

Neonatal Advancements in 2016

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Objectives

- * NRP 7th Edition Preview and Changes
- * VON: What it is and what is being accomplished?
- * Aerosurf

Abbreviations/Definitions

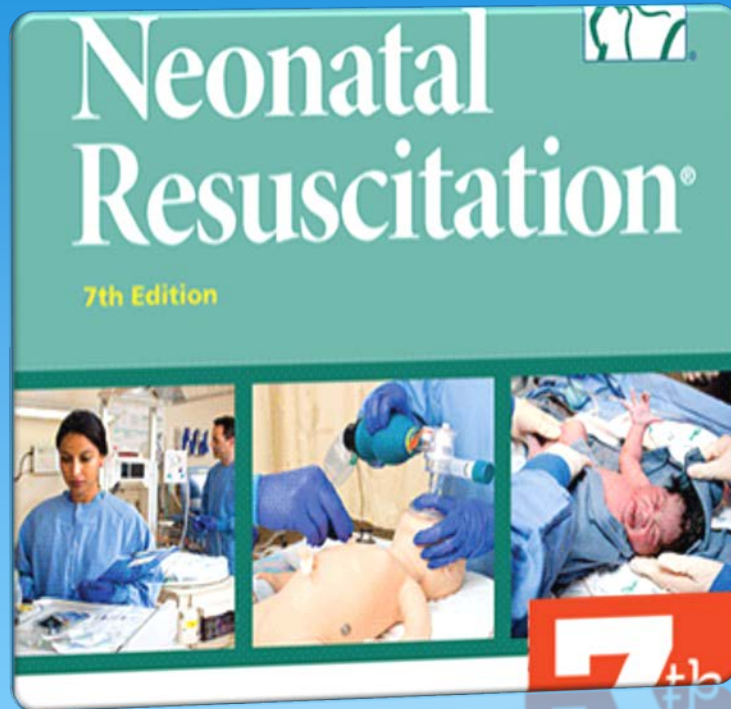
- * AHA – American Heart Association
- * NRP – Neonatal Resuscitation Protocol
- * HR – Heart Rate
- * ETT – Endotracheal Tube
- * LMA – Laryngeal Mask Airway
- * BPD – Bronchopulmonary Dysplasia
- * RDS – Respiratory Distress Syndrome
- * BW – Birth Weight
- * IVH - Intraventricular Hemorrhage
- * PVL - Periventricular Leukomalacia
- * IUGR – Intrauterine Growth Restriction
- * IV - Intravenous Therapy
- * nCPAP- Nasal Continuous Positive Airway Pressure
- * AE- Adverse Event
- * ADE – Adverse Drug Event
- * SpO₂ – Oxygen Saturation
- * FiO₂- Fractional Inspired Oxygen Concentration

Creation of NRP 7th Edition

- * Every five years the ILCOR (International Liaison Committee On Resuscitation) organizes an in-depth international review, debates the science, and determines new international resuscitation treatment recommendations for newborns, children, and adults.
- * Key resuscitation issues are defined and volunteer experts from around the world review and evaluate peer-reviewed literature and then develop a summary of evidence-based knowledge for each topic.
- * The summaries are then reviewed, debated, and their level of evidence is rated and classified then posted online for public comment.
- * Finally, based upon the consensus of the assembled international experts, treatment recommendations are generated.

Adaption of NRP 7th Edition

- * Each council that makes up the ILCOR then uses the CoSTR document to develop resuscitation guidelines applicable to their country.
- * Members of the NRP Steering Committee who participated in the ILCOR neonatal task force develop the guidelines for neonatal resuscitation.



NRP at Mott

The RT checking the Neopuff is Tony Iannetta, RRT.

The editor of NRP 7th Edition is Gary Weiner, MD, FAAP.

Revised NRP Guidelines

Delayed Cord Clamping

- * Current evidence shows cord clamping should be delayed 30-60 seconds for most vigorous term and preterm newborns.
- * If placental circulation is not intact, the cord should be clamped immediately after birth.
 - * There is deficient evidence to recommend an approach to cord clamping for newborns who require resuscitation at birth.

Assessment of Heart Rate

- * Initial assessment of HR will be with the stethoscope.
- * If you can't determine the HR by auscultation and the baby isn't vigorous, you must quickly connect a pulse oximeter and ECG leads to assess HR.
 - * When PPV begins, consider the use of a cardiac monitor for correct assessment of HR.

Revised NRP Guidelines Cont'd

Oxygen Management

- * PPV of newborns \geq 35 weeks' gestation = 21% to begin.
- * PPV of newborns < 35 weeks' gestation = 21-30% oxygen to begin.
- * Free-flow oxygen administration may begin at 30% (adjust the blender to achieve the oxygen saturation target by pulse oximetry).
- * If the newborn is labored or oxygen saturation can't be sustained within target range despite 100% free-flow oxygen, consider CPAP trial.

Chest Compressions

- * Intubation is strongly recommended before beginning chest compressions.
- * If intubation is unsuccessful or not feasible, a LMA may be used.
- * Chest compressions are administered with the two-thumb technique.
- * Once the ETT or LMA is secured, the compressor administers chest compressions from the head of the newborn.
- * Chest compressions continue for 60 seconds before checking a HR.

Positive-Pressure Ventilation

our expertise!

- * If PPV is required, a device that can provide PEEP is favored.
- * When PPV begins, someone listens for an increase in HR for the first 15 seconds.
- * The second assessment of HR is performed after 30 seconds of PPV that moves the chest.
 - * If HR is at least 100 bpm: continue PPV 40-60 breaths/minute until newborn has spontaneous effort.
 - * If HR is 60-99 bpm: reassess ventilation. Perform corrective steps if necessary.
 - * If HR < 60 bpm: reassess ventilation. Perform corrective steps. Insert an alternative airway (ETT or LMA). If no improvement in HR but chest is moving with PPV, administer 100% oxygen and chest compressions.

Revisions Cont'd

Medication

- * The recommended solution for acute treatment of hypovolemia is 0.9% NaCl or type-O Rh-negative blood.
- * All medications and fluids that can be infused into a UVC can be infused into an IO needle in term and preterm newborns.

Thermoregulation

- * The temperature in the resuscitation room should be 74-77°F.
- * For newborns < 32 weeks' gestation:
 - * Cover the baby in food-grade plastic wrap or bag and use a hat and thermal mattress.
 - * Consider CPAP immediately after birth as an alternative to routine intubation and prophylactic surfactant (more on this to come!)

Ethics and End of Life Care

- * If the physicians responsible believe that there is no chance for survival, initiation of resuscitation is not an ethical treatment option and should not be offered.
- * If the fetus has conditions associated with a high risk of mortality or significant burden of morbidity, caregivers should discuss the risks and benefits of life-sustaining treatment and allow the parents to participate in the decision making.
 - * If there is an agreement between parents and caregivers that intensive medical care won't improve the chances for the baby's survival, it is ethical to provide compassionate palliative care.

Vermont Oxford Network

- * Nonprofit voluntary collaboration of health care professionals working together as an interdisciplinary community
- * Their mission: *To improve the quality and safety of medical care for newborn infants and their families through a coordinated program of research, education, and quality improvement projects.*
- * Founded in 1988
- * Level I and II neonatal intensive care units around the world
- * In 1989, 34 NICU teams began submitting data
- * Now; 1,000 centers throughout the world
- * Their database holds information on over 2 million patients totaling **over 63 million patient days!!!**

Newborn Improvement Collaborative for Quality (NICQ)

- * This collaborative brings together interdisciplinary teams for learning through virtual and in-person activities, with the shared mission to continually improve the quality, safety, and value of newborn care.
- * Teams can investigate and apply critical concepts and lessons for quality improvement with specific aims.
- * The VON databases are used to provide comprehensive, confidential member reporting that serve as a critical foundation for local quality improvement projects for participating centers.

Michigan

- * Ann Arbor - St. Joseph Mercy Hospital
- * Ann Arbor - University of Michigan, C.S. Mott Children's, Brandon NICU
- * Dearborn - Beaumont Hospital - Dearborn
- * Detroit - Children's Hospital of Michigan
- * Detroit - DMC Sinai-Grace Hospital
- * Detroit - Henry Ford Hospital
- * Detroit - Hutzel Women's Hospital
- * Detroit - St. John Hospital & Medical Center
- * Flint - Hurley Medical Center
- * Grand Rapids - DeVos Children's, Spectrum Health
- * Grand Rapids - Mercy Health Saint Mary's
- * Jackson - Henry Ford Allegiance Health
- * Kalamazoo - Children's Hospital at Bronson
- * Lansing - Sparrow Hospital
- * Marquette - DLP Marquette General Health System
- * Pontiac - St. Joseph Mercy Oakland
- * Royal Oak - William Beaumont Hospital
- * Saginaw - Covenant Healthcare
- * Southfield - Providence Hospital & Medical Center
- * Traverse City - Munson Medical Center

Ideas for Change Using NICQ

The Research

- * Recent studies show that early CPAP with **selective** use of surfactant is a reasonable alternative to intubation and prophylactic surfactant.
- * If intubated, try to minimize duration on ventilator.

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What to Expect

- * Retractions are not a sole indication for intubation but should be monitored.
 - * Same with tachypnea
- * Apnea is **NORMAL** in premature babies.
 - * Apnea of prematurity alone should not require intubation.

New Approach to RDS Management

Our Old Process

- * Intubate and give surfactant to all babies < 28 weeks
- * No extubation criteria
- * Extubate to any support device
- * Wean CPAP to cannula as tolerated

Overall: Guidelines favored mechanical ventilation

Our New Process

- * Intubate and give surfactant to those that fail CPAP
- * Extubation criteria
- * Extubation to bubble CPAP
- * Remain on CPAP until 30 weeks corrected

Overall: Guidelines favor non-invasive ventilation

RDS Management Progress Report

- * Like we know, some premature newborns will need surfactant and others won't.
- * Since September 1st, 2015 CPAP was trialed initially in 20/23 patients.
 - * 10/20 ultimately were intubated for surfactant in the delivery room.
 - * We are currently on track toward improving survival without morbidity for our babies ≤ 28 weeks gestation from 2014-2015. We have been continuing this work in 2016-2017.

NICQ “Golden Hour”

What is the Golden Hour Protocol?

- * A systematic, standardized, scripted, TEAM BASED approach to care of the infant in the critical first hour of life.
- * All babies < 30 weeks or anticipated BW < 1500 grams.
- * Goal: To improve teamwork and communication with families and staff before, during and after resuscitation.

Special Considerations for the Preemie

- * Poor respiratory drive
- * Surfactant deficiency
- * Poor thermal control
- * Poor energy stores
- * Immature adaptive systems
- * Susceptibility to IVH and PVL
- * Often born after a complication
- * Highly stressed family

The Team, The Team, The Team

-Bo Schembechler

- * Any critical situation, it's easy for the team leader to get lost in the shuffle.
- * Without having a clear leader, tasks didn't flow and time was wasted waiting on others/ equipment/ direction.
- * Intubation was too reflex and time to IV fluids was too long as well.

Solution?

A team-focused, multidisciplinary protocol used at VLBW infant deliveries!



First Hour of Life Flow

Pre-Delivery

- * Teamwork
- * Efficient communication
- * All team members and equipment ready
- * Delivery room timeout
 - * Script used and initiated by team leader

Birth to Five Minutes

- * Smooth and effective neonatal resuscitation
- * Clear delineation of roles
- * Developmental care starts at delivery
 - * Focusing on neuroprotection

We're Almost There



Five to 30 Minutes of Age

- * Further respiratory stabilization
 - * CPAP if spontaneously breathing
 - * Sensible use of PPV
 - * Surfactant if necessary
- * Placement of umbilical lines
 - * Start IV fluids
- * Developmental Care
 - * Calm and quiet
 - * Dim lights (when able)
 - * Containment and positioning
 - * Parental touch

30 to 45 Minutes of Life

- * Clinical information reviewed
 - * Xray, lab values, etc.
- * Family updated on plan
- * Continued monitoring of status
- * Medication administration

Golden Hour Complete

- * One Hour Goal = TOP DOWN
 - * Baby stable
 - * Respiratory support established
 - * IV fluid running
 - * Family updated
 - * Neuroprotective care continued

NICQ Golden Hour Updates

- * Historically, families have always been updated on the plan after birth.
 - * Now they are being introduced to the care team before delivery!
- * Admission temperatures have risen from 40% normothermia to 78%!
 - * Hypothermia is associated with mortality.
- * 3 hypoglycemic babies, with one coming in under 60 minutes time to fluid.
 - * Still room to improve to below the golden hour.
- * Average time to top down as dropped from 92 minutes to **66 minutes!**
 - * Time to top down is a marker of an effective and efficient resuscitation.
 - * A closed isolette promotes quiet, rest, and humidity.

VON and NICQ

Through the amazing efforts by our multidisciplinary team in the NICU and under VON's guidance, we have started making improvements in the tiniest of patients. We are staying dedicated in our efforts to improve into the next fiscal year!

What is Aerosurf?

- * Created by Discovery Labs
- * Aerosolized version of lucinactant
- * Synthetic mixture of phospholipids
- * Able to survive the aerosolization process
- * Capability to administer surfactant as an aerosol while providing nCPAP; avoid intubation and mechanical ventilation

Common Problems with Aerosolization

- * Surfactant must be broken down into small enough particle size
- * Delivery has to avoid as much airway deposition as possible
- * Particles have to penetrate and disperse deep into the lungs
- * Particles must re-aggregate and regain their bioactivity

Phase 2b

A multinational, multicenter, masked, randomized, controlled study to assess the safety and efficacy of lucinactant for inhalation in preterm neonates 26 to 32 weeks gestational age with RDS

Phase 2b Aim and Endpoints

Objective

- * Evaluate safety and efficacy of lucinactant for inhalation in preterm neonates 26-32 weeks receiving nCPAP for RDS

Primary Endpoint

- * Time to respiratory failure or death due to RDS within 72 hours of life

Safety During the Study

Secondary Endpoints

- * Incidence of respiratory failure or death due to RDS
- * Incidence of BPD and survival without BPD at 36 weeks
- * All-cause mortality
- * Common complications of prematurity (especially air leak)
- * Change in FiO₂ and PCO₂

Safety Endpoints

- * Survival
- * AEs, ADEs, peri-dosing events, air leak
- * Use of respiratory support and supplemental oxygen
 - * Need for intubation
 - * nCPAP and FiO₂
- * Complications of prematurity
- * Physical exam
- * Tolerability
- * Vital signs, SpO₂, electrolytes, weight, defecation, chest Xray

Study Design

- * Preterm neonates 26-32 weeks \leq 21 hours of age
- * Controlled nCPAP within 90 minutes of birth
- * Within 20 hours of birth, respiratory support with:
 - * nCPAP 5-6 cm H₂O
 - * FiO₂ 0.25-0.45 to maintain SpO₂ 90-95%
 - * Stable settings for at least 30 minutes
- * Randomized
 - * nCPAP + Lucinactant for inhalation
 - * nCPAP alone (standard care)

Criteria

Inclusion Criteria

- * Signed consent
- * Gestational age 26-32 weeks
- * Spontaneous breathing
- * Chest Xray consistent with RDS

Exclusion Criteria

- * Recurring apnea
- * Hemodynamically unstable
- * Major congenital/chromosomal anomalies
- * Intubation
- * Administration of surfactant or post-natal steroids

Early Discontinuation

Device failure, malfunction or error with or without AE or ADE can cause the treatment to end early. If the PI decides to end the treatment, they may or if the patient has increased respiratory rate or respiratory effort.

Respiratory's Role

During Dosing

- * Adjust CPAP/FiO₂ as clinically indicated
- * Use other support (ie intubation) as clinically indicated
- * Stop treatment if patient significantly worsens during dosing

Following Dosing

- * CPAP tubing must be changed
- * Keep patient on CPAP for at least six hours
- * Re-dosing can only be done with patient on CPAP
- * Re-dosing not permitted after 36 hours of life

RDS in Infants and Beyond!

Lucinactant has been initially developed to treat RDS in premature infants. After it becomes FDA approved, the hope is it will be able to potentially address a range of indications in neonatal, pediatric, and adult critical care patient populations.

Acknowledgments

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Websites

- * <http://www2.aap.org/nrp/7thedinfo.html>
- * <http://discoverylabs.com>
- * <https://public.vtoxford.org/about-us/>



Questions?

Thank You!!