 Wk of gestation					
Survival	23.6 (20.7–26.9)	24.8 (10.3–32.1)	33.3 (29.4–37.5)	30.8 (23.8–37.1)	
Survival without severe impairment	17.9 (15.3–20.9)	16.8 (7.3–25.2)	25.2 (21.7–29.2)	25.0 (15.1–28.0)	48%
Survival without moderate or severe impairment	11.3 (9.2–13.9)	8.7 (3.6–13.4)	16.0 (13.1–19.4)	14.2 (6.7–18.9)	
24 Wk of gestation					
Survival	54.9 (51.9–57.8)	53.7 (45.4–65.9)	56.6 (53.6–59.5)	58.0 (47.2–66.8)	
Survival without severe impairment	44.7 (41.7–47.7)	44.3 (37.1–54.5)	46.1 (43.1–49.1)	44.3 (38.2–56.2)	55%
Survival without moderate or severe impairment	30.0 (27.3–32.8)	30.0 (18.4–33.3)	30.9 (28.2–33.8)	30.5 (18.7–33.6)	
25 Wk of gestation					
Survival	72.0 (69.4–74.5)	71.2 (65.7–79.5)	72.3 (69.7–74.8)	71.7 (65.7–79.5)	
Survival without severe impairment	61.1 (58.3–63.8)	59.3 (54.7–64.3)	61.4 (58.5–64.1)	59.9 (56.2–64.5)	61.5%
Survival without moderate or severe impairment	44.3 (41.5–47.2)	46.0 (34.9–51.7)	44.5 (41.7–47.4)	46.5 (35.0–51.7)	
26 Wk of gestation					
Survival	81.4 (79.2–83.6)	81.0 (78.2–84.0)	81.6 (79.3–83.7)	81.3 (78.9–85.7)	
Survival without severe impairment	75.6 (73.2–78.0)	75.7 (69.5–80.0)	75.7 (73.3–78.1)	76.4 (70.8–80.3)	
Survival without moderate or severe impairment	58.5 (55.8–61.3)	58.9 (51.6–65.4)	58.6 (55.9–61.4)	59.8 (53.6–67.0)	72%

Hospital Variation NEJM

Figure S1. Rates of Neonatal Active Treatment for Infants Born at 22 to 26 Weeks' Gestation in 24 Hospitals in the NICHD Neonatal Research Network



Point values represent the proportion of infants of the specified gestational age that were born at 1 of 24 hospitals in the NICHD Neonatal Research Network and received active treatment. Bars represent 95% confidence intervals. The x-axis represents hospital rank order by mean active treatment rate (ordered from lowest to highest).

Counseling Goals

- Provide information
  - Survival
  - NICU issues – 3 letter library, procedures, length of stay?
  - Long term outcomes/morbidities
- Assess family values and goals?
- Make recommendation for DR plan of care?
- Why?
  - Underlying assumption is that they have a choice

AAP Guidelines

- Neonatology counseling in anticipation of extreme preterm birth should include the following information:
- A range of the current possible survival rates (preferably institution-specific figures)
- An overview of potential medical problems and their treatment and complications
- The possibility of long-term disabilities, including mental retardation, cerebral palsy, blindness, deafness, and learning disabilities/need for special education
- The possibility that expectations may change after delivery, based on a more accurate assessment of the gestational age and condition of the newborn
- Care should be taken not to include interventions of unproven benefit as "doing everything possible" for the neonate.

MacDonald H. Committee on fetus and newborn
Pediatrics, Nov 2002, vol.110

Tools for Counseling

- NICHD prematurity Calculator
  - http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx?start=16:04:11
  - Gestational age: 22-25
  - Birth weight: 401-1000
  - Sex: Female/male
  - Singleton: yes/no
  - Antenatal steroids: yes/no

Gestational Age *(Best Obstetric Estimate in Completed Weeks):* 23 weeks
Birth Weight: 600 grams
Sex: Male
Singleton Birth: Yes
Antenatal Corticosteroids: Yes
Estimated outcomes* for infants in the **NRN** sample are as follows:

Outcomes	Outcomes for All Infants	Outcomes for mechanically ventilated
Survival	30%	40%
Survival Without Profound Neurodevelopmental Impairment	17%	23%
Survival Without Moderate to Severe Neurodevelopmental Impairment	9%	12%
Death	70%	60%
Death or Profound Neurodevelopmental Impairment	83%	77%
Death or Moderate to Severe Neurodevelopmental Impairment	91%	88%

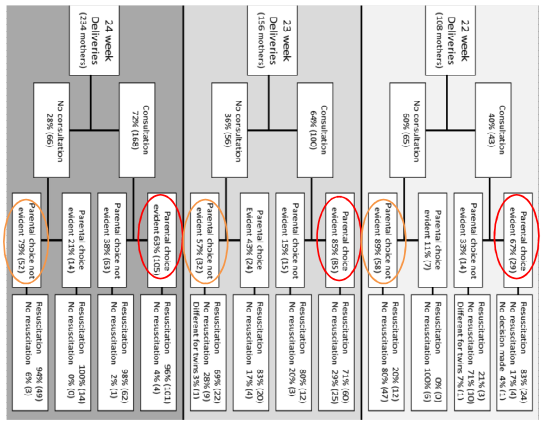
What do we all do?

- INDEED Project
- Antenatal Periviability Counseling and Decision-Making at 6 U.S. Centers
- Retrospective Chart Review of all OB and Neo datasets
- Reviewed documented counseling and neo consultation

Feltman, 2019

Consultation		Yes n=311	No n=187
Maternal age years, mean ±SD (range)		27.3±6 (16-43)	27.4±6 (13-44)
Race	African American	173 (56%)	115 (61%)
	Caucasian	104 (33%)	51 (28%)
	Asian	4 (1%)	4 (2%)
	Native American	2 (0.6%)	2 (1%)
	Other/unknown	19 (6%)	15 (8%)
Ethnicity	Hispanic	22 (7%)	20 (11%)
	Non-Hispanic	278 (89%)	162 (87%)
	Unknown	11 (4%)	5 (3%)
Primary language	English	296 (95%)	172 (92%)
	Spanish	12 (4%)	14 (7%)
	Other	3 (1%)	1 (1%)
Insurance	Public	173 (56%)	121 (65%)
	Private	117 (38%)	47 (25%)
	Unknown	2 (0.6%)	4 (2%)
	None	19 (6%)	15 (8%)
Admission gestational age mean ± SD (range)		23w2d ±5.5d (20w2d-24w6d)	23w2d ±6.5d (20w1d-24w6d)
First pregnancy		93 (30%)	63 (34%)
Singleton		250 (80%)	158 (84%)
Regular prenatal care		282 (91%)	157 (84%)*
Time from admission to delivery, median (range)		58.7 h (0.4-1519)	8.7 h* (0-1920)
mean ±SD‡		95.2 ± 133	34.4 ± 144
Time from admission to consult, median (range)		5.2 h (0-628)	
mean ± SD§		24.8 ± 64	

Documented Details by Gestational Age at Delivery		22 Weeks n=43 (40%)	23 Weeks n=100	24 Weeks n=168 (72%)
Consult age gestation mean ± SD (range)		22w3d±2d (21w0d-22w6d)	23w1d±3d (21w3d-23w6d)	23w6d±4d (21w3d-24w6d)
Topics discussed†				
	Survival	34 (79%)	83 (83%)	132 (79%)
	Neurodevelopment	24 (56%)	68 (68%)	101 (60%)
	Comfort care	19 (44%)	46 (46%)	35 (21%)*
	Interventions	24 (56%)	80 (80%)	141 (84%)*
	Redirection of care	7 (16%)	39 (39%)	76 (45%)*
Care plan discussion				
	Resuscitation only	1 (2%)	15 (15%)	69 (41%)*
	Resuscitation rec	4 (9%)	0 (0%)	6 (4%)*
	No recommendation	15 (35%)	57 (57%)	73 (43%)*
	Comfort care rec	8 (19%)	19 (19%)	4 (2%)*
	Comfort care only	8 (19%)	3 (3%)	3 (2%)*
	Not documented	7 (16%)	6 (6%)	14 (8%)
Statistics cited		24 (56%)	47 (47%)	74 (44%)
Provider				
	Fellow	15 (35%)	34 (34%)	61 (36%)
	Attending	15 (35%)	28 (28%)	38 (23%)
	Fellow & Attending	4 (9%)	20 (20%)	23 (15%)
	NNP	0 (0%)	3 (3%)	4 (2%)
	NNP & Fellow	0 (0%)	0 (0%)	1 (1%)
	NICU RN	6 (14%)	16 (16%)	37 (22%)
OB Co-consultation		3 (7%)	9 (9%)	5 (3%)
Parent(s) expressed decision	Yes	21 (49%)	66 (66%)	75 (45%)
	No	2 (5%)	9 (9%)	9 (5%)
	Unclear	5 (12%)	12 (12%)	23 (14%)
*p<0.05	none to be made	15 (35%)	13 (13%)	61 (36%)



The Medical and Legal Fallacy of the Emergency Exception to Consent in the Delivery Room

- I believe there are emergent situations in the delivery room
- I will argue that ***all*** are not emergent
- I believe in allowing trials of treatment
- I will argue they are ***not*** always required