University of South Carolina Protocol

Study Title: “Examining current standards for packed red blood cell (PRBC) transfusions for preterm infants in neonatal intensive care units (NICU) across the United States (US)”

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A. SPECIFIC AIMS
This study is a national survey of blood transfusion practices to examine standard practices used for PRBC transfusions for preterm infants in NICUs across the United States. The survey will address the following research questions:

1. What are the determining variables indicating an infant should be transfused with PRBCs?
2. What are the standards for feeding infants before, during, and/or after transfusion of PRBCs?
3. Are PRBC transfusions warmed prior to infusion and if so, how is this accomplished?
4. How are infants assessed physiologically before, during and after PRBC transfusions?

B. BACKGROUND AND SIGNIFICANCE
Over 100,000 early preterm infants (EPIs), infants that are less than 34 weeks gestational age (GA), were born in 2017 in the United States (US). Incidence and complications of prematurity are a national health crisis which is not decreasing. Incidence and complications of prematurity are a national health crisis which is not decreasing. Necrotizing Enterocolitis (NEC) is a devastating gastrointestinal (GI) complication which occurs in 5-15% of EPIs and mortality can reach 50% in infants needing GI surgery for NEC. This disease can greatly increase hospital length of stay and costs for preterm infants. The etiology of NEC has remained vague for over 50 years, however, scientists know the major contributing factors are GI immaturity, microbial colonization, and central ischemia.

As a result of their immature circulatory system and frequent laboratory testing, EPIs experience anemia, evidenced by a decrease in hemoglobin and hematocrit. Mineral and electrolyte imbalances can lead to decreased red blood cell counts and EPIs have low iron stores because they are born prior to the bulk iron transport from the mother’s placenta and before fetal bone marrow stimulation of erythropoietic activity due to immature liver function. Thus, EPIs often receive repeated blood transfusions with packed red blood cells (PRBC) over their NICU hospitalization. PRBCs are used as this is the component of whole blood which provides the red blood cells needed to increase hemoglobin and hematocrit levels and eliminates giving extra fluid volume to the fragile EPI.

Recent evidence suggests PRBC transfusions are associated with the onset of NEC in EPIs; but, researchers have not determined the causative pathway. Possible explanations include the stress of the blood transfusion and the influence of feedings before, during and/or after the blood transfusion, as well as the presence of anemia. PRBCs are sent from the blood bank freezer to the neonatal intensive care unit (NICU) for transfusion; most NICU protocols dictate the blood is allowed to sit at room temperature before infusing to the fragile preterm infant. Very few NICU protocols dictate the use of a blood warmer on these small transfusions and researchers have noted central hypothermia after transfusions in EPIs anecdotally in previous studies. Nurses infuse PRBCs over 1-4 hours and monitor infant stability during the transfusion. There are no published standards for giving blood transfusions to preterm infants and inconsistent practices are the norm.

C. PRELIMINARY STUDIES
Data from a completed literature review have informed the development of the survey to make sure incorporation of variables that have been identified as being associated with morbidity outcomes related to PRBC transfusion.
D. RESEARCH DESIGN AND METHODS AND DATA ANALYSIS

This survey aims to examine standard practices used for packed red blood cell (PRBC) transfusions for preterm infants in Neonatal Intensive Care Units (NICU) across the United States. The responses gathered from this national survey (see attachment A) will help to generate knowledge regarding PRBC transfusion practices in NICUs and provide evidence to inform studies of the relationship between PRBC transfusions and NEC in EPIs. I have developed the survey using RedCap software to answer the research questions. The questions will be in the form of “yes or no” and short open narrative responses to provide specific detail for analysis. The survey should take 10-15 minutes to complete. The RedCap database is an online data collection tool and is password protected; therefore, these data will only be able to be reviewed by my dissertation committee and myself.

E. PROTECTION OF HUMAN SUBJECTS

1. TARGET POPULATION:
Any nurse or nurse practitioner that currently works in a NICU in the US. Nursing is the target audience for survey participation as they are the personnel that perform the PRBC transfusion in the NICU and will be able to provide firsthand experience.

2. RECRUITMENT PLANS:
Working with leadership of The Academy of Neonatal Nursing (ANN), a link to the survey will be sent to its members on my behalf as the email list is confidential. ANN is a professional organization dedicated to informing neonatal nursing to optimize clinical practice through conference dissemination, clinical guidelines, and sponsoring research and education. ANN’s membership consists of over 6,000 neonatal nurses. Upon IRB approval, and email (attachment B) and survey (attachment A) approval, I will use SPARC funds from UofSC to have ANN distribute a link to the survey, by email to ANN members. This will be a one time dedicated blast email. ANN would send the email on my behalf, due to confidentiality. Social Media platforms will also be utilized for survey distribution. I will provide an electronic link to the survey which will be maintained by RedCap of Health Sciences South Carolina. The design, significance and a thank you will be included in all distribution formats and announcements.

3. EXISTING DATA/SAMPLES: N/A

4. CONSENT/ASSENT:
Participants will not be asked for their personal identification and consent to participate in the research survey will be obtained within the introduction of the survey. My intention is to gain nurses’ perceptions of practices used in their NICU for EPIs receiving blood transfusions.

5. POTENTIAL RISKS:
No personal identifying information is collected; however, we do ask demographic information such as age, years of experience, education level and the location of the NICU where you work. Additionally, if you choose to participate in a drawing of gift cards, you may provide your e-mail. All surveys are securely stored on an encrypted and password protected research server. If there is a concern regarding this survey, please contact: The University of South Carolina Institutional Review Board (IRB) at the Office of Research Compliance 1600 Hampton Street, Suite 414 Columbia, SC 29208; 803-777-6670.

6. POTENTIAL BENEFITS:
The goal of this study is to examine current PRBC transfusion practices in US NICUs. By examining current PRBC transfusion practices, the second phase of this dissertation study will be informed and may expose variations in practice which could affect preterm infant outcomes. Results from this study may lead to standardization of PRBC transfusion practices across the US.

7. CONFIDENTIALITY
No personal identifying information is collected; however, we do ask demographic information such as the participant’s age, years of experience, education level and the location of the NICU where
they work. Additionally, if the participant chooses to participate in a drawing of gift cards, the participant may provide their e-mail. All surveys are securely stored on an encrypted and password protected research server.

8. COMPENSATION:
   To maximize the rate of completion, I will offer one random drawing each week of the survey period (1 month) from non-duplicate survey responses received during that week, for one VISA gift card valued at 50 US Dollars. To be eligible for the drawing, the participant must specify their email. Only one survey should be submitted per respondent. To receive the gift card, the participant must reply to an email from the researcher and give their name and address. I will re-advertise the survey link every week to increase the completion rate and offer prizes for two cycles. If I do not have a 30% completion rate of the surveys, I will work with the leadership of ANN to implement an alternative route to advertise the survey in their monthly journal or keep the survey open than the proposed 1-month timeframe.

9. WITHDRAWAL:
   There is no obligation to complete the survey and one may withdraw from the survey at any time. There is no penalty for withdrawing from the survey.
F. REFERENCES/LITERATURE CITATIONS


G. APPENDIX

*Attachment A*: A national survey of blood transfusion practices to examine standard practices used for PRBC transfusions for early preterm infants in NICUs across the United States.

*Attachment B*: Email content to accompany survey.