Management of Periviable Births at JHACH
Clinical Pathway
This pathway is intended as a guide for physicians, physician assistants, nurse practitioners and other healthcare providers. It should be adapted to the care of specific patient based on the patient's individualized circumstances and the practitioner's professional judgment.
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Rationale

When delivery is anticipated near the limits of viability, families and health care teams are faced with complex and ethically challenging decisions. Periviability is defined as the earliest stage of fetal maturity when there is a reasonable chance, although perhaps not a high likelihood, of extrauterine survival. The American Academy of Pediatrics (AAP) typically defines this period as 22 0/7 to 24 6/7 weeks, the American College of Obstetricians and Gynecologists (ACOG) range is from 20 0/7 to 24 6/7 weeks. When born at this gestational age, neonates are at significant risk for death, or survival with significant morbidity, often requiring complex medical care. There is an inherent gray-area at these periviable gestational ages, making decision-making management of these neonates challenging.

Since the foundation of the field of Neonatology and care for the premature infant, a steady improvement has been seen in neonatal survival rates. With this improvement, there has been a downward shift in gestational age as to the “limits of viability.” Recent data has shown significant variation in “active treatment” or neonatal delivery room resuscitation, so much so that among children born at 22 or 23 weeks, the individual hospital rate of active treatment accounts for the majority of between hospital variation in outcomes. (1) After these variations in rates were published, nationally, rates of “active treatment” and overall survival have improved each year. (2)

Background / Published Data and Levels of Evidence

1. Periviability Practices
   - Ethical framework
     - Beneficence
       - Requires physicians to seek, on balance, a greater amount of clinical good than harm for the patient
     - Respect for autonomy
       - Requires physicians to empower patient autonomy by providing the information needed for informed consent and to implement the competent patient’s decisions about management unless there is a compelling beneficence-based objection
     - Justice
       - Requires fairness in allocation of limited resources
   - Ethical analysis/approach
• When approaching ethical analysis regarding periviability, it's important to consider relevant rights of the infant and the parents, and the obligations of the clinical team. Rights and obligations that we consider relevant to these decisions include, but may not be limited to, the following:
  o The infant has a right to treatment, when feasible, that has a reasonable chance of saving his or her life. The infant also has a right to mercy, meaning a right not to be subjected to painful procedures that are extremely unlikely to benefit him or her (ie, improve survival and/or decrease morbidity). (19,20)
  o The parents have a right to information they need to make informed decisions on their child's behalf. They have a right to decide what is done to their child, but that may, in rare situations, be overridden by the child's rights (eg, if they refuse a treatment that clearly would benefit the infant, or demand one that clearly would be harmful to their child). (19,20)
  o Clinicians have an obligation to present parents with the relevant information, such as morbidity and mortality data (as well as the limitations of those data), and to help them with the profoundly difficult decisions for the care of this age group. An honest presentation of the relevant information and the available options (including, if feasible, transfer to another institution) is paramount. The clinical team should recognize the enormous stress that decision making in this setting causes parents, and work closely with them to reach management decisions together, based primarily on an assessment of the perceived benefits and burdens to the infant of treatments under consideration. (19,20)

• Periviable Management Strategies:
  o Based on the above ethical approach and considerations, periviable infants can be assigned to one of three management categories for resuscitative and intensive care based on prognosis with regard to mortality and morbidity:
    a. Poor Prognosis:
      i. Prognosis is so poor that the infant should not be made to undergo any resuscitative and intensive care measures. In this case, these procedures would be ethically impermissible.
    b. Favorable Prognosis
      i. Prognosis is so good that resuscitative and intensive care measures should be provided, at least initially, and are ethically obligatory.
    c. Unclear Prognosis
      i. The prognosis is unclear and it is difficult to determine the relative benefit and burden of
resuscitative and intensive care measures for the infant. In this setting, clinicians should generally defer to the values and preferences of informed parents. Attempted resuscitation in this setting could be considered ethically permissible, but not obligatory.

- **Antenatal Counseling**
  - Antenatal counseling is a crucial component of periviable care and counseling.
  - The American Academy of Pediatrics (AAP) recommends an individualized approach to decision-making for births at 22-24 weeks taking into account “known fetal and maternal risk factors as well as parental beliefs regarding the best interest of their child.” Key components to be taken into consideration include assessment of risks, communication of those risks and ongoing support. The primary goal of periviable antenatal counseling is to allow parents to make an informed decision regarding intervention. (3)
  - There are a number of published periviable prenatal counseling “tools” in circulation in the literature, focusing on personalized communication. (4)
  - The NICHD Extremely Preterm Birth Outcomes Tool/Calculator is often utilized to provide the best available information to families and healthcare providers about the health, survival and development of infants born extremely prematurely.
  - Visual aids have also been utilized in studies to help aid in counseling. (5)

- **Perinatal Management**
  - **Antenatal Corticosteroids**
    - Recent studies and experience support that antenatal corticosteroid administration for births at \( \leq 23 \) weeks of gestation reduces infant mortality and morbidity. (6,7,8)
    - A 2016 meta-analysis of observational studies demonstrated a significant reduction of mortality from antenatal steroid exposure among postnatally treated infants at 22-23 weeks,38 which was subsequently supported by an additional large US observational study. (7,9)
    - Updated with recent evidence, the American College of Obstetricians and Gynecologists now recommends that clinicians “consider” administering antenatal corticosteroids when threatened and imminent periviable birth is anticipated at 22 0/7 weeks to 23 6/7 weeks. They recommend administering antenatal corticosteroids from 24 0/7 weeks forward. (18)
• **Transfer**
  - Rates of morbidity due to extreme prematurity are greater in outborn infants than in infants born in the same hospital where they receive NICU care, even when including only infant transferred on the day of birth and after adjustment for illness severity. (10,11,12)
3. Periobility Outcomes

- National and International Published Survival Data:

<table>
<thead>
<tr>
<th>Study</th>
<th>Region/country</th>
<th>Study years</th>
<th>Survival [n/N (%)] by gestational age (weeks)</th>
</tr>
</thead>
</table>

NICU = neonatal intensive care unit; NNH = Neonatal Research Network; ANS = antenatal steroid therapy; AT = active treatment.

* Survival of NICU admissions to discharge.

† Survival of live births to 1 year.

‡ Survival of live births surviving infants who died in the delivery room and were not admitted to the NICU.

§ Survival of NICU admissions to 1 year.

|||
• **22 0/7-22 6/7 weeks gestation**
  - JHACH Data (from 2012 to 2022)
    - 25% survival
    - All survivors with associated morbidities (defined by the Vermont Oxford Network (VON)) as **Severe IVH, CLD Infants <33 Weeks, NEC, Pneumothorax, Any Late Infection, or PVL.**
    - Mean birth weight: 537 grams
    - 50% with severe intraventricular hemorrhage (grade III or grade IV IVH)

• **23 weeks**
  - JHACH Data (from 2012-2022)
    - 59% survival
    - 24% of survivors without with associated morbidities (defined by the Vermont Oxford Network (VON)) as **Severe IVH, CLD Infants <33 Weeks, NEC, Pneumothorax, Any Late Infection, or PVL.**
    - Mean birth weight: 599 grams
    - 46% with severe intraventricular hemorrhage (grade III or grade IV IVH)

• **24 weeks**
  - JHACH Data (from 2012-2022)
    - 80% survival
    - 27% of survivors with associated morbidities (defined by the Vermont Oxford Network (VON)) as **Severe IVH, CLD Infants <33 Weeks, NEC, Pneumothorax, Any Late Infection, or PVL.**
    - Mean birth weight: 702 grams
    - 31% with severe intraventricular hemorrhage (grade III or grade IV IVH)

4. **Delivery Room Management**
   - **Endotracheal Intubation**
     - **2.0 ETTs**
       - When approaching perivable births, 2.0- mm internal diameter endotracheal tubes are at times necessary for tracheal intubation of infants born at these early gestations and can be effectively used with various ventilator modalities. A recent study showed similar survival in perivable neonates intubated with 2.0 (77% survival) and 2.5 (87% survival) endotracheal tubes, without increased risk of endotracheal tube malfunction or plugging. (13)

   - **Delivery Room CPR (DR-CPR)**
     - Effective ventilation is the cornerstone of neonatal resuscitation. This allows for lung liquid clearance and aeration is the critical first step that initiates a series of cardiopulmonary events needed for successful newborn transition at birth.
     - Studies have shown that the need for DR-CPR is a prognostic marker for higher rates of mortality and neurodevelopmental impairment (NDI) for
extremely low birth weight infants (14,15,16). There are very few studies that have fully stratified the risk of DR-CPR down to 22 and 23 infants but overall, outcomes are significantly worse and mortality and morbidity worsen by decreasing gestational age. (17)

Clinical Management

When counseling families at the borders of viability, namely 22 0/7 to 24 6/7 weeks, an individualized approach is necessary. From an ethical framework, at these gestational ages, the prognosis is often unclear and it is difficult to determine the relative benefit and burden of resuscitative and intensive care measures for the infant. In this setting, clinicians should generally defer to the values and preferences of informed parents. Attempted resuscitation in this setting could be considered ethically permissible, but not obligatory.

The following is a guideline for management of periviable births at JHACH based on consensus agreement, available national and international published data and review of JHACH center-based outcomes, aimed at providing ethically appropriate, individualized and compassionate care to these neonates and their families.

1. Imminent delivery prior to 22 0/7 weeks gestation
   - Consultation
     o MFM/OB to counsel parents/family
     o No indication for neonatal consultation
   - Resuscitation
     o No indication for intrapartum interventions
     o No indication for neonatal resuscitation
     o Offer comfort care and support to families

2. Imminent delivery between 22 0/7 and 22 6/7 weeks gestation
   - Consultation
     o MFM/OB to counsel parents/family
     o Neonatology to consult
       ▪ Physician-to-physician discussion prior to consultation
       ▪ Consultation to occur in conjunction with MFM/OB
     o Proposed Script:

   “Here at JHACH the statistics run similar to the largest and most experienced units in this country. Out of 100 babies born at 22 weeks gestational age 75 will die within the first 2 weeks of life. Out of the survivors 80% will have serious disabilities in life such as trouble breathing on their own, eating by mouth, speaking, walking or learning. Most of them will need equipment to home like oxygen tanks, gastric tubes to feed and maybe a tracheostomy and ventilator.

We recognize that this is a lot of information. Our goal is to communicate the known risks associated with being born this prematurely—those of both death and potential severe disabilities. We do this to allow to you make the best informed-decision for your baby and your family. We will support you as you make this decision.”
• **OB/MFM intrapartum care**
  o If after counseling, parents request resuscitation:
    ▪ Management from an obstetrical perspective include:
      • Antenatal Steroids
        o *It is appropriate to start antenatal steroids at 21 5/7 weeks if family desires resuscitation*
      ▪ Additional obstetrical intrapartum care at the discretion of OB/MFM, possibly including: MgSO4 for neuroprotection, intrapartum antibiotics, electronic fetal monitoring, tocolysis, mode of delivery.
      ▪ If at outside facility, encourage maternal transfer if feasible/mother willing to accept the risks of transport

• **Resuscitation**
  o If after counseling, parents request resuscitation:
    ▪ Resuscitation will consist of attempted endotracheal intubation by an experienced provider at the discretion of the attending neonatologist and positive pressure ventilation
    ▪ Size 2.5 or 2.0 endotracheal tube can be utilized for intubation
      • Chest compressions and the administration of epinephrine are not recommended at this gestational age.

3. **Imminent delivery between 23 0/7 – 23 6/7 weeks gestation**
   • **Consultation**
     o MFM/OB to counsel parents/family
     o Neonatology to consult
       ▪ Physician-to-physician discussion prior to consultation
       ▪ Consultation to occur in conjunction with MFM/OB
   • **OB/MFM intrapartum care**
     o If after counseling, parents request resuscitation:
       ▪ Management from an obstetrical perspective should potentially include:
         • Antenatal Steroids
         • MgSO4 for neuroprotection
         • GBS prophylaxis
         • Electronic fetal monitoring
         • Tocolytics
         • Potential cesarean delivery (after thorough risk/benefit discussion by OB/MFM)
       ▪ If at outside facility, encourage maternal transfer if feasible/mother willing to accept the risks of transport

• **Resuscitation**
  o If after counseling, parents request resuscitation:
    ▪ Resuscitation will consist of attempted endotracheal intubation by an experienced provider at the discretion of the attending neonatologist and positive pressure ventilation
    ▪ Size 2.5 or 2.0 endotracheal tube can be utilized for intubation
      • Chest compressions and the administration of epinephrine are not recommended at this gestational age.

4. **Imminent delivery at ≥ 24 0/7 weeks gestation**
• **Consultation**
  - MFM/OB to counsel parents/family
  - Neonatology to consult
    - Given overall survival (80%) and significant reduction in risk of neurodevelopmental impairment, and morbidities at this gestational age at JHACH, resuscitation is recommended.
      a. The current published literature, looking at outcomes at 18-22 months of age, shows a 25% risk of moderate to severe neurodevelopmental impairment in infants born at ≥ 24 0/7 weeks gestation.

• **OB/MFM intrapartum care**
  - Management from an obstetrical perspective should potentially include:
    - Antenatal Steroids
    - MgSO4 for neuroprotection
    - GBS prophylaxis
    - Electronic fetal monitoring
    - Tocolytics
    - Potential cesarean delivery (after thorough risk/benefit discussion by OB/MFM)
  - If at outside facility, encourage maternal transfer if feasible/mother willing to accept the risks of transport

• **Resuscitation**
  - Resuscitation will consist of attempted endotracheal intubation by an experienced provider at the discretion of the attending neonatologist and positive pressure ventilation
    - Size 2.5 or 2.0 endotracheal tube can be utilized for intubation
    - Chest compressions and the administration of epinephrine may be provided at this gestational age if necessitated.

**Summary**

If delivery is imminent at less than 22 0/7 weeks gestation, counseling will be performed by obstetrics and maternal fetal medicine and comfort care will be provided when delivery occurs.

Extremely premature infants born between 22 0/7 and 22 6/7 weeks have both high mortality and significant neurological morbidity in the small proportion of infants who survive. Neonatology will be consulted, and counsel the mother/family accordingly, with the primary goal of allowing parents to make an informed decision regarding intervention. If the family wishes to provide active treatment and resuscitation, MFM/OB will provide intrapartum care as appropriate to improve neonatal outcomes, including antenatal corticosteroids. Neonatal resuscitation at the time of delivery will consist of endotracheal intubation, with no chest compressions or epinephrine provided if CPR is needed.

Babies born between 23 0/7 and 23 6/7 weeks gestational age have an improved mortality but remain at significant risk of long-term morbidity in survivors. Neonatology will be consulted, and counsel the mother/family accordingly, with the primary goal of allowing parents to make an informed decision regarding intervention. If the family wishes to provide active treatment and resuscitation, MFM/OB will provide intrapartum care as appropriate to improve neonatal
outcomes, including antenatal corticosteroids. Intrapartum interventions are recommended to enhance fetal maturation and to afford neuroprotection. Neonatal resuscitation at the time of delivery will consist of endotracheal intubation, with no chest compressions or epinephrine provided if CPR is needed.
Imminent Delivery in the Periviable Period Algorithm / Pathway

- **<22 0/7 weeks**
  - MFM/OB Counseling
  - Discuss long term outcome data
  - Discuss survival data
  - Comfort Care ONLY
    - Support family
    - Palliative Care

- **22 0/7-22 6/7 weeks**
  - MFM/OB Counseling
  - Neonatology consultation
  - Proposed Script
  - Comfort Care
  - Parental request for resuscitation
  - MFM/OB Care:
    - Antenatal corticosteroids
    - Additional intrapartum care at the discretion of MFM/OB.
  - Delivery room:
    - Attempted intubation, use of 2.5 or 2.0 as indicated
    - No epinephrine or chest compressions
Glossary
- Periviability:
  Earliest stage of fetal maturity where there is a reasonable chance, although perhaps not a high likelihood, of extrauterine survival. This period is generally between 22 and <26 weeks gestational age (GA). Most infants born at ≥26 weeks GA have a high likelihood of survival, whereas virtually none born at <22 weeks GA survive.

-NICHD- National institute for child health and development
-NRN- Neonatal research network
-NRP- Neonatal resuscitation program

References

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Outcome Measures

Vermont Oxford Network (VON) Data

- Survival
- Morbidity
- Intraventricular hemorrhage (IVH)
- Retinopathy of prematurity (ROP)
- Bronchopulmonary dysplasia (BPD)
- Birth weight
- Delivery room management
- Early and late onset sepsis
- Periventricular leukomalacia (PVL)
- Necrotizing enterocolitis (NEC)
- Antenatal corticosteroids
Clinical Pathway Team

Management of Periviable Births

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Disclaimer

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