Update from the American Academy of Pediatrics Committee on Fetus and Newborn (COFN)

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The speaker has signed a disclosure form and indicated she has no significant financial interest or relationship with the companies or the manufacturer(s) of any commercial product and/or service that will be discussed as part of this presentation.

Session Summary

The current NANN liaison to the American Academy of Pediatrics Committee on Fetus and Newborn (COFN) will provide an overview of COFN functions and recent clinical practice policies and recommendations.

Session Objectives

Upon completion of this presentation, the participant will be able to:

- describe the purpose and function of the AAP Committee on Fetus and Newborn (COFN);
- list recent policy statements and clinical reports published by AAP COFN.

References


Session Outline

See presentation handout on the following pages.
Updates from the American Academy of Pediatrics  
Committee on Fetus and Newborn (COFN)

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What/Who is COFN?
Committee out of Section of Perinatal Pediatrics
Chair – Kristi Watterberg (4 year total term)
Members – 7 neonatologists (6 year total term – 2x3 y)
Susan Aucott  
James Cummings  
Eric Eichenwald  
Brenda Poindexter  
Dan Stewart  
Jay Goldsmith  
Karen Puopolo

Members designated by Sections
William Benitz (SoPPe)  
Kasper Wang (Surgery)

Liaisons
• American College of Obstetricians and Gynecologists, Committee on Obstetric Practice (committee chair)
• Canadian Paediatric Society (committee chair)
• Centers for Disease Control (CDC) – Wanda Barfield MD
• National Association of Neonatal Nurses – Erin Keels APRN
• NICHD: Tonse Raju MD

Role of a Liaison
• Actively participate in the review, development and revisions of statements
• Work to ensure congruence between organizations’ statements, policies, etc
• Collaborate on topics of shared interest
• Organizational updates

Purpose of COFN
• Established in 1937
• Review issues and current advances in fetal and neonatal care
• Make recommendations regarding neonatal practice
  • Published in Pediatrics
• Collaborate with the American College of Obstetricians and Gynecologists (ACOG) to consider perinatal issues on which the practices of obstetrics and pediatrics merge
• Work cooperatively with ACOG on new editions of Guidelines for Perinatal Care.

Types of Statements
• AAP Policy statement: “Organizational principles to guide and define the child health care system and/or improve the health of all” (850-1200 words); Includes recommendations
• Clinical report: offers guidance for the clinician regarding best practices, state of the art: “does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.”
• Technical report: gives background information for a Policy Statement or can stand alone; Does not include recommendations
Statements

• All statements are reviewed every 3 years
• Statements expire after 5 years unless:
  – Reaffirmed
  – Revised
  – Retired before that time

Life Course of a Statement

1. COFN chooses topic, lead author identified
2. Literature review, objectives defined
3. Intent submitted
4. AAP Board of Directors (BOD) reviews intent
5. BOD approves (or not)
6. If approved, lead author/s write, input from COFN and others, revisions made
7. Final draft sent to internal and external review, revisions made
8. Final document sent to AAP Executive Board for approval (or not)
9. Approved document printed in Pediatrics

2 year process

Statements Under Review/Development

• Prevention and Management of Pain:
  – assessment, sucrose, SSC, BM
• The APGAR score
  – consistency with NRP
• Antenatal Counseling Regarding Resuscitation at an Extremely Low Gestational Age
  – “how tos”
• Hospital Stay for Healthy Newborns:
  – 48 hours, provider neutral language
• Postnatal Glucose Homeostasis in Late Preterm and Term Infants:
  – with Section of Endocrinology

Statements Under Review/Development

• Safe Transportation of the Term and Low Birth Weight Infants
  – with Section on Transportation
• Vitamin K
  – commentary
• Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia
  – no changes
• Age Terminology
  – no changes
• Standard Terminology for Fetal, Infant and Perinatal Deaths
  – under review

Collaboration with ACOG

• Maternal Levels of Care
• Perinatal Guidelines

Intents/Statements Under Development

• Emergency Preparedness in the NICU
• Apnea of Prematurity
• Skin to Skin Care
• Newborn Screening for Biliary Atresia
• PDA
• Donor Human Milk
• Reflux
• Non-invasive Respiratory Support
Topics Under Consideration in the Future

- Probiotics
- Oxygen Saturations
- Umbilical Cord Care

AAP Endorsement of NANN Policy Statement

- AAP Executive Board endorsed the NANN/NANNP Policy Statement “Advanced Practice Registered Nurse: Role, Preparation and Scope of Practice”
- Endorsement and electronic link from Pediatrics to the NANN website in August edition

Sometimes, a controversy is born…….

- 2013 Home Birth Statement:
  - Intent of statement to support the autonomy of the family, while ensuring same level of care for baby as recommended in Guidelines for Perinatal Care
  - Organizations collecting data to support safety of home births

Published since May 2013

- Surfactant Replacement Therapy for Preterm and Term Neonates with Respiratory Distress (January)
- Use of Inhaled Nitric Oxide in Preterm Infants (January)
- Respiratory Support in Preterm Infants at Birth (January)
- Immersion in Water During Labor and Delivery (April)
- Hypothermia and Neonatal Encephalopathy (June)

Surfactant Replacement Therapy for Preterm and Term Neonates With Respiratory Distress

http://pediatrics.aappublications.org/content/133/1/156.short

- Clinical Report
- Update of 2008 report

Background

- Studies in 1990s established that surfactant administration for RDS was safe and effective.
  - Studies in PTs showed that prophylactic or early administration for RDS decreased mortality, incidence of air leaks, risk of CLD.
- Recent RCTs- no evidence of the benefit of prophylactic admin of surfactant in groups of infants with routine use of NCPAP
Review of Evidence

• Effectiveness: published trials since 2000:
  – 23-43 weeks GA; 500-2000gm
  – surfactant decreased mortality most effectively in GA less than 30 weeks and BW less than 1250
    • effective in mature PTs with RDS
  – reduced incidence of pneumothorax, PNE, combined outcome of death or BPD compared to no surf
  – no impact on BPD, IVH, NEC, acquired infections, ROP, PDA
    • significant overall decrease in mortality may attribute to this

Review of Evidence

• Prophylaxis vs. Rescue:
  – prophylaxis/preventive= intubation, surf admin to neonates at high risk for RDS; typically in DR or 10-30 min after birth
  – rescue/treatment= evidence of established RDS, given within first 12 hours
  – Meta-analysis without routine use of NCPAP showed that prophylaxis decreased mortality and air leaks compared to rescue
  – Meta-analysis (SUPPORT & VON) including routine use of NCPAP showed no sig benefit between prophylaxis or rescue
    • higher incidence of BPD or death in prophylaxis vs stabilized on NCPAP
    • no difference in ROP, PDA, PVL

Review of Evidence

• NCPAP and early or late rescue:
  – 2012 Cochrane Review
    • N= 3050
    • Early, selective surfactant administration (1-2 hrs after birth) decreases risk of mortality, air leak, CLD, and CLD or death

Review of Evidence

• INSURE: intubate, surfactant, extubate to NCPAP
  – RCTs prior to 2008 found INSURE (vs rescue) reduced need for CMV, and need for 02 at 28 days
• VON Delivery Room Management Trial
  – 3 treatment arms:
    • intubation, prophylaxis, continued CMV
    • intubation, prophylaxis, extubate CPAP (INSURE)
    • CPAP without surfactant
    – NO differences among the 3
    – higher risk of death or BPD in intubation/surf/CMV group vs. INSURE

Review of Evidence

• Surfactant selection:
  – animal derived (Survanta, Infasurf, Curosurf) have advantages over 1st generation, protein free (Exosurf):
    • lower mortality rate
    • fewer pneumothoraces
  – synthetic (Lucinactant)
    • seems equivalent to animal derived

Review of Evidence

• Surfactant Administration:
  – strategies for dosing, frequency modeled after research protocols
  – dosing intervals less than 12 hrs not recommended unless surfactant is being inactivated
  – must have expertise in managing quickly changing airway compliance
  – no sig evidence for method (bolus, small aliquot or infusion) of administration or body position
  – newer methods without intubation being investigated :
    • aerosols
    • pharyngeal
    • intratracheal admin

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Review of Evidence

- **Severe MAS**: surfactant improves oxygenation and decreases need for ECMO, does not reduce mortality or air leaks
- **Pneumonia**: small N; surfactant improves oxygenation and decreases need for ECMO
- **Pulmonary Hemorrhage**: small retrospective and observational reports; can’t make clear recommendation
- **CDH**: large series; surfactant increased need for ECMO, CLD and mortality

Review of Evidence

- Antenatal Steroids (AS) and Surfactant Replacement:
  - AS sig decrease mortality, RDS, need for surfactant in babies 28-34 GA
  - AS does not reduce incidence of RDS for 27 GA and less
  - AS decreases death or neurodevelopmental impairment at 18-22 months for 23-25 GA
  - AS + surfactant= significant decrease in mortality, severe resp distress, air leaks in 32 GA and less

Conclusion

- PTs <30 GA with RDS who need ventilation should be given surfactant after initial stabilization
- Early CPAP use with selective use of surfactant should be considered (vs prophylactic intubation and surfactant admin)
  - probably best to administer before 2 hours of life
- Rescue surfactant should be considered for hypoxic resp failure r/t secondary surfactant deficiency
- Clinicians must be knowledgeable and competent to administer and provide care to babies receiving surfactant therapy

Background

- Evidence established effectiveness of surfactant administration for treatment of RDS at or shortly after birth
- Recent studies published since 2004 demonstrate effectiveness of alternative therapies

Respiratory Support in Preterm Infants at Birth

http://pediatrics.aappublications.org/content/133/1/171.short

- Policy Statement

Review of Evidence

- COIN (CPAP or Intubation) trial:
  - compared effectiveness of 8 cm NCPAP vs. intubation and CMV in PTs with spont breaths at 5 min of age
  - In NCPAP group:
    - lower rate of BPD
    - less steroid use
    - shorter during of ventilation
    - higher rate of pneumothorax
    - 46% needed ventilator
    - 50% received surfactant (75% of controls received surf)
Review of Evidence

• SUPPORT (Surfactant Positive Pressure and Pulse Oximetry Randomized Trial):
  – N=1310; 24-27 GA
  – compared NCPAP with selective surf and limited vent immediately after birth vs. intubation and prophylaxis within 60 min
  – NCPAP group = 48% rate of death or BPD for all
    • 20% for 24-25 GA
    • 2/3 of all received surf
  – Prophylaxis group = 51% rate of death or BPD for all
    • 29% for 24-25 GA

• SUPPORT cont:
  – less ventilator days in NCPAP group (25d vs 28d)
  – less steroid use (7% vs 13%)
  – no difference in air leaks
  – At 18-22 month follow up- less death or neurodevelopmental impairment (28% vs 30%) and less respiratory morbidity

Review of Evidence

• VON Delivery Room Management Trial
  – 26-29 GA
  – 3 treatment arms:
    • intubation, prophylaxis, continued CMV
    • intubation, prophylaxis, extubate CPAP (INSURE)
    • CPAP without surfactant
  – NO differences among the 3
  – higher risk of death or BPD in intubation/surf/CMV group vs. INSURE

Use of Inhaled Nitric Oxide in Preterm Infants

http://pediatrics.aappublications.org/content/133/1/164.short

• Clinical Report

Conclusion

• For spontaneously breathing PTs- CPAP in DR with selective use of surfactant
• For apneic PTs- intubation, ventilation and administration of surfactant with rapid weaning and extubation to CPAP

Background

• Evidence established for use of iNO for HRF in term infants
• Use of iNO for PT infants less than 34 weeks increased from 0.3% to 1.8% between 2000-2008
• 2010 NIH consensus panel reviewed data, available evidence does not support its use
• Meta-analysis of 14 RCTs (N= 3430) showed the same
• 1 small trial (N=40) showed improved survival
Review of Evidence

- **Impact on Death, BPD- Conflicting Results:**
  - **Kinsella study**
    No significant difference in primary outcome of death or BPD; But decreased Gr 3 and 4 IVH, PVL and ventriculomegaly
  - **NRN study**
    - iNO reduced rates of death, BPD in infants with BW greater than 1000gm
    - Increased mortality and severe IVH in infants with BW less than 1000gm

- **Impact on Pulmonary Outcomes:**
  - 2009 iNO vs Ventilatory Support Without iNO Study:
    - no difference in FRC, wheezing, readmission, use of resp medications between groups
  - 2 meta-analyses:
    - no overall significant effect of iNO on mortality, BPD, IVH, neurodevelopmental impairment
  - NOCLD study group (N= 456)
    - less use of bronchodilators, inhaled & systemic steroids, diuretics, O2 during the 1st year for PTs with iNO
    - no sig differences in frequency of wheezing, hospitalization

Review of Evidence

- **Impact on BPD and Neurodevelopmental Outcomes:**
  - 2 of 3 large RCTs (Kinsella, EUNO trial) found no significant benefit of iNO use for PTs and survival without BPD
  - 2006 Ballard trial found modest beneficial effect of iNO in PTs on survival without BPD (44% vs 37%), but used later (7-14 days of life) and longer duration of treatment
  - Of 6 trials, only one showed favorable neurodevelopmental outcomes over controls at 1 year of age; no difference in CP

Immersion in Water During Labor and Delivery

http://pediatrics.aappublications.org/content/early/2014/03/18/peds.2013.3794.abstract

- Clinical Report
- Joint statement with ACOG

Conclusions

- iNO use does not improve survival, or prevent BPD, IVH or other neonatal morbidities in PT infants with respiratory failure
- iNO does not impact incidence of CP, neurodevelopmental and/or cognitive impairment for PTs
- 1 small trial suggests that tx with high dose (20ppm) beginning in 2nd week of life may slightly reduce rate of BPD...must be replicated
- Limited, inconsistent data regarding pulmonary outcomes in early childhood
Background

- True prevalence in the US unknown
- 143 US birthing centers offered water immersion during various times of labor
- 2005 COFN report did not support underwater delivery
- Most studies retrospective, single center, observational or personal testimonials
- No basic science studies in animals or humans
- Lack of uniform definition of “water birth”
- No masking of therapy

Review of Evidence

- 2009 Cochrane Review
  12 RCTs (N=3243)
  - small sample sizes, risk of bias
  - 9 trials 1st stage only
  - 2 trial 1st and 2nd stages
  - 1 trial compared 2nd stage immersion with control

Review of Evidence

- Results inconsistent and most individual trials showed no benefit
- Combined data showed, that immersion during the 1st stage of labor:
  - decreased use of epidural, spinal, paracervical analgesia (478 vs 520)
  - reduction in duration of 1st stage labor by 32 minutes
  - no difference in perineal trauma/tear, need for assisted vaginal delivery, need for C Section
  - no difference in neonatal outcomes

Gaps and Concerns

- actual and potential complications:
  - risk of maternal and neonatal infection
  - neonatal thermoregulation
  - umbilical cord avulsion, rupture
  - water aspiration or drowning (4 cases)
  - asphyxia, seizures
  - health and safety of the healthcare professional
  - 2004 BMJ study: 12 % admitted to NICU after immersion delivery

Conclusions

- No evidence to support improved neonatal outcomes
- Probably ok during first stage with intact membranes
- NOT recommended during 2nd and 3rd stages due to rare but serious events
  - Should only be performed in context of research study
- Concerns about healthcare worker safety during all stages

Hypothermia and Neonatal Encephalopathy

http://pediatrics.aappublications.org/content/133/6/1146?etoc
Clinical Report
Review of Evidence

Evidence:
- 6 large, RCT (N= 1200) between 2005-2011
- head or whole body cooling

Method:
- within 6 hours of birth
- target temp 33.5°C -34.5°C
- intervention period= 72 hrs
- slow rewarming (0.5°C/hr)

Outcome Measure:
- Rate of death or disability at 18-22 months of age

Results:
- All 6 RCTs showed benefit for moderate and severely encephalopathic infants
  • 4 out of 6 RCTs reached statistical significance
- Meta-analysis (N= 1505) showed 25% reduction in death or disability overall; 32% for moderate; 18% for severe
- NNTT: 6 for moderate; 7 for severe

Long Term Follow Up:
- NICHD: no stat. difference between usual care and cooling for death or IQ <70 at 6-7 years

Conclusions

• Cooling can be offered to encephalopathic infants who are:
  - 35 weeks GA or older
  - pH ≤ 7 or BDz≥16 mmol/L from umbilical blood or within 1st hour of life
  - hx of acute perinatal event
  - 10 min APGAR <5
  - assisted ventilation started at birth, cont for 10 min
  - neurologic exam that confirms moderate to severe encephalopathy
  - if head cooling used, EEG or aEEG should be used

Conclusions

• Centers offering cooling must be able to offer comprehensive services
• Cooling programs should be organized and reliable with education and competency training and maintenance
• Outreach education to the community to identify encephalopathic infants in a timely manner and prevention of hypo or hyperthermia
• Use of cooling outside of inclusion criteria should only be part of formal clinical trials in a research setting and with informed consent

What Can You Do?

• Be informed
• Get involved
• Become a member of AAP
• Become a member of NANN/NANNP