

Wireless Assessment of Heart Rate For Neonatal Delivery Room Resuscitation

(Technical Paper)

The Ethical Landscape of American Neonatal Healthcare

(STS Paper)

A Thesis Prospectus submitted to the Department of Engineering and Society

Presented to the Faculty of The School of Engineering and Applied Science
University of Virginia, Charlottesville, VA

In Partial Fulfillment of The Requirements for The Degree
Bachelor of Science, Biomedical Engineering

Andrew Carey

November 8th, 2024

Technical Project Team Members

Alex Carmona-Perez, Angela Taetsch, Mahi Gudi

On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

ADVISORS

Professor Gerard Fitzgerald, Department of Engineering & Society

Dr. Karen Fairchild, Department of Neonatal Perinatal Medicine

Dr. Nicholas Heitkamp, Department of Neonatal Perinatal Medicine

Craig H. Meyer, Department of Biomedical Engineering

Introduction:

Approximately 10% of the estimated 4 million infants born each year in the United States require some level of assistance to begin breathing at birth (American Family Physician, 2011). These children, designated “at-risk infants”, present with respiratory depression, failure or distress, and undergo resuscitation performed by healthcare providers to attempt to save the child. Specifically, newborn resuscitation focuses on elements of airway viability, breathing, circulation, and administering proper medicine to save the infants. During this process timing is imperative; that is, as soon as the baby is born, a timer is started and evaluation of respiratory effort is assessed. The two vital characteristics in determining newborn resuscitation are respirations and heart rate (whether or not the child presents a heart rate greater or less than 100 beats per minute). When the heart rate is below 100 beats per minute (bpm), the infant is in danger and requires life-saving resuscitation (American Heart Association, 2010).

The infants' delicate size, slippery skin, and a risk of time pressure creates a challenging environment for physicians and nurses to assess resuscitation. Breakdowns in teamwork unity, biomedical equipment, and an inadequacy of timely diagnostic measurements can lead to perinatal injury and death (American Heart Association, 2010). In addition, various stimuli including a cacophony of sounds and limitations of space add to this tense situation. Due to the complexity of variables of assessing newborn resuscitation, better regulation and medical innovation must be researched to ensure greater health outcomes for infants. Therefore, this issue is twofold; that is, firstly to improve the biomedical technology used for resuscitation and secondly to regulate the medical training required to use it.

The connection behind these ideas lies in the dynamic of how medical staff utilizes equipment to make life-saving decisions. Decision-making is one of the predominant forces behind health outcomes, and is one of the most important skills medical providers must be equipped with (Acta Inform Med, 2022). In particular, neonatology has a complicated intersection with decision-making because a physician's patients are infants who cannot formulate any decisions for themselves. Therefore, the principles of autonomy, beneficence, nonmaleficence, and justice must be adhered to in order to sharpen ethical decision-making in neonatal medicine. In addition, the landscape of ethical cognition becomes

complex when elements of social, cultural, and religious views must be taken into consideration in regard to medicine. However, decision-making and ethical training is widely inconsistent, with most medical students reporting immense variability among training programs in terms of ethics content and assessment (Pediatric Child Health, 2014).

Therefore, the technical topic for this prospectus will address the need for the creation of a wireless neonatal heart rate device that assesses newborn resuscitation in the delivery room. To complement this scope, the STS topic will consider how medical training in ethical decision-making relates to medical outcomes, specifically by understanding neonatal ethics in the range of autonomy, beneficence, nonmaleficence, and justice.

Technical Topic:

Approximately 1% of all live births result in cardiopulmonary resuscitation (CPR) due to perinatal asphyxiation and around 0.1% of newborns require administration of epinephrine (American Heart Association, 2010). Once a newborn is delivered, heart rate and breathing is immediately assessed as the primary vital signs (NIH, 2023). Intervention is administered to a newborn if the heart rate is determined to be less than 100 bpm, and CPR is administered if the heart rate is determined to be less than 60 bpm.

Due to the implementation of the Neonatal Resuscitation Program (NRP) in 1987, there has been a steady decrease in infant mortality which can largely be attributed to increases in technological innovation (NIH, 2023). Specifically, the NRP recommends guidelines for heart rate assessment using a stethoscope, pulse oximetry, and/or electrocardiogram (ECG) in the delivery room. Specifically, in the United States neonatal mortality has decreased to approximately 4 in 1000 births from nearly 20 in 1000 births in the 1960s (American Heart Association, 2020). However, each of these methods is still susceptible to human error, resulting in inaccurate estimates of heart rate, delaying care, and leading to unwarranted/misguided medical intervention. Also, preterm babies, babies born between 25 weeks and 36 weeks gestation are at even higher at-risk for respiratory failure due to the lack of physiological

respiratory mechanics, which typically develop in the final weeks of pregnancy (StatPearls, 2024).

Currently, there are a variety of heart rate measurement devices incorporated in the delivery room; however, most experience limitations and are not fully fit in assessing proper heart rate in preterm infants.

Modern pulse oximeters, which measure blood oxygen, require an average of 62 seconds to assess heart rate and are researched to have been only accurate approximately 89% of the time (American Heart Association, 2020). Another method, stethoscopes, also do not provide a numerically measurable approximate for heart rate and only identify breathing patterns. Rather, in typical medical environments, the ECG is referred to as the “gold standard” for heart rate detection, but requires dry, clean skin for proper adherence

of the electrodes. Multiple lead electrodes also consume space, are at risk for tripping, and require an average of 28 seconds to achieve a signal (American Heart Association, 2020).

Thus, the goal of this technical analysis is to develop a wireless heart rate detection device which fully adheres to the surface of the smallest babies, includes visual and auditory alerts, and overall reduces human error. This will be accomplished by incorporating device visual cues to indicate need for resuscitation based on detected heart rate, constructing the device from safe biomaterials, and developing an algorithm that collects and transforms heart rate data into visual, auditory, and/or diagnostic display.

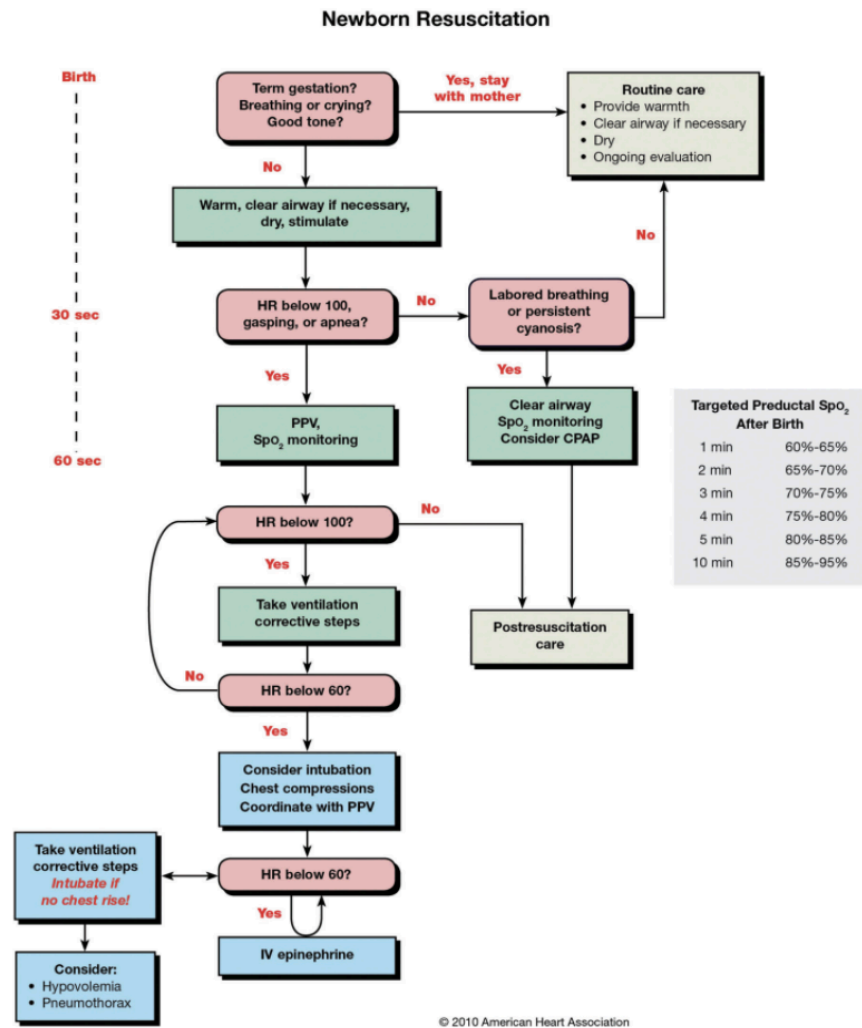


FIGURE I. Newborn Resuscitation Algorithm
(American Heart Association, 2020)

STS Topic:

Historically, the concept of neonatal intensive care is relatively new. As late as the 1950's, at-risk infants received minimal post-delivery specialized care and were sent home. In most cases, these babies did not live past their first birthday. In hospitals, the infant mortality rate in America during this time was 29.2 infants out of every 1,000 births (Institute of Medicine, 2003). After this realization, Congress deemed the neonatal mortality rate unacceptable and began producing efforts to combat at-risk births. Thus, the ideal of neonatal specialized care was derived from a push in contemporary newborn medicine out of the 1960's. This resulted in the creation of the first Neonatal Intensive Care Unit (NICU) in the United States of America established in 1960 at Yale New Haven Hospital. During this process, immense technological advancement such as the advent of the incubator, respirators, and ventilator systems were developed (Journal of Perinatology, 2000). For the first time in modern healthcare, technology was being innovated for neonates.

Despite the advances in neonatal treatments and technology making the NICU one of the most innovative fields of medicine, it has also brought about ethical dilemmas in neonatal healthcare. While approaches to ethical care can sometimes vary, it is critical for healthcare providers to adhere to a regulated routine for ethical-decision making in the NICU. Therefore, the framework for ethical decision making has predominantly been discussed using four key principles –autonomy, beneficence, nonmaleficence, and justice (Newborn and Infant Nursing Review, 2013).

To comprehend the role of these ethical principles, defining them in context to neonatology is a priority. *Autonomy* refers to self-determinism and encompasses confidentiality, informed consent, and making autonomous decisions for babies who cannot make decisions for themselves. For this reason, both medical providers and parents must uniformly come to agreement about the best interests for the child. *Beneficence* consists of acting out of compassion, sound-mind, and of the spirit in order to benefit others. Parents and healthcare professionals may disagree on the benefits of treatment plans for sick children; nevertheless, both must consider respectful viewpoints and all the information in order to act in the best interests of the infant. *Nonmaleficence* means reducing the infliction of pain as much as possible in order

to reach a beneficial outcome. This is especially considered when treatments are futile. In addition, a cross analysis of short-term and long-term “harm vs beneficence” is imperative when performing life-saving treatment in the NICU. Finally, *justice* refers to acting out of fairness for all individuals with consideration of differences in social, cultural, religious, and lifestyle views. These principles should work in unison and be understood by neonatal healthcare workers who are responsible for family-focused decision-making. By understanding ethical frameworks in the NICU, neonatal care can become more comprehensive and safe within the vast technological field of neonatology (Newborn and Infant Nursing Review, 2013).

Adjacent to ethical rumination, there is discussion of who should have the right of decision-making for infants in the NICU – should priority go to healthcare professionals or parents? The latter promotes parental involvement in making healthcare decisions on the basis that they are “mutuals” in a moral environment, may suggest treatment choices, and establishes a trusting relationship between patient-and-provider. Involving parents in ethical decision-making most relates to principles of justice, and especially blends the boundaries of considering family-specific qualities of culture, religion, and social viewpoints. Irregardless on the avenue of ethical decision-making, a regulated practice must be established in healthcare professionals by adhering to guidelines formed with common knowledge and a base of evidence (Pediatric Child Health, 2014). These guidelines must not only include bioethical standards, but should be adjustable for governing and legal mandates as well. To have a consistent regulated management system for ethical decision-making will proactively assist both healthcare providers and families; thus, overall contributing to a safer environment in neonatology.

Research Questions and Methods:

For my STS research, it is necessary to study how current ethical medical training is conducted, and specifically, how it positively or negatively impacts healthcare outcomes in the NICU. The experimental design of my research will be a retrospective meta-analysis that will analyze training protocols and formal education curriculum on the basis of neonatal ethical care at large Academic

Medical Centers (AMCs). Large establishments will provide the most available public information, and should be the most reliable sources of information to draw from. Analysis will be twofold – firstly, understanding and drawing conclusions about *how* medical ethical training is conducted in the modern century. Then, secondly, I will assess the statistics of medical outcomes and conduct tests of statistical significance to evaluate any correlations. Overall, my thesis will aim to answer how medical ethical considerations are trained in the healthcare space of neonatology, how biotechnology affects these considerations, and why it is important to have a standardized guideline system in place for healthcare providers.

Conclusion:

In conclusion, my proposed technical project aims to address the critical challenge of timely and accurate heart rate assessment for newborns requiring resuscitation in the delivery room. By developing a wireless, biomaterials-based device, it seeks to improve the precision and efficiency of neonatal resuscitation, reducing human error and enhancing outcomes for vulnerable infants. Complementing this, my STS research explores the ethical complexities integral in neonatal care, emphasizing the need for standardized medical training in decision-making frameworks that prioritize autonomy, beneficence, nonmaleficence, and justice. Uniformly, these efforts highlight the crossover of biomedical innovation and ethical practice in neonatology. The technical solution and ethical inquiry both aim to optimize neonatal healthcare, ensuring that medical professionals are equipped with both the tools and ethical frameworks necessary for life-saving interventions in the delivery room and beyond. A standardized approach is essential to fostering better outcomes and guiding future advancements in this vital area of medicine.

REFERENCES:

1. Raghuveer TS, Cox AJ (2011). "Neonatal resuscitation: an update". *Am Fam Physician*. 15;83(8): pp. 911-8. PMID: 21524031.
2. Kattwinkel, J., Perlman, J. M., Aziz, K., Colby, C., Fairchild, K., Gallagher, J., Hazinski, M. F., Halamek, L. P., Kumar, P., Little, G., McGowan, J. E., Nightengale, B., Ramirez, M. M., Ringer, S., Simon, W. M., Weiner, G. M., Wyckoff, M., & Zaichkin, J. (2010). "Part 15: Neonatal Resuscitation". *Circulation*, 122(18_suppl_3), pp. 909–S919.
3. Daboval, T., Moore, G., Rohde, K., Moreau, K., & Ferretti, E. (2014). "Teaching ethics in neonatal and perinatal medicine: What is happening in Canada?" *Paediatrics & Child Health*, 19, pp. 6–10.
4. Masic I (2022). "Medical Decision Making - an Overview". *Acta Inform Med*. 30(3): pp. 230-235. doi: 10.5455/aim.2022.30.230-235. PMID: 36311160; PMCID: PMC9560052.
5. Nerdrum Aagaard E, Solevåg AL, Saugstad OD (2023). "Significance of Neonatal Heart Rate in the Delivery Room-A Review". *Children (Basel)*.10(9):1551. doi: 10.3390/children10091551. Erratum in: *Children (Basel)*. 2024 Jan 18;11(1):120. doi: 10.3390/children11010120. PMID: 37761512; PMCID: PMC10528538.
6. Aziz, K., Lee, H. C., Escobedo, M. B., Hoover, A. V., Kamath-Rayne, B. D., Kapadia, V. S., Magid, D. J., Niermeyer, S., Schmölzer, G. M., Szyld, E., Weiner, G. M., Wyckoff, M. H., Yamada, N. K., & Zaichkin, J. (2020). "Part 5: Neonatal Resuscitation: 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care". *Circulation*, 142(16_suppl_2), pp. 524–550.
7. Doherty TM, Hu A, Salik I (2024). "Physiology, Neonatal. [Updated 2023 Apr 24]. In: StatPearls [Internet]. Treasure Island (FL): *StatPearls Publishing*; pp. 8-19.
8. Field MJ, Behrman RE, editors (2003). "When Children Die: Improving Palliative and End-of-Life Care for Children and Their Families". Washington (DC): *National Academies Press* (US); 2003. CHAPTER 2, PATTERNS OF CHILDHOOD DEATH IN AMERICA.
9. Baker, J (2000). "The Incubator and The Medical Discovery of The Premature Infant". *Journal of Perinatology*, Volume 5. pp. 321-328.
10. Sundean, L. J., & McGrath, J. M. (2013). Ethical Considerations in the Neonatal Intensive Care Unit. *Newborn and Infant Nursing Reviews*, 13(3), 117–120.
11. Daboval T, Shidler S (2014). "Ethical framework for shared decision making in the neonatal intensive care unit: Communicative ethics". *Paediatr Child Health*. 19(6): pp. 302-4. doi: 10.1093/pch/19.6.302. PMID: 25332659; PMCID: PMC4173956.

12. Prentice, R. A. (2014). Teaching Behavioral Ethics. *Journal of Legal Studies Education*, Volume 31. (Issue 2), pp. 325-365.
13. Mills, M. and Cortezzo, DE. (2020). "Moral Distress in the Neonatal Intensive Care Unit: What Is It, Why It Happens, and How We Can Address It". *Front. Pediatr* Volume 8. pp. 1-10.