LAC+USC Medical Center

ATTENDING STAFF GUIDELINES

Subject: **THRESHOLD OF VIABILITY GUIDELINES**	Original Issue Date: 8/3/11	Policy # **ASA 112**
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Departments Consulted:	Reviewed & Approved by:	Approved by:
Pediatrics / Newborn, Obstetrics / Maternal Fetal Medicine, Palliative Care Team Services, Fetal, Infant, Child Ethics Committee, Risk Management, Medical Administration, Decedent Affairs Office, Medical Social Service, Nursing Services & Education.	Credentials and Privileges Advisory Committee Attending Staff Association Executive Committee	(signature on file) President, Attending Staff Association

PURPOSE

To establish guidelines for the resuscitation of the extremely low birth weight infants at extremely low gestational age of $22^{0/7}$ to $24^{6/7}$ weeks (gestational age is defined as the number of weeks and days from the first day of the last menstrual period).

GUIDING PRINCIPLES

The importance of individualized decision-making is emphasized by a statement from the summary of international guidelines: “because of the uniqueness of every pregnancy and neonate, to protect mothers and infants from futile treatment, as well as incorrect withholding of life-sustaining treatment, the specific circumstances of every individual situation must always be kept in mind.” It is clear that individualized decision-making is required for this complex issue, and many factors have to be considered when providing antenatal counseling to parents (Ref 1).

Prenatal Counseling: Adapted from Committee on Fetus and Newborn (Ref 2). Clinical Report—Antenatal Counseling Regarding Resuscitation at an Extremely Low Gestational Age

Parents should be given the most accurate prognostic morbidity and mortality data available for their infant. In some situations, these may be hospital-specific data, and in other situations, regional or national data (www.nichd.nih.gov/neonatalestimates) may be more appropriate (Ref 3). Parents need to be informed that despite the best efforts, the ability to give an accurate prognosis for a specific infant either antenatally or immediately after delivery remains limited. Parents should be told that even with resuscitation and intensive care, many infants born at an extremely low gestational age die within the first few days after delivery. Parents also need to be informed that infants who survive the first few days are likely to survive until hospital discharge, but prediction of long-term neurologic outcome remains limited. It should be made clear to parents that if resuscitation is attempted and is successful, situations may occur later in which it is reasonable to consider withdrawing treatment. If the parents’ preferences regarding resuscitation are either unknown or uncertain, resuscitation should be initiated pending further discussions. Parents should also be told that if the decision is not to initiate resuscitation or if resuscitation is unsuccessful, their infant will be provided comfort care and they will have the opportunity to hold their infant after delivery.

General Principles:

1. Decisions made by a parent or surrogate on behalf of a child must be based on the best interests of the child and mother.
2. There is a strong presumption that parents will act in the best interest of the child.
3. Unless disqualified through due legal process, parents are the decision-makers for their minor children.
4. Parents should be provided the most accurate prognostic data available to help them make decisions. These predictions should not be based on gestational age alone but should include all relevant information affecting the prognosis.
5. It is not possible to develop specific criteria for when the initiation of resuscitation should or should not be offered.

GUIDELINES are summarized in Table 1.

Guidelines for Perinatal Care:

1. When delivery of an infant at the threshold of viability is likely (gestational age 22 0/7 – 24 6/7 weeks), the obstetrician team, responsible for the mother, and the neonatologist team responsible for the infant, members should confer with one another as early as possible and discuss with the parents the range of possible outcomes and management options. Parents should be informed that expectations and recommendations may be altered after birth when an assessment of the newborn can be performed.
2. In this Medical Center, infants are not routinely considered to be viable when the gestational age is less than 23 weeks. Exceptions are made when the newborn is unusually vigorous for presumed gestational age or birth weight.
3. Infants judged to be non-viable because of immaturity should not be resuscitated routinely.
4. If the physicians consider a good outcome to be very unlikely, then parents should be given the choice of whether resuscitation should be initiated, and clinicians should respect their preference.
5. When the physicians' judgment is that a good outcome is reasonably likely, clinicians should initiate resuscitation and, together with the parents, continually reevaluate whether intensive care should be continued.
6. Whenever resuscitation is considered an option, a qualified individual should be involved and present in the delivery room to manage this complex situation.
7. Comfort care should be provided for all infants for whom resuscitation is not initiated or is not successful.

Guidelines for Care in the Newborn Intensive Care Unit:

1. All medical treatment considered beneficial should be provided.
2. Treatment recommendations should be based on frequent evaluation of the newborn's medical condition. Changes in condition and prognosis should be communicated to the parents as promptly as possible.
3. Modifications in the treatment regimen that are indicated by changes in the newborn's medical condition should be discussed with parent(s) before implementation, especially if they may change prognosis.
4. Treatment judged to be futile may be discontinued after discussion with the parent(s).
5. When the newborn's condition is judged to be incompatible with survival regardless of interventions, only those measures deemed to be necessary to maintain the newborn's comfort need be provided and the parent(s) informed of the reasons. Such measures may include maintenance of temperature, fluids, and social contact, including contact with the parent(s).
6. When difficult ethical decisions must be made or when there is disagreement between the medical staff and the parents, appropriate consultation with senior physicians should be undertaken. When disagreements between staff and family or within staff cannot be resolved through discussion, the case should be referred to Fetal/Infant/child Bioethics committee for review.
7. When a parent's decision appears to be clearly contrary to the best interest of the newborn, it is the duty of physician to challenge the decision. If differences cannot be resolved after discussion and/or review by the Bioethics committee, it may be necessary to refer the matter to the courts.

Notes:

1. Certain Federal regulations apply to medical treatment decisions in the cases of disabled newborns with life threatening conditions. Physicians caring for newborns should be familiar with these regulations. References are available at the Neonatology Division, if needed.
2. Guidelines cannot anticipate all circumstances surrounding individual cases. Deviations from these guidelines may be justified as indicated by clinical judgment.
3. Neonatal Resuscitation Program (NRP) 8th Edition and American Heart Association/American Academy of Pediatrics Guidelines from 2021: No Gestational age or birth weight-based guidelines. Refer to ACOG/SMFM consensus report (Ref 8).

If confirmed absence of HR after all appropriate steps performed, consider cessation of resuscitation efforts around 20 minutes after birth (decision individualized on patient and contextual factors).(Ref: NRP 8th Edition, 2021)

Table 1: LAC+USC Healthcare Network Perinatal-Neonatal Staff Guidelines for Resuscitation of the Extremely Low Birth Weight Infants at an Extremely Low Gestational Age ($22^{0/7}$ – $24^{6/7}$ weeks): Threshold of Viability Guidelines (Ref: ACOG and SMFM Consensus, October 2017)

Gestational Age, Weeks at Birth	Obstetric Care Reasonable Clinical Judgment Required in All Cases	Neonatal Care Reasonable Clinical Judgment Required in All Cases
$22^{0/7}$-$22^{6/7}$	• Tocolysis if indicated. • Steroids not routinely offered. • No routine cesarean delivery for fetal indication.	• No routine resuscitation offered • Consider Neonatal assessment for resuscitation • NICU care not offered • Comfort care offered
$23^{0/7}$ -$23^{6/7}$	• Consider Tocolysis • Consider Antenatal • Consider Magnesium sulfate for Neuroprotection • Consider Antibiotics to prolong latency during expectant management of PT-PROM if delivery is not imminent • Consider cesarean delivery for fetal indication based on parental preference	• No routine resuscitation recommended. • Selective resuscitation based on parental preference. • NICU care not recommended routinely because of very high mortality and neurologic disability rate. • Comfort care offered.
$24^{0/7}$ -$24^{6/7}$	Recommended: • -Tocolysis • -Antenatal Steroids • -Magnesium sulfate for neuroprotection • -Cesarean delivery for fetal indication and/or based on clinical scenario.	• Routine resuscitation offered • NICU care provided

ASA 112: Attachment A: PROCEDURE DOCUMENTATION. Attending Staff Association Manual
Neonatal Prenatal Consultation Note content:

Requesting Consultation Obstetrician/MFM Specialist: ☐ Attending: ☐ Fellow:	Date:	TIME:
Supervising Consulting Neonatologist: ☐ Attending: ☐ Fellow:	LMP:	GA (weeks): EFW (grams):
Reasons for Consult:		

Maternal data:_____y/o G_____P_______Blood Type_____Rh____Antibody_____
PMH:____

Pregnancy Complications/Medications:
- □ Preterm Labor
- □ Maternal Fever __________
- □ PROM – Time: ____________
- □ Preeclampsia □ Magnesium Sulfate
- □ Diabetes □ Class________□ Insulin
- □ Abruption
- □ IUGR Sex: □ Male □ Female
- □ Oligo/Polyhydramnios
- □ Abnormal Fetal HR
- □ Chromosomal abnormality
- □ Malformations
- □ Breech
- □ Tobacco □ Alcohol □ Other drugs ______________________________
- □ Multiple Gestation: □ Twins □Triplets □ Quads
- □ Maternal Antibiotics ______________________________
- □ Antenatal Steroids: # of doses_________Last Dose-Date/Time: ________________________

Screens:

	Positive		Negative	Unknown
GBS	□		□	□
VDRL	□	Reactive	□Non-reactive	□
HepB SAg	□		□	□
GC	□		□	□
Chlamydia	□		□	□
HIV	□		□	□
Rubella	□	Immune	□Non-Immune	□
PPD	□		□	□
CXR	□		□	□

Other Information:

Discussed with ____

Overview:
- □ Listened to parents' understanding of situation
- □ Discussed survival odds/Morbidity & Mortality
- □ Discussed uncertainty of dates/prognosis
- □ Explained NICU team presence/role at delivery

Long-term morbidities:
- □ Risk of chronic lung disease
- □ Risk of intraventricular hemorrhage
- □ Risk of mental disability/Cerebral palsy
- □ Risk of deafness and blindness

Immediate morbidities/treatments:
- □ Risk of RDS/Intubation/Surfactant/Mechanical ventilation
- □ Vascular access/UAC/UVC `
- □ Risk of infection/ Need for antibiotics
- □ Possible need for blood/ blood products

Other:
- □ Location of NICU/Visiting Policy
- □ Potential questions and concerns addressed
- □ Parent(s) verbalized understanding the discussions
- □ Approximate length of stay
- □ Benefits of breast milk/ Nutrition

Discussion/Plans: □ Comfort care only □ Full Resuscitation □ Parents told baby may be born alive & may take minutes to hours before the baby may die. □ Parent(s) told plans may need to be modified after the baby has been born and examined.
Physician:_____________________Signature____________________SID___________

Date and Time:_________________________Discussed with Attending/Fellow:______________________

RESPONSIBILITY

Attending Staff
House staff
Medical Center Employees

PROCEDURE DOCUMENTATION

Attending Staff Manual, Rules and Regulations, Policies, Procedures and Guidelines

REFERENCES

1. Serenella M, Donzelli G. Perinatal care at the threshold of viability: an international comparison of practical guidelines for the treatment of extremely preterm births. *Pediatrics.* 2008;121(1). Available at: www.pediatrics.org/cgi/content/full/121/1/e193.
2. Clinical Report—Antenatal Counseling Regarding Resuscitation at an Extremely Low Gestational Age. Pediatrics, 124:422-427, 2009.
3. Tyson Je, Parikh NA, Langer J, Green C, Higgins RD. Intensive care for extreme prematurity: moving beyond gestational age. N Engl J Med 2008;358(16):1672-1681.
4. Joint Commission Standards 9 Ethics, Rights, and Responsibilities)
5. California Health & safety Code, sections 7054.3, 7100, 10175, 10180, 10190, 10250
6. DHS policies # 316, Patient deaths, and 153, Assisting the Coroner
7. American Academy of Pediatrics; American Heart Association. Lesson 9: ethics and care at the end of life. In: *Textbook of Neonatal Resuscitation.* 8th ed. Elk Grove Village, IL: American Academy of Pediatrics and American Heart Association; 2021..
8. ACOG and SMFM Consensus: 6, OBGYN, October 2017

REVISIONS

August 2011; May 4, 2022