Delivery Room Management

<u>Quality Improvement Toolkit</u>

California Perinatal Quality Care Collaborative

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Best Practices Related to All Deliveries

1. **Organize Delivery Room Care of all deliveries as you would NICU care: (Primary Author: Neil Finer, MD)**

   This toolkit is designed to provide guidelines for the resuscitation of all infants following delivery using the best information available to date. We believe that the smallest and most immature of infants have unique requirements to ensure an effective transition from fetal to extra-uterine life. These infants have immature organ systems, and without appropriate preparation and intervention can develop severe degrees of hypothermia, and respiratory failure that can significantly increase mortality and morbidity. At the other end of the spectrum, many full-term infants will experience difficulties following delivery, and the basic principles of resuscitation can be applied in a similar fashion for all newborns infants for all gestational ages.

   Previous resuscitation guidelines (American Heart Association 2005), while having sections discussing specific issues of prematurity, have not been designed for the most immature of infants. For these infants resuscitation interventions are required more frequently with an almost 100 fold increase in the need for compressions or epinephrine when compared with the term infant (Finer, 1999a, Finer 1999b, Wyckoff 2005). The new guidelines, as reflected in the 6th Edition of NRP and discussed by Kattwinkel et al and Perlman et al reflecting the 2010 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations, have expanded sections on the resuscitation requirements and interventions for the preterm infant.[i] [ii]These areas include the recommended use of oximeters and a targeted oxygen strategy to gradually increase the SpO2 for intrauterine values to acceptable neonatal values over at least the first 10 minutes of life using the most appropriate FiO2; this requires the use of air and an oxygen blender.

   While there remains a dearth of prospective research on actual resuscitation interventions for VLBW infants there is some evidence regarding the optimal resuscitation environment and a number of effective practices that can assist in stabilizing VLBW infants.
   A guiding principle of this toolkit is that whenever possible/feasible, the delivery room/resuscitation room environment should mimic as closely as possible that of the Neonatal Intensive Care Unit, and that every effort should be made to establish homeostasis as soon as possible after birth for all newborn infants.

2. **Utilize a standardized, scripted multidisciplinary approach to guide the initial management of all newborn infants. (Primary Author: William Rhine, M.D.)**

   The resuscitation and initial stabilization of newborn infants is a transition that consists of several discrete processes and requires the coordination of both personnel and equipment. The methods of quality and process improvement can be used to measure and optimize these processes. We recommend that a standardized, scripted, multidisciplinary approach be utilized to enhance the coordination and guidance of the effort.

   Rationale

   The resuscitation of all newborn infants requires that a skilled and capable team be present and prepared to offer the most appropriate resuscitation, support and evaluation. However, depending on the urgency of the clinical situation and the relative instability of the newborn, the situation can become anxiety provoking, highly intensive, and even chaotic. Given the multiplicity of the tasks involved, the confined space and limited equipment immediately available, and the variability of the team composition, there are numerous opportunities for miscommunication and even errors in performance and decision-making. The presence of two or more caregivers requires deliberate coordination and optimal communication. In reviewing the processes, personnel and equipment involved in the resuscitation and admission process, we will also present markers of process quality as well as relevant questions that institutions may want to address on a site-specific basis. Finally we will also describe how scripting and rehearsal of resuscitations can lead to improved uniformity of practices and improvement of process measures.

   The resuscitation of all newborn infants is a well-defined analyzable series of processes that routinely occurs in a specific location, usually conducted by a well-defined team of individuals using appropriate equipment. Process analyses and improvement techniques can be utilized to improve team function in this critical situation.

Preparatory and Initial Management Tasks

Pre-admission activities can be viewed as a series of multiple processes or tasks that may happen simultaneously or in a sequence. Many of these tasks are common to resuscitations performed for newborns at any gestational age, though VLBW infants will need special attention to their respiratory and thermal stabilization. Other high-risk conditions, e.g. abdominal wall defects, may necessitate preparation for and application of other interventions and processes. Therefore, those responsible for resuscitation may want to include education around, and evaluation of, these critical tasks. It is important to appreciate that some of these processes ideally will occur before the resuscitation team arrives in the delivery room. There is a need for discussion with parents on possible limitations to be placed on resuscitative efforts for ELBW infants before or near the edge of viability. While the basics of resuscitation are well covered in the 2011 Textbook of Neonatal Resuscitation Program the transition from birth to the NICU for VLBWs is more complex and completed only after admission to the NICU.

The following are pre-delivery tasks for any high risk delivery:

Pre-Delivery Tasks

- Review maternal records
- Counsel parents on the need to consider maternal or neonatal transport, if applicable, for more specialized care, addressing both benefits and risks.
- Review relevant morbidity and mortality statistics
- Explain delivery room practices
- Introduce NICU care
- Offer NICU tour
- Discuss breastfeeding, plans for breast milk expression, collection and storage.(see CPQCC's Nutritional Support of the VLBW Infant Toolkit, Section 4 and accompanying appendices, which are applicable to any gestational age infant in the NICU).

The following delivery room and admission tasks are for all newborn infants, unless specified as for VLBW infants:

Delivery Room Tasks (see NRP Guidelines for more complete description). Note: Several of these activities should be occurring simultaneously, so that their order in this listing does not imply their sequencing.)

- Pre-warm radiant warmer
- Prepare polyethylene wrap and hat for VLBW infant
- Check resuscitation bag, oxygen flow and blender, manometer & select an appropriately sized mask, set oxygen blender to preferred concentration for expected infant
- Check suction – bulb and wall
- Check availability of resuscitation medications and other equipment
- Receive baby (sterilely, if need be)
- Dry baby; wrap baby if VLBW
- Evaluate breathing
- Assess pulse and prepare to continuously monitor
- Apply temperature probe and hat
- Apply pulse oximeter
- Respiratory support to the degree indicated

- Initiate support as indicated (e.g. none, continuous positive airway pressure, bag/mask, intubation)
- Confirm intubation (auscultation and CO_2 detector)
- Provide ongoing support (controlling peak inspiratory pressure with use of a manometer or a T-piece resuscitator device)
- Assign APGAR scores
- Document
- Prebriefing

Delivery Room Tasks - As Needed

- Cardiac support
  - Compressions
  - Draw up, administer epinephrine (dose varies by route)
- Volume support
  - Obtain emergency vascular access (typically umbilical venous access)
  - Draw up, give volume (caution rate of administration)
- Respiratory support
  - Draw up and administer surfactant, if done in the delivery room setting
- Obtain cord gases (if not already addressed by Labor and Delivery protocols)

Admission Tasks - As Needed

- Transport to NICU/Stabilization area (to/from resuscitation area)
- Weigh
- ECG monitoring
  - Initialize machine, attach leads
- Oxygen saturation monitoring
- Obtain and document initial vital signs
- Establish vascular access
- Place appropriate vascular access device (Umbilical catheter(s), PIV,)
- Provide respiratory support, as indicated
  - Set up ventilator, CPAP, hood or nasal cannula device(s) and oxygen as indicated
- Prepare and administer appropriate medications, e.g. aquamephyton, and erythromycin eye ointment
- Prepare and administer surfactant, if indicated and not already administered in DR
- Assess gestational age and size
- Screen infant per protocol (e.g. blood glucose screening for preterm, SGA, LGA, etc
- Prepare and administer other medications, e.g. antibiotics, as indicated

- Obtain initial radiographic, laboratory, and blood gas studies as indicated
- Document information
- For hospitals planning to transport:
  - Refer for transport as soon as feasible (even before delivery).
  - Care during the First Hour in the non-NICU setting (prior to transport)
  - Contact receiving center as soon as need for transport is identified (prior to delivery or immediately following)
    - Provide significant data and condition report
    - Obtain care recommendations
    - Carry out recommendations, evaluate response and communicate with receiving center
- Obtain consent for transport and provide family with anticipatory guidance
  - Prepare needed documentation for transport
    - Copy of maternal and neonatal chart
    - Blood sample (maternal and neonatal)
    - Duplicate radiology films, laboratory results
  - Complete referring hospital section of Neonatal Transport Form
  - The STABLE Program
    - May be helpful in providing additional assistance with stabilization. (http://www.aap.org/bst/showdetl.cfm?&DID=15&Product_ID=4162)

Implementation Strategies:
The following critical tasks need to be successfully addressed when implementing the standardized, scripted approach:

- Obtain consensus on the policies/procedures that will be utilized for high-risk deliveries
- Develop policy/procedure for special deliveries and determine how it will be communicated that special actions will be needed for a particular delivery
- Ensure that there are systems in place that enable all providers to know the roles for which they have responsibility
- Ensure that there is an evaluation process and that there is feedback about how the actions taken during a specific delivery actually work
- Ensure that there are process or outcome measures to assess, monitor and trend task performance
- Determine how your standardized approach can be adopted and applied in non-standard delivery locations (e.g. in the Emergency Department, in an elevator during transport, etc.).

Personnel/Team Composition

Optimizing the delivery and admission process is a team effort.

Accordingly, consideration should be given to understanding the need to identify the key players involved, and their anticipated roles, in each step of the process. Furthermore, an appreciation of the number of individuals involved is needed to optimize the patterns of communication that constitute effective teamwork.

Specific issues regarding personnel, team composition and role assignment include**:**

Pre-Delivery Counseling

- Ensure that antenatal counseling team is available as necessary
  - Team members may include neonatologists, neonatal nurse practitioners, NICU RNs, social workers as available and others appropriate to the situation
- Ensure that obstetrical colleagues can easily identify and contact the counseling team
- Ensure that team members provide all relevant data about morbidity and mortality, as well as the NICU experience
  - Data (local and national) about morbidity and mortality of VLBW infants; some centers provide handouts for parents, e.g. describing limitations of care at extreme viability (See Appendix A for examples – **coming soon**)
  - Information for parents about NICU care – consents, handouts, video
- Ensures family/medical decisions regarding type and extent of resuscitation are available to the resuscitation team

Team Composition - Delivery Room

- Composition varies widely depending on clinical resources as well as individual patient needs. Team composition should be standardized based on the unique circumstances within each facility.
- Team members must have appropriate training and experience in resuscitation practices & communication.
- At least two health care providers must be available and committed solely for the evaluation and care of the newborn.
- Most teams have a lead (MD, NNP or advanced practice RN), as well as an additional RN or RCP.
- Many hospitals add a RCP or RN as the third member for the highest risk, ELBW infants.
- Team members should be known and immediately available to the delivery room, whether by phone, beeper, or overhead page.

- Labor and delivery room staff should have policies/procedures addressing the need to contact neonatal resuscitation team in a timely fashion and to provide resuscitation until the team arrives.
- Contingency plans should be created and clarified for multiple deliveries, be they multiple gestation or simultaneous deliveries by multiple mothers.

Team Composition - Admission to NICU

- NICUs or Labor/Delivery may have additional staff, beyond those individuals who attend a delivery, available to assist with the admission tasks.
- Some pre-admission tasks, e.g. pre-heating a warmer or obtaining surfactant, preparing intravenous fluids or setting up respiratory support (e.g. NCPAP or a ventilator) for a high risk delivery can be addressed by these additional staff members.

Implementation Strategies:
The following critical implementation strategies need to be addressed when implementing the standardized, scripted approach:

- Identify key players for the tasks necessary leading to a newborn stabilization area.
- Identify specific, identifiable patient populations that require a different team composition.
- Insure that team members are readily available and easy to contact.
- Develop contingency plans for forming additional teams to be called to multiple deliveries.

Equipment and Materials Issues-

Successful resuscitation requires anticipation of all the necessary information, equipment and supplies ("right equipment at the right place at the right time"). The delivery room environment is unique as it is a shared space – between the obstetrical and neonatal care teams. While there may be equipment common to the delivery room and NICU environments, the former is still differentiated by its transitional nature. Equipment and material issues that need to be appreciated include:

Delivery Room

- Temperature support – radiant warmer, warm blankets, chemical blankets, caps, polyethylene wrap, temperature probe with insulating cover, and ambient room temperature
- Respiratory support – masks, bags, endotracheal tubes, intubation equipment, CO_2 detectors, tidal volume measurement devices, suction
- Monitoring equipment – oxygen saturation monitor & probes
- Crash carts – must accommodate the needs of both maternal and neonatal emergencies.

Equipment Issues - Admission to NICU

- Transport equipment from delivery room to Newborn stabilization area need depends on distance, must include battery power, ventilator, heating source, extra warmed blankets
- Scale
- Radiant warmer
- Monitoring equipment – ECG, O_2 saturation, and cardio-respiratory monitors, and hemodynamic pressure monitor & cables
- Respiratory care equipment - ventilator, CPAP, hood, nasal cannulae, blended oxygen
- Vascular access catheter(s), insertion supplies, & infusion pumps - PIV's, umbilical lines.
- Intravascular fluids - dextrose solutions, TPN, lipids, arterial line solutions.

***Implementation Strategies*:**

The following critical implementation strategies need to be successfully addressed when implementing the standardized, scripted approach:

- Identify what equipment should be available for all deliveries.
- Identify additional equipment needs for specific high-risk deliveries.
- Identify where this equipment can be stored yet remain easily accessible.

- Identify who is in charge of getting equipment to the resuscitation setting in a timely fashion.
- Identify who is responsible for periodic checking of equipment and restocking supplies after use.

Quality and Process Improvement Methodologies and Measurements Applicable to Delivery Room Care

Analyzing and understanding the processes, personnel and equipment essential to the resuscitation of all newborn infants is necessary in order to improve the reliability and quality of those resuscitations. The following is a list of quality improvement methodologies that may be particularly applicable to neonatal resuscitation.

Quality Improvement Methodologies that can be Used to Improve Care and the Transition to NICU Admission

- Scripting/Role Modeling (See Appendix B and the following section of the toolkit – **COMING SOON**)
- Process Mapping - fishbone diagrams, value stream mapping (See Appendix C – **COMING SOON**)
- Lean Thinking (reducing wastes of time, materials) (See Appendix D – **COMING SOON**)
- Evaluating Process Parameters – Take items of interest from the Problem Identification Worksheets (PIW's – **COMING SOON**) and track and trend them over time.

Given the multi-factorial nature of long-term outcomes of VLBW infants, it is unlikely that an institution could ever prove that implemented changes in resuscitation directly improved such outcomes. Therefore, we must utilize short-term care process and clinical measurements as indicators of the quality of our resuscitative efforts. This approach is supported by the fact that some of these process measurements, such as admission temperature, have been associated with long-term outcomes of VLBW infants. Other measurements will reflect the preparedness of the team and the consistency of the resuscitative efforts, both of which should be associated with improved clinical outcomes.

Resuscitation Process and Quality Measurements

- Measurements of personnel and equipment readiness; evaluations of resuscitations (Take items of interest from the Problem Identification Worksheets (PIW's) and track and trend them over time.)
- Time to surfactant administration
- Admission temperature
- Initial ABG - pO2, pCO2 values in acceptable range
- Time to completion of an established stage of stabilization (i.e., respiratory support (NCPAP/ETT, etc) in place, oximeter functioning, lines in place, blood glucose determined using a point of care testing, weight, vital signs (including BP),

temperature, time of temperature, laboratory specimens sent). If one defines a set of agreed upon initial stabilization steps, looking at the timing of reaching this stage of NICU admission may be a very helpful metric for improving care. While such a standard is not reported in CPQCC databases, a single center could conceivable track this over time as a quality metric.

Putting it all together: Planning and scripting care

Given the analysis described above, the question arises as to how to plan and practice for the provision of the highest quality resuscitation of newborn infants as well as for their admission to the NICU. Uniformity of practice is more likely to lead to the following care improvements:

Improved consistency in performing resuscitation tasks.

- eases teaching of practices to new participants
- facilitates identification of outlying practices and process-associated outcomes
- increases ease in evaluating and comparing alternative practices with one another

Evidence of improvement associated with consistency in practice is found in data from non-medical fields, including high-risk activities such as commercial aviation, nuclear energy and the military (Leape 1994). The benefit of such a planned, scripted approach in health care can be found in reports on managing cardio-vascular surgeries (Edmondson 2001) emergencies and trauma (Rosenstein 1997, Cornwell 2003). For neonatal resuscitations, the benefits are as follows:

Planning/Scripting:

- Defines separate roles with common goals
- Clearly outlines tasks of each team member (may be defined each shift, may use identifying flash cards, may want to include recorder)
- Facilitates awareness and communication between team members
- Establishes a timeline
- Allows for rehearsal

Cooperation & Communication:

- Involve multiple team members in establishing goals
- Enables viewing of protocols by all team members
- Facilitates review and revision of the script by the multi-disciplinary team in order to establish and amend the time line and role assignments
- Encourages team learning of resuscitation strategy, incorporating “super-users”
- Enhances communication
- Allows for continuous, safe real time feedback

- Educates staff as to the rationale behind interventions

Facilitating uniformity:

- Allows widespread visibility of the script
- Encourages use of the plan of care present at the bedside
- Supports use of orders including ventilator orders
- Other times of standardization could include identify complex delivery types and hospital guidelines: Hydrops, Abdominal wall or spine defect, etc
- Examples of applying the standardized, scripted multidisciplinary approach to VLBW resuscitations can be found in the attached appendices of “Golden Hour” scripts from Lucile Packard Children’s Hospital (Palo Alto, CA, See Appendix E – **COMING SOON**) Kaiser Foundation Hospital-Walnut Creek (Walnut Creek, CA – See Appendix F – **COMING SOON**) and Doctor’s Hospital (Modesto, CA – See Appendix G – **COMING SOON**).

3. Implement an effective process for teaching, developing and assessing individual and team-related delivery room care processes. Consider the complementary approaches of a) simulation-based perinatal team training, b) videotaped assessments of delivery room resuscitations, and c) formal observation of delivery room resuscitations.

3. A. Simulation-Based Perinatal Team Training: Rationale (Primary Author: Louis P Halamek, MD)

Skills to be learned

The delivery room is a highly technical, complex, dynamic environment where emergencies are not uncommon. An emergency in the delivery room is potentially life-threatening to both mother and baby, and the physicians and nurses in attendance assume mutual responsibility for the health of both of these patients. Optimal maternal and neonatal outcomes require in-depth understanding of maternal, fetal and neonatal physiology; proficiency in the technical skills of fetal delivery and adult and neonatal resuscitation; and management of all resources (technologic, pharmacologic, and human) in a coordinated team response. The management of collective resources by teams of individual professionals with diverse abilities is a critical element in the successful resolution of medical crises yet is rarely specifically addressed during medical training (Howard 1992). Thus those in attendance in the delivery room must possess cognitive (content knowledge), technical (hands-on procedures) and behavioral (teamwork) skills that enable them to safely deliver care to the more than four million neonates born annually in the U.S.

Adult learning theory

In 1956, Bloom developed the Taxonomy of Educational Objectives that has remained the foundation of critical thinking theory for nearly fifty years (Bloom 1956). His taxonomy of the cognitive domain suggests that learning evolves from the lowest levels of critical thinking, defined as knowledge, comprehension and application, to higher levels of cognitive complexity, defined as analysis, synthesis and evaluation. While the acquisition, recall and application of content knowledge provide an essential foundation for effective medical education and training, it is nevertheless insufficient preparation for the complexity of modern healthcare.

Adult cognitive processing has the potential to reach far beyond the simple absorption, processing and regurgitation of factual knowledge (Merriam 2001a). Transformational learning theory, the idea that "significant learning experiences change the learner in fundamental ways", emphasizes the importance of critical reflection in the learning process (Merriam 2001b, Sokol 2003). It is through critical reflection on learning and life experiences that learners are empowered to take action in solving real life problems. Another model, constructivist learning theory, suggests that learners construct their knowledge based on previous life experiences (Kaufman 2003). In this model, instructors should function as guides who facilitate the learning process, providing opportunities for students to develop knowledge based on their individual life and professional experiences by actively solving relevant problems in collaboration with others. Effective medical educators have a responsibility to acknowledge these fundamental characteristics of adult learners and use instructional strategies that resonate with their learners.

<u>The methodology</u>

In contrast to traditional medical training methodologies, simulation-based training seeks to acknowledge these characteristics of adult learners. Simulation-based medical training replicates real life clinical situations using realistic human patient simulators, authentic working medical equipment, interactive human colleagues and a team of experienced instructors. Simulation-based training immerses learners in realistic scenarios in which they must respond to the authentic visual, auditory and tactile cues provided in the simulated environment by identifying and applying appropriate interventions while coordinating their actions with a team of real human colleagues. By providing multiple realistic visual, auditory and tactile cues, simulation-based training facilitates this deep learning and lasting memory (Douglas 2000, Hill 2000, Hill 2001). At the conclusion of each scenario, constructive debriefings of individual and team performance are held to reinforce important educational objectives and build learners' confidence. During these debriefings, instructors facilitate (rather than monopolize) the discussion.

Because the action in the simulator takes place in real time, learners are unable to simply talk through or practice hypothetical interventions in imagined situations. Rather, they must actually demonstrate the appropriate cognitive, technical and behavioral skills that are necessary for optimizing patient care. Their experiences in the simulator are individualized, directly related to their personal strengths and weaknesses, scaled to fit their level of experience and expertise and immediately applicable and transferable to practice in the real medical domain. As is rarely the case in preclinical training or real practice, learners are provided with the opportunity to thoughtfully critique their performance immediately following the scenario, thereby enabling them to analyze their interventions, synthesize their performance and evaluate areas for future improvement of their skills. The reflective discussion that occurs during debriefings inspires the transformative learning that fundamentally improves the healthcare professionals' practice of medicine.

The rationale

Simulation-based training has been long utilized in a number of industries where the risk to human life is high. Examples of such industries include aerospace (flight simulators), the military (realistic war games), and nuclear engineering (power plant simulators and nuclear submarines). Commercial aviation was one of the first high-risk professions to critically assess its training methodologies. Flying commercial aircraft requires assimilation of a large body of content knowledge, a requisite set of technical skills enabling the crew to interface with and utilize the technology present within the cockpit, and the behavioral skills necessary to achieve optimal communication and teamwork. Because the crash of an airliner is associated with tremendous cost, in both irreplaceable human lives and expensive technology, the aerospace industry has long been interested in preventing such tragedies. Flying large commercial aircraft has been described as "hours and hours of boredom interspersed with moments of terror"; one might assume that these moments of terror are secondary to massive mechanical failures and the crew's inability to compensate for them. However, in two-thirds of these accidents analysis of "black box" recordings of instrument readings and cockpit communications revealed that it was primarily poor teamwork by the crew that prevented the aircraft from landing safely (Billings 1984). The fact that highly skilled professional pilots with thousands of hours of flying experience failed to adequately manage their collective technologic and human resources in times of crisis led the aerospace industry to develop training programs in crew resource management (CRM) (Helmreich 1993). CRM programs teach both the appropriate mechanical intervention to a crisis situation as well as the management of personal and collective resources during these adverse events. CRM programs are carried out in realistic flight simulators capable of mimicking the visual, auditory, tactile and kinesthetic cues encountered during actual flight. Completion of CRM training is mandated annually for all flight crews working for major U.S. airlines.

Medicine, although unique as a profession in many ways, nevertheless shares many features with other high-risk industries. Because of this, medical educators can benefit from the many decades of training experience in commercial aviation and these other industries, learning from their successes and failures and adapting and modifying methodologies to meet the needs of the adult learners in their midst.

The evidence

The team at the Center for Advanced Pediatric Education at Packard Children's Hospital at Stanford has more than a decade of experience in simulation-based medical training in neonatal resuscitation and perinatal team training (http:www.cape.lpch.org) This group and others have generated a growing body of evidence to support the feasibility, utility and efficacy of using simulation-based learning methodologies to enhance the skills of those caring for pregnant women and their newborns. Briefly, the literature reflects that:

- Current methodologies and technologies allow for the simulation of important visual, auditory and tactile cues present in the delivery room in a manner sufficient to achieve "suspension of disbelief" on the part of trainees. (Halamek 2000)

- Human trainees exhibit the same physiologic responses and markers of mental workload/stress in the simulated delivery room as they do in the actual delivery room when resuscitating real human newborns. (Kaegi 1999, Murphy 2004a, Murphy 2004b)
- Simulation-based methodologies are more effective than traditional training methodologies in creating active learning environments and therefore are more in line with the tenets of adult learning. (Murphy 2004c)
- Technical and behavioral skills can be acquired and refined in the medical simulator. (Anderson 2004a, Anderson 2004b)

This body of work is complimented by more than a decade of anecdotal evidence of the perceived value of simulation-based training to trainees at all stages of clinical practice. Indeed, trainees have often spontaneously commented verbally and in writing that the opportunity to participate in debriefings, watching what they do and hearing what they say, facilitated by content and debriefing experts, is THE SINGLE MOST VALUABLE learning experience that they have ever had.

Implementation strategy

Implementing simulation-based training at any institution requires human, financial and technologic resources. An effective implementation strategy is to clearly define the patient safety aspects of the training and work closely with groups such as Quality Improvement and Risk Management Departments to help reduce these risks. We call this process the “Circle of Safety.”

Current recommendations

The concept that difficult and potentially risky tasks should first be practiced in a safe environment is not novel; even ancient civilizations held war games before going into battle against their enemies. This concept also has been implemented in a number of high-risk industries even though in some of these instances high-level evidence proving its efficacy is lacking; rather than waiting for such evidence the leaders in these industries maintain that such practice in a realistic setting is simply common sense and ethically mandated. Although there is no definitive evidence that simulation-based training in delivery room medicine saves human lives, the Joint Commission for the Accreditation of Healthcare Organizations published Sentinel Event Alerts in 2004 and 2010 that made the following recommendations to all healthcare institutions that care for pregnant women and their newborns:

1) Conduct team training in perinatal areas to teach staff to work together and communicate more effectively. For high-risk events, such as shoulder dystocia, emergency Cesarean delivery, maternal hemorrhage and neonatal resuscitation, conduct clinical drills to help staff prepare for when such events actually occur, and conduct debriefings to evaluate team performance and identify areas for improvement. (http://www.jointcommission.org/assets/1/18/SEA_30.PDF)

2) Identify specific triggers for responding to changes in the mother's vital signs and clinical condition and develop and use protocols and drills for responding to changes, such as hemorrhage and pre-eclampsia. Use the drills to train staff in the protocols, to refine local protocols, and to identify and fix systems problems that would prevent optimal care. (http://www.jointcommission.org/assets/1/18/SEA_44.PDF)

Publications by the Neonatal Task Force of the International Liaison Committee on Resuscitation reviewed the science underlying simulation and debriefing and issued the following statements:

1) There is a lack of uniformity in the definition of simulation as a learning methodology, determination of relevant outcomes, and use of appropriate measurement tools. Use of simulation as an adjunct to traditional education methodologies may enhance performance of healthcare professionals in actual clinical settings and simulated resuscitations. Some studies did not show any difference in performance between standard training and simulation training in a clinical setting or using other means of evaluation. No studies were found that revealed simulation-based training produced inferior results compared with traditional methodologies. Simulation should be used as a methodology in resuscitation education. The most effective interventions and evaluation methodologies remain to be defined.

2) Evidence from 1 prospective randomized controlled study and 17 other studies of briefings and debriefings document improvement in the acquisition of content knowledge, technical skills, or behavioral skills required for effective and safe resuscitation. Only a single study revealed no effect of briefing/debriefing on performance, and no studies indicated that the use of briefings and debriefings had any negative effects. It is reasonable to recommend the use of briefings and debriefings during learning activities while caring for simulated patients and during clinical activities.

3) Based on available evidence, it is recommended that the AAP/AHA Neonatal Resuscitation Program adopt simulation, briefing, and debriefing techniques in designing an education program for the acquisition and maintenance of the skills necessary for effective neonatal resuscitation

Based on the work performed by the investigators in the fields of adult learning and medical education as well as the recommendations published by professional, advisory and regulatory bodies, simulation-based team training in high-risk delivery and neonatal resuscitation is one component of "best practice" in the care of pregnant women and newborns.

Goals:

1. Conduct and debrief simulated difficult deliveries in training (classroom) and/or real (hospital) environments.

2. Conduct and debrief simulated neonatal resuscitations in training (classroom) and/or real (hospital) environments.
3. Conduct and debrief simulation-based team (obstetric + neonatal) training in training (classroom) and/or real (hospital) environments.
4. Pre-Brief and debrief real labors/deliveries and neonatal resuscitations.
5. Simulate new delivery room processes/systems before they are implemented.
6. Determine the weaknesses of the processes/systems during simulations.
7. Institute corrective actions to addresses these weaknesses before the processes/systems are used for real patient care.

Measures:
1. Number of pre-briefings conducted/number of deliveries
2. Number of debriefings conducted/number of deliveries
3. Number of simulations conducted
4. Number of simulations conducted/number of real deliveries
5. Number of skilled simulation instructors/number of staff in labor and delivery
6. Number of skilled simulation instructors/number of staff in the neonatal intensive care unit

3.B Videotaped Delivery Room Quality Assessment: (Primary Author: Neil Finer, MD)

The American Academy of Pediatrics and the American Heart Association developed the Neonatal Resuscitation Program as a method of standardizing the implementation of neonatal resuscitation for the care of newborn infants immediately after birth. The program utilizes a series of modules for didactic education and manikin training. Individuals review written material, take an exam, and then participate in mock scenarios. Such methodology allows for participation by large numbers of individuals in a timely and cost efficient manner. It is limited, however, in its ability to provide realistic interactive training. Intra-trainer differences, including training skills, time allotted for specific sections, available equipment, and trainer bias can affect the quality and consistency of training using this format. All of these types of training programs require reinforcement because of poor retention over time especially for skills not used on a regular basis.

One method for dealing with these challenges is to utilize video recordings of actual events that can later be reviewed to evaluate and reinforce specific practices. Video has been used as an educational tool in medicine since 1969 when it was instituted in the emergency room (Peltier 1969). Since that time the most frequent use of video in the medical setting has been in trauma centers (Hoyt 1988, Oakley 2006). The use of video offers advantages both in education and quality improvement.

An organized approach to video review is essential for its effectiveness. To achieve the most educational benefit from reviewing videos, it is best if the videos are reviewed in a group setting which includes all members of the team or at least their respective disciplines. The discussion is ideally maintained in a positive light without punitive implications. Any criticisms should be presented in a constructive context so that individuals may learn from the experience and have the opportunity to improve in the future. Procedural training is improved with video review as trainees are able to visualize their own performance and compare and contrast it with other displayed performances. When procedures are performed well the video allows educators to objectively credit the trainee for performing the procedure and document the trainee’s competency.

As an educational tool, video offers trainees an increased number of resuscitation experiences to witness even if they are not personally present for the event. The review of resuscitation on a regular basis reinforces the practices taught in resuscitation courses. This consistent review and increased exposure to various situations offers providers an opportunity to become more familiar and more comfortable with the practice and therefore more prepared to manage an ill patient in the future. Unlike experience that is gained individually without the opportunity for review as occurs in most aspects of medical education, experience that is captured on videotape can be evaluated by more senior practitioners who can offer suggestions for improvement in the future.

Hospitals considering initiating a video process should be aware that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has issued a standard regarding "recordation or filming" of patients for purposes other than identification, diagnosis or treatment.iii The standard defines recordation or filming to include photographic, video, electronic or audio media. Standard RI.2.50 distinguishes between recording or filming for internal organizational purposes (e.g., performance improvement or education), and for external purposes, as delineated in the Elements of Performance Internal recordings, including those used for performance improvement and quality assurance, may be covered by a statement in the general consent to treat. External recordings, those which will be seen by the public, require a separate consent. Additionally, the Standard requires that anyone who engages in recording or filming, if not already bound by the hospital's confidentiality policy, must sign a confidentiality statement to protect the patient's identity and confidential information. Because of the difficulty in obtaining consent before delivery, we recommend that institutions consider adding language to the Consent for Maternal treatment to include permission for video recording for quality teaching and/or research purposes. Such language may include such statements as follows:

> I authorize the Hospital and my physicians to photograph, videotape or make digital images of me or parts of my body (if I am signing as a parent, next-of-kin, agent or conservator, I am consenting for my child, family member, principal or conservatee) while under the care of the Hospital for use in medical evaluation, quality improvement, patient safety education or research in compliance with Hospital policy. Such photographs, video or digital images may or may not be retained as part of my medical record.

The physical storage of the videotapes should be taken into consideration to ensure their security pending their destruction after the QA review. These may be kept in a locked cabinet/drawer until they are reviewed and they are erased following the review. (See Appendix H for videography implementation considerations **– COMING SOON**).

Implementation Strategies:

- Because Delivery Room video-taping is both multi-disciplinary and so personally revealing (and therefore threatening), we recommend that its initiation should proceed through a multi-disciplinary process that gains positive support from all NICU caregivers.
- Meetings to discuss videotaped events should only be held under the auspices of your center's protected Quality Improvement/Assurance review process, with reports flowing, as appropriate in your institution, to the equivalent of a, what we shall generically describe, as your center's Perinatal Morbidity and Mortality Review Committee. Reports that identify system issues, e.g. equipment preparation problems, communication bottlenecks, training opportunities, are far more likely to be useful than those that focus on individual performance problems. Reports should include notation about suggested changes to address the system issues and the re-evaluation of these changes' efficacy.

- Technical challenges in establishing the infrastructure are few. (Appendix K – **COMING SOON** - contains a list of recommended items, including the description of the physical security provided for the tapes

- One team member needs to be assigned the task of loading the videotape, turning the machine on, and delivering the finished tape to a properly secured.

- The Review committee must establish a process for the timely, periodic destruction of the tapes in accord with the Hospital Policy and Procedure that you implement.

- Patient privacy/consent concerns should be addressed in a manner that conforms with JCAHO Guidelines (see above)

Measures:

- The process of making structured observations of delivery room care events, such as exemplified in the **Problem Identification Worksheets # 2, 4 and 5**, - **COMING SOON** - enables collation and trending of your center's experiences.

- The process of making structured observations that address the social dynamics of the resuscitation effort is exemplified by the **Problem Identification Worksheet #5:** Team Performance Observation Tool and can be used to collate and trend your center's experiences **– COMING SOON**

3 C. Formal Observations of Delivery Room Resuscitations:

This is a variation of 3.B that has been utilized by one CPQCC member center in which there was substantial reluctance to allowing direct videotaping. In this method, an observer (one not involved in rendering care) goes to the delivery room with the responding team. They make direct observations of the delivery room activity and then report their findings (and recommendations if any) to the team in a QI meeting (Richard Bell, MD, *personal communication*). This method overcomes some of the defensiveness that surrounds the videotaping method. The observer should ideally use some sort of structured observational tool, of their own making or one based on the tools illustrated in the Section V: Analyzing Your Practices.

Continuity of Delivery Room Team Training and Evaluation Methodologies:
The Panel believes that it is important for implementers of these techniques to understand that they are complementary, rather than competitive. Well-established programs strive to establish all of these efforts. The complementary nature of these approaches is reflected in the following observations on their comparability and contrasts:

- Simulation facilitates preparation and training for events, whereas real-time observation facilitates critique of actual competencies and the explication of lessons learned and further training needs;

- Simulation produces variable fidelity (dependent on the particular situation to be modeled), while real-time observations are the standard for high fidelity; (for instance, this is most apparent when considering evaluating the efficacy of efforts to initiate ventilation: simulation cannot as yet capture the nuanced responses to ventilatory support efforts in a 500 gm infant!).

- Simulation facilitates team and leadership training, whereas real-time observation facilitates critique of team and leadership dynamics and the explication of lessons learned and further training needs;

- Simulation enables repetitive practice of team activities until a defined performance goal can be reached, whereas real-time observation can not impact the viewed performance.

4. Maintain normal infant temperature: (Primary Author: Tina Leone, MD)

Maintain normal core body temperature (i.e. 36.5-37.5°C) by considering and utilizing a variety of techniques:

- Ensure proper use of the radiant warmer in the DR, by
    - place VLBW baby on exothermic mattress
    - ensuring timely placement of the sensor,
    - selecting "servo" control
    - and setting the appropriate "target" temperature for the servo control (often starting the skin temperature at 37°C).

- Ensure that one person is assigned the task of monitoring the infant's temperature and noting the infant's temperature every 5 minutes while in the delivery-resuscitation area.

- Additional techniques of use for extremely low birth weight (e.g. <1,000 gm or approximately < 28 weeks GA) include:
    - wrapping the infant *without drying* with a polyethylene occlusive dressing or placing the infant in a standard one-gallon food quality polyethylene bag;
    - place a cap on the infant's head;
    - utilize neonatal chemically activated heat packs specifically designed for neonatal use below the pre-warmed blankets on which the infant is placed; and
    - ensure that the delivery or resuscitation room ambient temperature is at least 26^{o}C (77^{o}F).

Rationale
Infants lose heat quickly after delivery when transported from the warm intrauterine environment to the cooler delivery room environment. Preterm infants are at particular risk for becoming hypothermic during this time because of immature thermoregulatory mechanisms. This includes immature skin, decreased brown fat stores, and increased surface area to body weight ratio. The importance of avoiding hypothermia is illustrated by the EPICure study which demonstrated a high incidence of moderate hypothermia (defined as admission temperature <35°C) in infants born at <26 weeks gestation and treated with standard delivery room thermoregulatory measures. Those infants who were admitted with low core body temperatures were at higher risk of mortality (Costeloe 2000). Therefore, other measures of decreasing heat loss from preterm infants shortly after birth have been evaluated.

The World Health Organization recommends resuscitating infants in a warm room (at least 25˚C (77˚F) (World Health Organization 1997). The current 6th Edition of NRP will state a temperature of 26^{o}C (79 F) for the delivery area. The heating and air conditioning standard for U.S. hospital design and operations (reference listed in full as note) addresses temperature goals for LDRPs (75˚F ±2), patient rooms (75˚F ±2), and recovery rooms (75˚F ±2), and nurseries (75˚F ±3), without specifically addressing the stand-alone delivery room. An *Ad Hoc* Committee of members of the American Academy of Pediatricians has petitioned the Academy to extend these goals to the delivery room (specifically: Keep Delivery Room (DR) temperature 75˚F ±3 (72-78) (24 C) and humidity 30 (W), 50 (S). (Rosaler 2003). As part of a small study evaluating polyurethane bags for the prevention of hypothermia in infants <29 weeks, Knobel (Knobel 2005) found that infants who were cared for in delivery rooms >26˚C (79 F) and were wrapped in the polyurethane bags were the only subgroup of infants with an average admission temperature > 36.4˚C.

Use a modern servo-controlled radiant warmer which has been pre-warmed before delivery for the care of very low birth weight infants. Radiant warmers are required to decrease power after 15 minutes of use in manual mode and must be reset to continue providing adequate heat. Use in the servo-control mode can help avoid this problem and can help prevent over-warming the infant. The temperature probe must be placed as part of the routine of resuscitation by an assigned team member and should be placed according to the manufacturers instructions. Lightly drying the skin in the area where the probe will be placed may facilitate adherence to the skin. Remember that the temperature probe is monitoring the baby's skin temperature not the core temperature.

For infants less than 1000 grams or 28 weeks gestation use plastic wrap around the body without drying the infant. This has been shown in at least 3 trials to improve admission temperatures of infants <28 or 29 weeks (Knobel 2005, Vohra 1999 & Vohra 2004). In these trials the infant was wrapped in plastic wrap immediately after birth without first drying the skin. The infants head should be dried despite the use of plastic wrap around the body and a cap should be placed. The use of plastic wrap around the body does not include the head which is of large surface area and if remains wet will lose additional heat by evaporation and convection. The plastic barrier used in these studies was either a sheet of polyethylene wrap (Vohra 1999 and 2004) or a polyurethane bag (Knobel 2005). These authors recommend use of a wraps or bags similar to those tested in the trials and of similar levels of sterility to other neonatal resuscitation devices. (Knobel 2005). The new Neonatal Resuscitation Program textbook recommends use of a reclosable polyethylene bag which can be a "standard 1-gallon, food-quality polyethylene bag purchased in a grocery store." (Kattwinkel 2006).

Consider the use of a chemically activated neonatal mattress warmer as an additional source of external heat. A single study of 24 patients by Brennan in 1996 was reviewed in a Cochrane Review evaluating modes of preventing hypothermia (McCall 2005). This study evaluated patients of less than 1500 gram birth weight and randomized treatment with or without a Transwarmer Infant Transport Mattress™ which when activated heats to 40˚C. Infants treated with the mattress had a lower incidence of hypothermia than those treated without the mattress.

Temperature monitoring should occur every 5 minutes while in the delivery and resuscitation areas, since the average ELBW will spend approximately 23 minutes from the time of birth to actual admission to the NICU (Wang 2006).

Temperature control is maintained during transport from the delivery room area to the neonatal intensive care nursery environment by moving the baby in a warmed transport incubator and using chemical warmers as necessary.

Implementation strategies:

- Assign one team member responsibility for maintaining temperature
- Have equipment prepared prior to infant's delivery
- Turn warmer on full power in *manual mode* while awaiting delivery
- Increase temperature of delivery/resuscitation room
- Gently dry skin where temperature probe will be placed
- Ensure that warmer is *switched to "Servo"* mode after placing probe
- Plan to follow infants' admission temperatures

Barriers:

- Perception that baby will be more difficult to access when wrapped
- Coordination with other tasks of resuscitation
- Conflicts with other occupants of delivery room over ideal temperature

Measures:

Observe resuscitation team performance:

- Is the team able to coordinate function to accomplish all tasks? May require drills to develop comfort with additional tasks.
- Do the resuscitation team members and obstetricians understand the importance of avoiding hypothermia?
- How frequently are your desired actions implemented?

Benchmarking

Two sets of benchmarks exist or will exist soon for benchmarking temperature maintenance in the delivery room: the first can be derived from trials establishing the efficacy of many of the recommended measures; and the second will become available in 2006 as VON centers report their admission temperatures for VLBW infants.

1. Trials-based benchmarking

The table below identifies data from three randomized controlled trials in which plastic wrapping figured prominently in the infants' temperature maintenance protocols. Typically such trials, as well as the meta-analyses, express their effects in terms of the average temperature difference between the conventionally and specially treated cohorts, e.g.. Cramer found " after combining the results of three RCTs in which infants less than 31, 29 and 28 weeks GA respectively were wrapped, that the weighted mean temperature rose 0.63°C However, for quality improvement projects, it is often more useful to identify a target and then track what percentage of infants achieve the target. We have collated the results of these trials in order to develop a specific target: 70% of VLBW admission temperatures will be greater ≥ 36.5°C.

Note: this target is without specific regard to the delivery room temperature. A *post hoc* analysis of the Knobel 2004 trial indicates the significant effect that delivery room temperature can have: Those VLBW infants delivered in rooms with a temperature.>26°C and wrapped had no cool infants while over half of wrapped infants in a cool DR had temps < 36.4°C.

VLBW Infants' Admission Temperature ≤ 36.4°C : Effect of plastic wrapping (without concern for DR temperature):

	Wrapped	**Unwrapped**
Vohra 2004	7/27	18/26
Vohra 1999	7/27	18/26
Knobel 2004	18/41	33/47
Combined- Frequency/ Percentage ≤ 36.4°C	32/105 30.4%	69/99 69.7%

Suggested benchmark: no more than 30% of VLBWs admitted from DR with temps ≤ 36.4°C. (without regard to the DR temperature). One trial (Kobel 2004) indicates that keeping the DR room temp > 26°C (79 °F) was associated with no infants admitted at less than the threshold temperature for the benchmark.

We wish to add one cautionary note: overheating of infants may not be benign. We recommend that the QI effort also track admission temperatures ≥ 37.5°C in an equal effort to avoid overheating infants.

2. Empirical Benchmarking:

Beginning in 2006, VON/CPQCC centers are being asked to report the admission temperatures of their VLBW infants. The item and instructions for its collection are as follows:

Outcome measure: 1st temp on admission to NICU (recorded in first hour).

Instructions:

"If the infant's core temperature was measured and recorded within the first hour after admission to the NICU, enter the infant's temperature in degrees centigrade to the nearest tenth of a degree. Use rectal temperature or, if not available, esophageal temperature, tympanic temperature or axillary temperature, in that order."

By year's end, the interim reports should provide empirical data on how units are maintaining temperatures among their admits and realistic achievable benchmarks can be shared.

PQIP recommends that its members adopt a more disciplined approach to recording and tracking their admission temperatures, so that the collected data are more meaningful to their QI efforts. PQIP recommends that the first temperature be recorded as soon as possible after the infant has been placed on the infant warmer or in an incubator.

National Survey relative to Temperature Maintenance Practices:

Qualitative data from a 2002 national (Leone2006a) and a 2005 California survey (Leone2006b) are available. Doubtlessly, practice equipment and process has evolved further in the interval to now, but, at least these data provide a minimal estimate of capabilities and practice upon which California units might benchmark their own capabilities and practices.

2002 National Survey: Extremely low birth weight infants were wrapped in plastic to prevent heat loss in 29% of programs surveyed. When the plastic wrap is used, it is applied after the infant is dried by 77% of the programs surveyed. (Leone 2006a)

2005 California Survey: Among a total of 59 respondents to a recent survey, extremely low birth weight (<1000 grams) infants or infants <28 weeks gestation are wrapped in plastic to prevent heat loss in 36% of programs. When plastic wrap is used it is applied after the infant is dried by 62% of programs. The delivery room is kept warm at 29% of programs with target temperatures ranging between 70-85°F. (21 C-29 C) A warmed heating device such as a chemical warmer is used by 39% of programs (Leone 2006b).

3. Recommended Performance Target-100%:

The above cited benchmarks describe actual practices and achievements. However, PQIP recommends that the goal of temperature management is ensure that the infant's temperature is maintained in the same range as would be desired in the NICU (36.5°C -37.5°C). Thus, we would encourage units to utilize as many cycles of improvement as needed and feasible to meet their infants' needs.

5. **Monitor the heart rate continuously: (Primary Author: Tina Leone, M.D.)**

Incorporate continuous heart rate monitoring into your DR care process, especially for unstable, or potentially unstable, infants. Potential techniques include: continuous palpation, auscultation or electronic heart rate monitors (with or without simultaneous oxygen saturation monitoring). Note that the current and future version of NRP recommend intermittent monitoring of heart rate by auscultation. Our recommendation remains that one team member continuously monitors and shows the heart rate to all team members till the pulse oximeter is functional or a separate ECG monitor is attached and functioning.

Initial Technique:

As soon as the infant is placed on the resuscitation bed, have one team member assigned to monitor and indicate the actual heart rate.
This can be done by palpation of the umbilical cord or auscultation of the precordium. Use hand signals and/or verbal prompts to indicate the actual heart rate. Immediately notify team if heart rate drops below target levels – 60, or 100 bpm. Continue heart rate monitoring (either manually or by auscultation) until a monitor is functional – i.e. oximeters or dedicated HR monitor.

Rationale:

Pulse Oximetry:

- Use a pulse oximeter whenever a high risk delivery is anticipated. The use of pulse oximeters has been advocated by the American Association for Respiratory Care[iv] for neonatal resuscitation since 1993.

- Cyanosis is sometimes difficult to visualize and may not be apparent until oxygen saturations are less than 70%. (O'Donnell 2005.) For more precise measurement of oxygen saturation it is necessary to use a pulse oximeter.

- A dedicated individual is assigned to place the pulse oximeter. This should be the same individual (i.e., respiratory therapist, nurse, or other depending on your hospital's resuscitation team composition) for all deliveries so that dexterity with placement is achieved and the performance of the task is not in question.

- The saturation probe is attached using a pre-ductal site, the right hand or wrist, to the patient before it is connected to the monitor to promote optimal time to signal display. The monitor is turned on while the team is preparing for the patients arrival. This approach decreases the time required for a useful signal to be displayed.[v]

- The audio is kept on so that the heart rate and saturation tone may be audible to all resuscitators. Therefore the oximeter serves the purpose of both monitoring oxygen saturation and providing a continuous heart rate that is automatically communicated to all resuscitators. Maintaining an audible heart rate facilitates resuscitation as most resuscitation decisions are based on heart rate determination.

- The normal oxygen saturation during the first 5 minutes of life increases slowly from the fetal level of approximately 50% to 60-70% at 2-3 minutes of life and 85-90% at 5 minutes of life (Kamlin 2005; Saugstad 1998) (See section on administration of oxygen for more discussion and associated figure.)
    i. It should be recognized that the saturation probe placed pre-ductally will demonstrate slightly higher values than if placed post-ductally.[vi]

6. Optimize oxygen administration: (Primary Author: Neil Finer, M.D.)

Administer oxygen using techniques comparable to those used in the NICU:

- Provide gas appropriate to the oxygen needs of the infant by utilizing a blender to mix oxygen and compressed air

- Initiate resuscitation with FiO_2 between 21% to 40% for term infants and between 21% to 40% for preterm infants < 32 weeks (Suggestion)

- Adjust the administered gas according to the infant's condition and your unit's targeted oxygen saturation goals. Measuring the infant's oxygen saturation levels avoids the many limitations associated with visual observation of the infant's color:

- Target SpO_2 to increase to 80% - 85% by 7 minutes and then aim for SpO_2 levels as used in your NICU

Rationale: Specific supporting points

Administer oxygen using techniques comparable to those used in the NICU:

- Provide gas appropriate to the oxygen needs of the infant by utilizing a blender to mix oxygen and compressed air – Note that many DR environments do not have such capability.

- Adjust the administered gas according to the infant's condition and your unit's targeted oxygen saturation goals. Measuring the infant's oxygen saturation levels avoids the many limitations associated with visual observation of the infant's color.

- Note that normal infants SpO_2 begins at birth at about 50% to 55% *in utero* prior to a normal delivery. By 5 minutes SpO_2 in infants not requiring resuscitation is around 85% to 90% in term infants and lower in preterm infants. (See Saugstad 2006-Figure #1 and Dawson Figure # 2[vii])

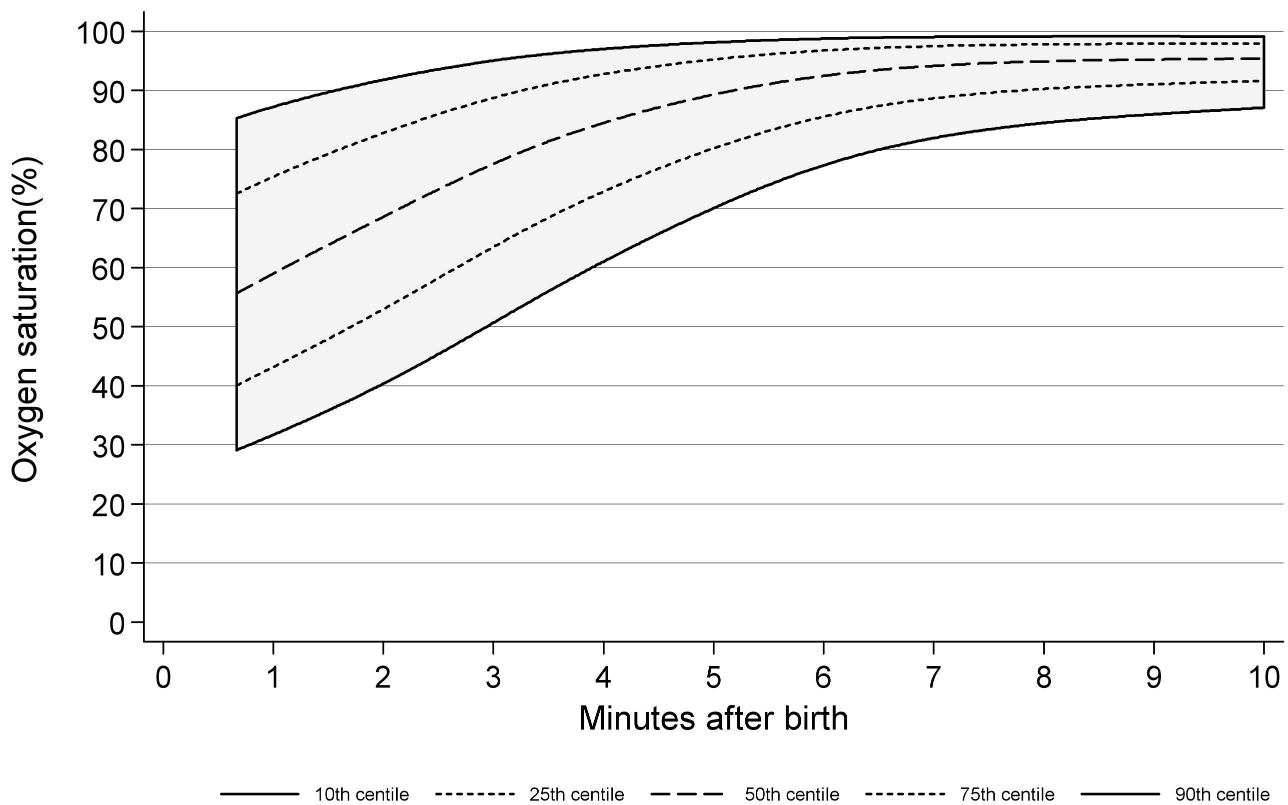
- Meta analyses of completed trials revealed a decrease in mortality overall with the use of room air compared with oxygen, and this reduction was seen for the preterm infants included in these trials (Davis 2004, Ramji 2005, Saugstad 2005a).

    - The use of 100% oxygen in previous trials was not associated with a more rapid rise in SpO_2 in the near term infant (Saugstad 2005b)

    - Use of a pulse oximeter will allow targeting SpO_2 values. Such devices usually are functional after 60-90 seconds and thus a good first target is an SpO_2 = 70% by 3 minutes, and 85% to 90% by 5 minutes**.**

    - Our recent experience with the ELBW infant demonstrates that SpO_2 values > 90% are achieved within 3 minutes of life in many such infants when using 100% oxygen during resuscitation. (See Saugstad 2006 Figure # 1, and Dawson Figure # 2[viii])

Figure 2. Shows the 10^{th}, 25^{th}, 50^{th}, 75^{th}, and 90^{th} SpO_2 centiles from 121 preterm infants (32-36 weeks gestation) with no medical intervention after birth. The shaded area indicates SpO_2 values between the 10^{th} and 90th centile.



Benchmarking:
Qualitative data from a 2002 national and a 2005 California survey are available (Leone 2006a, Leone 2006b). Doubtlessly, practice equipment and process has evolved further in the interval to now, but, at least these data provide a minimal estimate of capabilities and practice upon which California units might benchmark their own capabilities and practices.

Structure Measures:

2002 National Survey: 42% of NICUs responding to a national survey in 2002 (Leone 2006a) indicated that oxygen blenders were available in their delivery rooms.

Among all units responding to the survey, 52% had oximeters available in the delivery room.

Other types of monitors, such as for heart rate or temperature, are present in 61% of delivery rooms.

2005 California Survey: Of the 59 respondents to this survey 54% report having a blender available and 88% report having compressed air available in the delivery room area. Routine use of pulse oximeters was reported by 25% of programs and use during difficult resuscitations was reported by 36% of programs. On the other hand 34% of programs report never using pulse oximeters in the delivery room. Of those programs using oximeters, 33% report that the site of application is specified. The method of application was not standardized at 33% of programs using oximeters. (Leone 2006b)

Process measure:

2002 National Survey: Most (77%) of the units with blenders initiate resuscitation with 100% oxygen. 68% of units with blenders use pulse oximetry to adjust the concentration of the oxygen administered. (Leone 2006)

Among units using oximeters, 23% reported that the oximeters are applied and functioning within the first 1 minute of life. (Leone 2006a).

2006 California Survey: In this survey which was specific to infants of < 1500 grams birth weight, 78% of the 59 respondents report initiating resuscitation with 100% oxygen. Reported targeted saturation ranges at 5 minutes of life among programs utilizing oximeters were most frequently 86-90% (Leone2006b).

7. Optimize initial respiratory support:

Establish and maintain the newborn infant's respiratory efforts and functional residual capacity without injuring the lung from excessive use of positive pressure by:

- evaluating continually the infant's need for any respiratory assistance;
- considering administration of CPAP before intubation;
- when providing "bag and mask" ventilation, using a "T" piece resuscitator or other devices to more precisely control peak inspiratory pressures (PIP) and peak end-expiratory pressure (PEEP); and/or
- using volume targeted ventilation starting from the time of intubation
- Note that 6th Edition of NRP notes that the use of CPAP was associated with an increase in air leaks but this report did not take into account the more recent trials including the SUPPORT Study. Thus study demonstrated that early CPAP and a permissive ventilator strategy compared with surfactant in the first hour was not associated with any increase in air leaks and was associated with a decreased duration of ventilation, a lowered use of post natal steroids and a lower mortality for infants of 24 to 35 weeks gestation.[ix] We have confirmed that there is no increase in air leaks in a meta analysis of all current relevant trials.
- The 6th Edition of NRP states that PEEP should be used if suitable equipment is available

Note: each unit should ensure that it has at least two modes with which to support positive pressure ventilation, e.g. mask CPAP or nasal CPAP could be used prior intubation and ventilation.

Specific supporting points : Establish and maintain the newborn infant's respiratory efforts and functional residual capacity without injuring the lung from excessive use of positive pressure by:

- Evaluating continually the infant's need for any respiratory assistance, if demonstrating adequate effort consider administration of CPAP. Justification: In NICU all infants with respiratory distress receive CPAP/PEEP. This will facilitate establishment and maintenance of FRC.
- Initiate with 5 cm H_2O and increase to a maximum of 8 cm H_2O (no definitive evidence on the optimal starting PEEP in the delivery room is available, however ranges of 5-8 cm appear to be supported using the standard of care set in the NICU)

- If the infant requires assisted ventilation, provide such positive pressure with a device with which you are familiar. T piece resuscitators (e.g. Neopuff®) or anesthetic type bags have a lesser tendency to provide pressures above the targeted pressures, and are able to deliver CPAP/PEEP when compared with self-inflating bags (Bennett 2005, Finer 2001). Note: each unit should ensure that is has at least two modes with which to support positive pressure ventilation.

- The use of volume targeted ventilation may become more available in the future, but for now utilize the lowest pressure compatible with a good response, as seen by improvement in color and heart rate. We believe that a breath large enough to cause visible chest wall movement may be excessive for many infants.

- Note that the infant's response to even low pressure breaths may be very effective in helping to establish FRC, with the infant either exhaling against a positive pressure breath, or inhaling in response to such a breath.

- The most common problems seen during positive pressure ventilation are the lack of an adequate airway seal and the establishment and maintenance of a patent airway, and the distinction between these is often not easy.

- Adequately establishing pressure in the mask (and the manometer) does not mean that the infant will receive a positive pressure breath. If the airway is closed because the tongue is against the posterior pharyngeal wall the mask will pressure up, but no air will pass through the glottic opening.

- We have found that the use of a colorometric CO_2 detector is useful during bag and mask ventilation to ensure a patent airway[xxi]. The use of such devices are now mentioned in the 6th Edition of NRP and they state that it is not clear whether the use of such a device confers additional benefit above clinical observation. Our studies were done using clinical observation and video recording with analogue data collection and we found that airway obstruction is very common during PPV in the very premature infant. Subsequently Schmolzer et al have confirmed the presence of airway obstruction during ventilation during resuscitation in such infants using measure of airway flow.[xii]

- Initially begin with pressures of 20-30 cm H_2O, but if there is no or poor response, one can also try to use a prolonged inflation of 3-5 seconds before increasing the inspiratory pressure (Vyas 1981). If there is no response, consider increasing the pressure to as high as 60-70 cm H_2O. In rare circumstances such pressures are needed, especially in infants with possible pulmonary hypoplasia.

- Avoid passing an NG tube as this will open the esophagus and allow gastric distension. The pressure required to open the esophagus is in excess of 35 to 40 cm H_2O

Benchmarking:
Two types of comparative data are available. First, there are qualitative data from a 2002 national and a 2005 California survey of NICUs (Leone 2006a, Leone2006b). Doubtlessly, practice equipment and process has evolved further in the interval to now, but, at least these data provide a minimal estimate of capabilities and practice upon which California units might benchmark their own capabilities and practices. Second, VON collects and analyzes several delivery room ventilatory practices.

Structure:

2002 National Survey:

PPV Devices: The 2002 National Survey (Leone 2006a) indicates that reporting units provided positive pressure ventilation with flow-inflating bags (51%), self-inflating bags (40%) and T-piece resuscitators (14%). Only 7% of programs indicated the availability of more than one device in the resuscitation area and 16% during transport to the NICU. During transport to the NICU, 44% used flow inflating bags, 32% used self-inflating bags, 24% used transport ventilators and 11% used T-piece resuscitators.

CPAP OR PEEP: CPAP or PEEP was available in 76% of the delivery rooms. CPAP or PEEP was provided by flow-inflating bags (58%), self-inflating bags with PEEP valves (25%), T-piece resuscitators (19%), ventilators (13%). (Leone 2006)

2005 California Survey: (question not addressed)

Process:

2002 National Survey:

CPAP or PEEP are provided to all infants requiring positive pressure ventilation in 65% of all units, to all preterm infants < 1,500 gm in 19% of all units and to select infants in 27% of all units. The levels of CPAP pressure selected are: 5 cm H_2O-56%; 4 cm H_2O-14%; 6 cm H_2O-14%; and 7 cm H_2O- 0.5%. (Leone 2006a)

2005 California Survey: (question not addressed)

Process (VON Measures):

Disclaimer:

Description of what initial and subsequent respiratory support actions are being taken by NICUs begs the question of what is the evidentiary basis of these practices. In our Toolkit: Improving Initial Lung Function: Surfactant and Other Means, we provided, we cited the published experience from Columbia University's Babies and Children's Hospital as a benchmark for managing initial respiratory support without the use of intubation.

Table: Vermont-Oxford Network-Percentage of infants initially tried on NCPAP prior to being intubated, broken out by Gestational Age and Birth Weight

DATA UPDATE PENDING

	% Intubated In the Del Rm Median (IQR)	% First Attempted on Early CPAP Median (IQR)	% Ventilated after Early CPAP Median (IQR)	
VON				
All 501-1500	54 (43-65)	35 (18-48)	43 (29-60)	
501-750	81 (75-96)	10 (0-13)	78 (50-100)	
751-1000	74 (63-88)	22 (0-32)	58 (33-100)4	
1001-1250	49 (33-65)	39 (16-55)	42 (22-75)	
1251-1500	28 (14-39)	57 (33-75)	34 (16-55)	
Source: 2004 VON QMR Report				

8. Optimize airway management:

Rationale: (Primary Author: Neil Finer, MD)

Intubation: Do not attempt to intubate a newborn infant without an attempt to stabilize with positive pressure ventilation. If you are unable to adequately ventilate an infant after following the above steps, then intubation should be attempted. Otherwise stabilize the infant, monitor the heart rate and then intubate. However, recent evidence from large well designed and conducted multicenter randomized trials has now demonstrated that the use of early CPAP to stabilize the very preterm infant will result in a decreased need for intubation and surfactant without increasing morbidity

There are now at least 4 published trials that have prospectively compared early surfactant, given within 1 hour of life, with early CPAP. While early surfactant is not equivalent to prophylactic surfactant by the age at delivery, the SUPPORT trial did administer surfactant to all enrolled infants randomized to the Surfactant arm, and thus its use was prophylactic, as the infants were not required to have any respiratory symptoms. The recently completed VON trial compared prophylactic surfactant with early CPAP and with an approach that included prophylactic surfactant followed by immediate extubation.

The SUPPORT Trial enrolled 1316 infants from 24+0/7ths weeks gestation to 27+6/7ths weeks in 2 strata. The rates of the primary outcome of death or survival with physiologically defined BPD were not significantly different between the CPAP and surfactant groups, when adjusted for gestational age, center and familial clustering (47.8% vs. 51.0%, Relative risk(RR) =0.95 (95% Confidence interval (CI) 0.85, 1.05) . Results were similar (rates 48.7% vs. 54.1%, respectively; RR=0.91 (CI 0.83, 1.01), when BPD was defined by any oxygen requirement at 36 weeks gestation . Fewer CPAP treated neonates required intubation or post natal steroids for BPD, (p<.001) and more were alive and off mechanical ventilation by day 7, (p=0.011). Infants in the immature strata of 24 to 25+6/7 weeks gestation randomized to CPAP had a significantly lower mortality rate while hospitalized than those randomized to surfactant 23.9% vs. 32.1%, RR=0.74, (0.57, 0.98), p=0.034, Treatment with CPAP, versus surfactant, was not associated with increased risks for adverse neonatal outcomes.

The VON trial enrolled 648 infants from 26 to 29+6/7ths weeks gestation at 27 centers. There were no differences in baseline population characteristics. Fewer infants in the NCPAP vs the prophylactic surfactant group received surfactant (46 vs 99%) and were ventilated (45 vs 96%) during the first week of life. No differences were seen in the primary outcome of death or BPD at 36 weeks postmenstrual age. There were no statistically significant differences in mortality, other complications of prematurity or the composite outcome of death or major morbidity (severe ROP, CLD, PVL or severe IVH) between their groups. Death or BPD was lowest in their CPAP group, (40.6%) compared with the prophylactic surfactant group (53.1%), and the intubate/surfactant/extubate group (43.4%) although these differences did not reach significance.
As noted below under the CPAP section, the COIN trial did enroll infants who were spontaneously breathing at 5 minutes from 25 weeks to 28 weeks to receive either CPAP

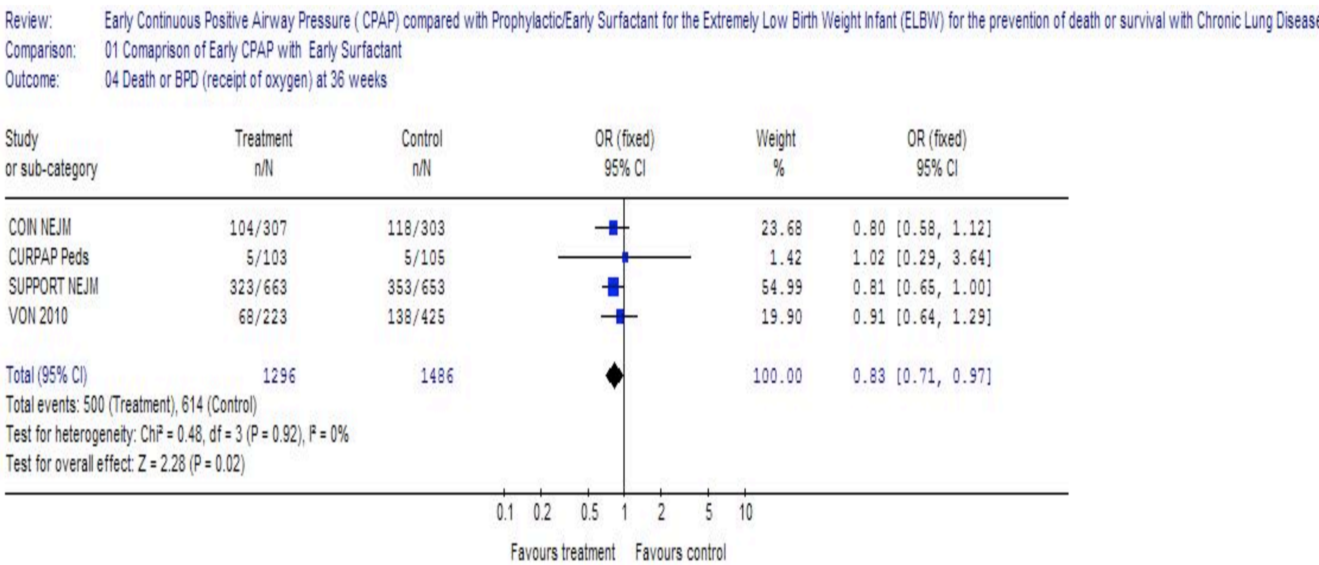
or to be intubated for conventional ventilation. Surfactant was not required by protocol in this trial and thus the results of this trial are not informative in comparing early CPAP with early surfactant.

The CURPAP trial results have just been published. This study enrolled 208 newborns from 25+0–28+6 wks with spontaneous breathing were randomized after birth to two groups: Group 1-intubation, prophylactic surfactant administration within 30 minutes from birth; Group 2-early stabilization on NCPAP with early rescue surfactant administration according to defined clinical criteria. The incidence of the need for mechanical ventilation in the first 5 days was similar between the two groups (Group 1: 31.4%,Group 2: 33.0%.RR:0.95;95% CI:0.64-1.41); 21.9% and 21.4% infants respectively required oxygen treatment or respiratory support or had died at 36 weeks PMA. There was no difference in the incidence of BPD (Group 1: 23.8%, Group 2: 22.3%.RR:1.05; 95% CI: 0.65-1.70). The incidence of pneumothorax was 6.7% in Group 1 and 1% in Group 2 (RR: 6.82; 95% CI: 0.86-53.75). There were no differences in the incidence of other complications.

A multicenter study from Colombia, South America prospectively evaluated 279 infants born between 27 and 31(6/7) weeks' gestation with evidence of respiratory distress and treated with supplemental oxygen in the delivery room.

(Rojas et al) Infants were randomly assigned within the first hour of life to intubation, very early surfactant, extubation, and nasal continuous positive airway pressure (treatment group) or nasal continuous airway pressure alone (control group). The need for mechanical ventilation was lower in the treatment group (26%) compared with the control group (39%). Air- leak syndrome occurred less frequently in the treatment group (2%) compared with the control group (9%) as was the percentage of patients receiving surfactant after the first hour of life was also significantly less in the treatment group (12%) compared with the control group (26%). The incidence of chronic lung disease was 49% in the treatment group compared with 59% in the control group. It should be noted that this trial enrolled infants of at least 27 weeks gestation, and thus represents a more mature population that those enrolled in SUPPORT (24 weeks- 27+6/7ths, or VON, 26 – 29+6/7ths weeks.

I have included a meta analysis that we have performed in an effort to compare the result of these trials. Overall while the interventions were not identical, as can be seen, the use of early CPAP compared to Surfactant or conventional treatment was associated with a significant decrease in death or BPD by oxygen use at 36 weeks. In addition the SUPPORT trial reported a significant reduction in Death for the CPAP infants in the 24 to 25 weeks strata.



Implementation Strategies:

- Observe and ensure the infant's stability during intubation attempts. (Allow up to approximately 30 seconds for each attempt; terminate the attempt sooner if the infant has significant bradycardia and/or cyanosis.) (Lane 2004).
- Select an appropriate ETT tube (diameter)
- Confirm intubation with a CO_2 detector, such as with a colorometric device (Aziz 1999). Note: the detectors may not turn color if there is no cardiac output or the sensor is wet or contaminated.
- Continue positive pressure breaths with PEEP
- Ensure adequate depth of insertion using a nomogram, and confirm by palpation (Jain 2004).
- Secure the tube quickly and effectively.
- For the VLBW infant, administer surfactant – there are few situations in the DR where intubation of a VLBW infant would not be followed by surfactant. You may wish to delay till the infant is in the NICU, especially to confirm ETT position. There is no advantage to giving surfactant immediately following delivery, up to 15 minutes is as good as giving it with the first breath, and may be better (Kendig 1998).

Benchmarking:

Two types of comparative data are available. First, there are qualitative data from a 2002 national and a 2005 California survey of NICUs (Leone 2006a, Leone 2006b). Doubtlessly, practice equipment and process has evolved further in the interval to now, but, at least these data provide a minimal estimate of capabilities and practice upon which California units might benchmark their own capabilities and practices. Second, VON collects and analyzes practices related to the timing of surfactant delivery.

Technique for confirming intubation:

2002 National Survey:

The national survey indicated that 32% of programs utilize a CO_2 detector to confirm intubation: 94% use a qualitative carbon dioxide detector and 6% use an end-tidal detector. Of programs using carbon dioxide detectors, 48% utilize them with each intubation and 43% use them when there is difficulty determining successful intubation (Leone 2006a).

2005 California Survey: Among the 59 respondents of this survey 36% report routine use of a CO_2 detector for confirming intubation and 19% use such a device only when intubation is in doubt (Leone2006b).

Timing of Surfactant Administration for VLBW Infants:

VON Measure: Time of first surfactant dosing is reported by VON broken out by birth weight cohorts,

CPQCC Measure: Time of first surfactant dosing in those infants noted to have intubated in the delivery room. (data to be displayed in subsequent drafts)

Rationale:
This measure reflects the notion that an infant intubated in the delivery room should be given surfactant as soon as possible.

VON and CPQCC* 2004 Data on Delivery Room Intubation and Surfactant Administration (Inborn VLBWs Only) –

DATA UPDATE PENDING

	% Intubated in Del Rm Median (IQR)	% Surfactant Administered in Del Rm Median (IQR)	Median Age in Minutes When Surfactant Administered	
VON				
501-1500 g	54 (43-65)	30 (7-45)		
501-750 g	81 (75-96)	48 (13-75)	15	
751-1000 g	74 (63-88)	44 (9-68)	20	
1001-1250 g	49 (33-65)	27 (0-43)	30	
1251-1500 g	28 (14-39)	13 (0-20)	60	
CPQCC				

(to be supplied in subsequent drafts)				

The following graphs are for illustrative purposes ONLY at this time. These data are from the CPQCC's benchmarking section of its 2004 Toolkit: Improving Initial Lung Function and refer to experience reported in 2002. (**DATA UPDATE PENDING)** The surfactant administration times are NOT differentiated by those intubated or not in the delivery room.

Figure: *Per Cent of Infants in each CPQCC NICU Who Received Surfactant Within 30 minutes Postnatal Age By Birthweight Cohort. Box shows percentages for the mean, 25th and 75th percentiles of these NICUs*

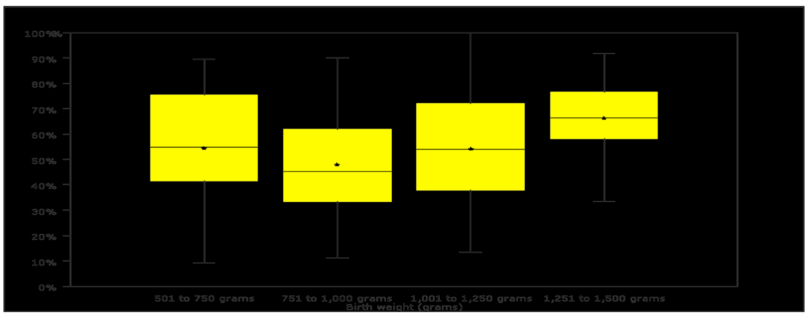
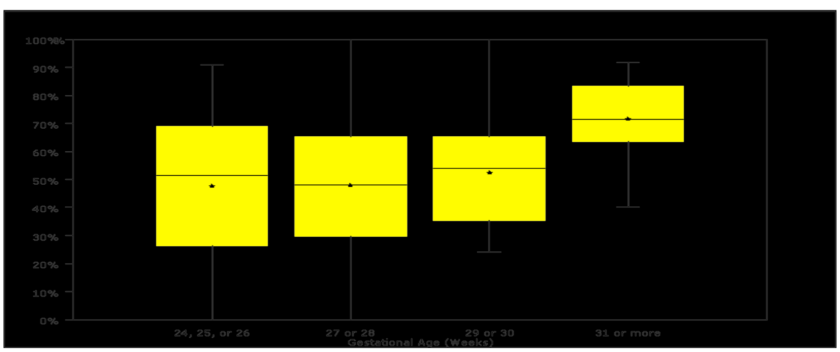


Figure*: Per Cent of Infants in each CPQCC NICU Who Received Surfactant Within 30 minutes Postnatal Age By Gestational Age Cohort. Box shows percentages for the mean, 25th and 75th percentiles of these NICUs.*



Subsequent drafts of this toolkit will contain updated reports.

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