

NICHD Neonatal Network

Physiologic Definition of Bronchopulmonary Dysplasia

OBJECTIVE To conduct a physiologic monitored reduction of oxygen in eligible infants at 36 +1 weeks corrected age who are receiving oxygen to establish the definition of bronchopulmonary dysplasia.

PURPOSE To standardize the definition of the Physiologic Definition of BPD as an outcome among the centers of the Neonatal Research Network.

ORGANIZATION

Clinical Centers: University of Alabama, Brown University, University of California at San Diego, Case Western Reserve University, University of Cincinnati, Duke University, Emory University, Indiana University, University of Miami, University of Rochester, Stanford University, University of Texas (Dallas), University of Texas (Houston), Wake Forest University, Wayne State University, Yale University

Subcommittee Chair: Michelle Walsh, MD

Exclusion Criteria:

- Need for mechanical ventilation or continuous positive airway pressure (CPAP)
- Oxygen by hood >30%.
- Oxygen by nasal cannula >30% *EFFECTIVE*** oxygen.

**majority defined as >90% of saturation reading during the 24 hour time period.
**EFFECTIVE oxygen applies to infants receiving oxygen via nasal cannula only.
EFFECTIVE oxygen is determined from tables in Appendix A of the protocol
^Supplemental oxygen requirement is determined at rest. Any temporary increases in O2 requirement (for desaturation episodes, apnea, bradycardia or procedures where infant returns to baseline in a reasonable amount of time [< 2 hours] is disregarded.
Supplemental oxygen given only with feeds is not included.*

DESIGN

Type: Prospective data collection

Inclusion Criteria:

- Infant with birth weight 401-1500 grams who are alive at 36+1 week corrected age
- Supplemental oxygen as follows:
 - Infants receiving oxygen by hood at rest[^]:
 - ❖ Oxygen by hood <27% with majority* of saturations $\geq 90\%$ in prior 24 hours.
 - ❖ Oxygen by hood 27-30% with majority* of saturations $\geq 96\%$ in prior 24 hours
 - Infants receiving oxygen by nasal cannula at rest[^]:
 - ❖ Oxygen by nasal cannula <27% *EFFECTIVE*** oxygen and majority* of saturations >90 in prior 24 hours.
 - ❖ Oxygen by nasal cannula 27-30% *EFFECTIVE*** oxygen and majority* saturations >96% on prior 24 hours.
 - Infants receiving room air by nasal cannula at ANY liter per minute (lpm) flow.

SCHEDULED EVALUATIONS

- Eligibility Screening
- Baseline Evaluations: Each infant will undergo baseline assessment and assessment during the 1 hour after the physiologic evaluation. Documentation of the frequency of apnea, bradycardia and desaturation.
- Clinical outcomes data at 36 +1 weeks corrected age to establish the definition of bronchopulmonary dysplasia

ENROLLMENT

- Began 03/2005 (On going)

TIMETABLE

Began:
Closure:

- March 2005
- Pending

CONCLUSION

DATA CENTER

- Pending
- RTI International