Improving Neonatal Resuscitation: Use of Audio and Visual Prompting to improve Resuscitation Performance in Simulated Neonatal Resuscitation

Victoria Blancha Eckels, MD, PGY2
CRC course project proposal, August 4 2017

Study Purpose and Rationale

Approximately 10% of all infants need some form of resuscitation at the time of birth and the interventions performed can have a significant impact on survival. Resuscitation is a complex process performed by a team of individuals coordinating many different functions. Substantial errors during resuscitations have been documented from both chart reviews and review of videotaped resuscitations. The underlying cause of errors is frequently attributed to a lack of relevant situational awareness. This lack of situational awareness can be seen as a team focusing on only one aspect of the resuscitation at the expense of other aspects. In addition, it can be difficult to maintain a realistic awareness of time during resuscitation, which may lead to interventions occurring later than desired.

For the most critically ill newborns, a delay or failure to perform a necessary intervention could be life threatening. Delays in achieving normal physiologic adaptation have the potential to contribute to impaired neurologic outcome in survivors. In the first minutes of life normal physiologic parameters, such as oxygen saturation and heart rate, are changing over time, making the identification of indicated interventions more complicated. The team must integrate the normal physiologic changes with the timeline of the resuscitation.

Newborn resuscitation has traditionally been thought of as a simple task, which takes only a few minutes to perform and does not require advanced equipment. However, in reality the average resuscitation usually lasts longer than 20 minutes. In recent years, the importance of oxygen saturation monitoring and prevention of hyperoxia have led to the use of pulse oximeters and blended oxygen concentrations during resuscitation, which can further complicate the integration of tasks.

We have developed a computerized system, the Interactive Resuscitation Assistant (IRA), to be used during resuscitations that provides a visual indication of the infants physiologic status over time and generates audio-prompts intended to focus the team's attention on the relevant clinical findings and indicated interventions consistent with the resuscitation algorithm. The IRA will display physiologic and intervention data in an easily visible format, showing changes over time.

The IRA gives appropriate audio prompts to address critical values of physiologic parameters.

The use of prompts to assist the resuscitation team acknowledges that resuscitation is a complicated process that is occurring in a time frame not easily managed in the moment. The idea of prompting is not entirely new. Apgar timers have been used on resuscitation beds to notify the team when the appropriate time to assign a score has come. Visual and audio feedback during resuscitation training has been used to improve the quality of chest compression performance. Metronomes of chest compression timing are available and improve chest compression performance. One trauma center has developed and evaluated a computer-assisted decision support system incorporating physiologic data and user input to generate prompts that would comply with trauma algorithms. In a clinical trial they found that when decision support was used there were fewer errors per patient, more error-free resuscitations, and less morbidity from shock management, blood use, and aspiration pneumonia. The neonatal resuscitation algorithm is unique in that normal physiologic values change over time and therefore graphical representation seems particularly helpful. Additionally, neonatal resuscitation may be the most amenable area for successful implementation of this type of integrated prompting device since the resuscitation algorithm is relatively simple with fewer possible interventions in comparison with trauma, adult, or pediatric resuscitation algorithms.

The purpose of this project is to test the IRA in a simulated environment to determine whether it can improve resuscitation performance. It is important that this device not be seen as a replacement to human intelligence during resuscitation. The prompts provide suggestions but the resuscitation team members need to confirm that the data is accurate before acting on any suggestions. The resuscitation teams will continue to make judgments about which interventions should be done, but the reminders are expected to improve performance by suggesting interventions which may not have been considered in a timely fashion and allow the resuscitation to more closely follow the expected algorithm.

Study Design and Statistical Procedures

Hypothesis: Resuscitation teams using the Interactive Resuscitation Assistant will have higher resuscitation scores compared with resuscitation teams using current standards of resuscitation.

This will be a prospective randomized controlled trial that will evaluate resuscitation performance using simulation. Resuscitation teams will be comprised of 3 team members. Each resuscitation team will be randomized to perform resuscitation using either the IRA (study group) or using a standard neonatal simulator (control group). The simulated resuscitations will be videotaped and

the videos will be assessed using a neonatal resuscitation-scoring tool. The neonatal resuscitation-scoring tool has been developed using the relevant items from the Neonatal Resuscitation Program (NRP) performance checklist and relevant items from a previously utilized video-resuscitation scoring tool. Two different observers will score each of the resuscitations. The scores of the 2 observers will be averaged for the final assigned score. Each team member may only participate on one team and will be asked to complete a survey regarding their perceptions of the simulated resuscitation experience.

The primary outcome of the trial will be the resuscitation score.

The study will use simulated resuscitation scenarios to evaluate the effect of the IRA on resuscitation performance. Study participants will be recruited from the current NICU staff and trainees to perform the simulated resuscitations. Simulated resuscitations will take place on the NICU in the dedicated simulation room. All simulated resuscitations will be performed using a standard simulation manikin. The study group will use the IRA during the simulated resuscitation. The IRA includes a numerical indication of heart rate (HR), oxygen saturation (SpO2), fraction of inspired oxygen (FiO2), and elapsed time, as well as a graphical display of airway pressure, HR, and SpO2 over time. The IRA will also play audio recordings of suggested interventions at set time points during the resuscitation depending on the clinical condition. A built-in metronome is available on the IRA for the team to use during chest compressions if desired. The control group will perform simulated resuscitations with a standard newborn simulator manikin (SimNew B) monitors available. The IRA will be connected for intervention data collection (FiO2 and airway pressure) but the display, audio files, and metronome will not be available to the team for use during the simulated resuscitation.

Randomization will occur just prior to the simulation session. Group assignment will be concealed in opaque, sealed serially numbered envelopes. Randomization will be stratified by resuscitation team experience level (see more details under Participants). Random numbers in blocks of 4 will be used to create group assignments. All instructions prior to each simulation session and all equipment availability will be standardized for all groups. All equipment will be made available in a standardized format so that each group has access to the same items in the same locations. Simulation scenarios will be standardized so that all teams are given similar circumstances and are expected to perform the same tasks. Each simulation scenario is expected to be approximately 20 minutes in duration. All simulated resuscitations will be videotaped. Videotapes will be used to score resuscitations after the simulation is complete. At the conclusion of each simulation, the participants will be asked to complete a post-simulation survey. Once they have completed the survey, a short debriefing session will be held with the team participants and

any additional comments regarding the IRA will be documented.

The sample size for this RCT will be 20 resuscitation teams per group, which allows 80% power to detect a 15% difference in resuscitation score (with 10% standard deviation) at an alpha level of 0.05. Videos of the resuscitations will be reviewed for timing of specific interventions. Secondary outcomes will include time to each designated intervention (initiation of positive pressure ventilation (PPV), increase in oxygen concentration, intubation, initiation of chest compressions, placement of umbilical venous catheter (UVC), administration of epinephrine, and administration of volume). Additional secondary outcomes will include each individual scoring-tool item and results from the participant survey.

The primary outcome will be evaluated using pairwise comparison between control and intervention (IRA) groups at each experience level (novice, intermediate, and expert).

Study Subjects

Study subjects will consist of Columbia Neonatology Faculty, Neonatology fellows, Pediatric residents, and medical students. Participants will be recruited via email. Participants will be compensated $50 via American Express gift card, as they will have to come into the hospital outside of working hours and will expect to spend one hour of their time for this study.

There are no direct benefits to the study subjects. However, the development and study of the IRA may benefit neontates in the future. Risks to the study subjects include feeling uncomfortable during the simulated resuscitation as they may feel required to perform tasks for which they do not have adequate skills.

References

1. Allwood ACL, Madar RJ, Baumer JH, Readdy L, and Wright D. Changes in resuscitation practice at birth. Arch Dis Child Fetal Neonatal Ed. 2003;88:375-379.
2. Lee ACC, Cousens S, Wall SN, Niermeyer S, Darmstadt GL, Carlo WA, Keenan WJ, Bhutta ZA, Gill C, and Lawn JE. Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, meta-analysis and Delphi estimation of mortality effect. BMC Public Health 2011, 11 (Suppl 3): S12. http://www.biomedcentral.com/147-2458/11/S3/S12
3. Carbine DN, Finer NN, Knodel E, Rich W. Video recording as a means of evaluating neonatal resuscitation performance. Pediatrics. 200;106:654-658.
4. Gelbart B, Hiscock R, and Barfield C. Assessment of neonatal resuscitation performance using

video recording in a perinatal centre. J Paediatr Child Health. 2010;46:378-83.
5. Clarke JR, Spejewski B, Gertner AS, Webber BL, Hayward CZ, Santora TA, Wagner DK, Baker CC, Champion HR, Fabian TC, Lewis Jr. FR, Moore EE, Weigelt JA, Eastman AB, and Blank-Reid C. An objective analysis of process errors in trauma resuscitations. Acad Emerg Med. 2000;7:1303-1310.
6. Ivatury RR, Guilford K, Malhotra AK, Duane T, Aboutanos M, and Martin N. Patient safety in trauma: maximal impact management errors at a level I trauma center. J Trauma. 2008;64:265-70.
7. Dawson JA, Kamlin COF, Vento M, Wong C, Cole TJ, Donath SM, Davis PG, and Morley CJ. Defining the reference range for oxygen saturation for infants after birth. Pediatrics. 2010;125:e1340.
8. Dawson JA, Kamlin CO, Wong C, te Pas AB, Vento M, Cole TJ, Donath SM, Hooper SB, Davis PG, Morley CJ. Changes in heart rate in the first minutes after birth.
9. Du JN and Oliver TK Jr. The baby in the delivery room. A suitable microenvironment. JAMA 1969;207:1502-4.
10. Wang CL, Leone TA, Rich W, Finer NN. Neonatal resuscitation of ELBW infants: Time spent in the delivery room. E-PAS 2006:59:2860.205
11. Peberdy MA, Silver A, Ornato JP. Effect of caregiver gender, age, and feedback prompts on chest compression rate and depth. Resuscitation. 2009;80:1169-74.
12. Niles D, Nysaether J, Sutton R, Nishisaki A, Abella BS, Arbogast K, Maltese MR, Berg RA, Helfaer M, and Nadkarni V. Leaning is common during in-hospital pediatric CPR, and decreased with automated corrective feedback. Resuscitation. 2009;80:553-557.
13. Sutton RM, Donoghue A, Myklebust H, Srikantan S, Byrne A, Priest M, Zoltani Z, Helfaer MA, and Nadkarni V. The voice advisory manikin (VAM): An innovative approach to pediatric lay provider basic life support skill education. Resuscitation. 2007;75:161-168.
14. Yeung J, Meeks R, Edelson D, Gao F, Soar J, and Perkins GD. The use of CPR feedback/prompt devices during training and CPR performance: A systematic review. Reuscitation. 2009;80:743-751.
15. Kern KB, Stickney RE, Gallison L, and Smith RE. Metronome improves compression and ventilation rates during CPR on a manikin in a randomized trial. Resuscitation. 2010;81:206-210.
16. Fitzgerald M, Cameron P, Mackenzie C, Farrow N, Scicluna P, Gocentas R, Bystrzycki A, Lee G, O'Reilly G, Andrianaopoulos N, Dziukas L, Cooper DJ, Silvers A, Mori A, Murray A, Smith S, Xiao Y, Stub D, McDermott FT, Rosenfeld JV. Trauma resuscitation errors and computer-assisted decision support. Arch Surg. 2011;146:218-25.
17. Textbook of Neonatal Resuscitation, 5th ed. Kittwinkel J, ed. American Academy of Pediatrics and American Heart Association. Elk Grove Village, Ill. 2006.