2017

Assessing Interprofessional Teamwork and Performance in Delivery Room Neonatal Resuscitations

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Assessing Interprofessional Teamwork and Performance in Delivery Room Neonatal Resuscitations

By

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A dissertation submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Graduate Studies

College of Nursing

July 2017

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ACKNOWLEDGEMENTS

This entire dissertation process has been a period of intense learning for me. I have several individuals I would like to acknowledge, whose support and warm words of encouragement have been invaluable to me. First of all, I would like to thank my dissertation chair, Dr. Susan Newman, who has served as an "unofficial mentor" prior to becoming my chair throughout my tenure in the program. She has been an excellent facilitator through this journey, and has shared her experiences and knowledge with me, enhancing my learning along the way. Dr. Leonard Goldsmith, my content area expert committee member, has been supportive and knowledgeable during this process. An excellent clinician and mentor, Dr. Goldsmith has always exemplified professionalism in his daily clinical practice, as an educator, and as a mentor. Dr. Barroso graciously joined my committee late during the process, and has been a joy to work with. I am fortunate to have a committee member with such knowledge and experience with qualitative methodologies. It has been a privilege to work with this uniquely talented group of scholars.

I would also like to acknowledge Dr. Charlene Pope, who served for a period as my dissertation chair. She spent numerous hours mentoring and advising me regarding my writing, and my pursuit of my research topic on a global level. Because of her support, I was privileged to complete two mentored research projects through which I gained invaluable experience working with other nurse scholars from the University of Johannesburg, and the University of Zimbabwe. None of this would have been possible without her guidance and support.

I would like to acknowledge Dean Stuart and the rest of the MUSC faculty for recognizing my potential, and providing me with excellent preparation to embark on my journey as a nurse educator and scholar. Most people never learn what their calling is, and because of the opportunities I now have available, I have found my calling. After a long career at the bedside, I am embarking on a new journey educating tomorrow's nurses.

I would also like to acknowledge Alida DuPlessis, a fellow PhD candidate at the University of Johannesburg, who has been a source of support and inspiration for me. Assigned to guide me through the Ethics Committee process at the University of Johannesburg, Alida's commitment to scholarship was evident as she tirelessly worked with me as I worked with the UJ Ethics Committee, administrators and nurse clinicians whom I interviewed as part of my mentored research project. I look forward to working with her in South Africa on a neonatal resuscitation project in the future.

I would like to acknowledge my nurse colleagues and nurse manager who covered shifts for me, made sure I was able to attend residencies, and made sure I always had time off to do what I needed to do as I worked through the coursework. I would like to also thank all the physicians, neonatal nurses, neonatal nurse practitioners and respiratory therapists who participated in this research. Also I would like to thank the labor and delivery nurses who tirelessly agreed to be interviewed, even after working a long 12-hour shift. I would like to thank them for their words of encouragement and support.

I would like to acknowledge my employer, Thomas Jefferson University, Jefferson College of Nursing, for providing me the opportunity to teach and share my knowledge with tomorrow's nurses. The former dean, Dr. BethAnn Swan, and the interim

dean, Dr. Ann Phalen, have been overwhelmingly supportive in my new role as a faculty member as Jefferson, and as I complete this PhD journey. My nurse faculty colleagues have been a source of strength and support as I have traveled down this lonely dissertation road. Their support and words of encouragement have meant more than they will ever know.

The PhD cohorts of 2011 and 2012 have been a source of support since the beginning, with some lifetime friendships established along the way. I appreciated their intellectual curiosity, mentorship, and professionalism. I acknowledge their unwavering support, guidance, proofreading and professional advice during this journey.

I would like to acknowledge my parents, the late Mary Catherine Clary, and the late John Clary Jr. They made me believe I could achieve whatever I decided to achieve. They sacrificed so that I might have opportunities not afforded to them. My father, although talented and bright, never attended college and instead worked to support his struggling family, his 2 sisters, aunt, and mother. My mother received a substandard education in rural South Carolina, and wanted to attend college, but did not receive the necessary academic preparation. They sacrificed to give me the best education they could afford in Philadelphia for 12 years, and for this I will be eternally grateful. These sacrifices changed the trajectory of my life. I hope I can use the academic preparation afforded to me to make a difference in the lives of students and others as I am afforded new opportunities.

Lastly, I would like to acknowledge the unwavering support of my husband, Elfigio Freeborn Muronda. Known affectionately as Alf, he has been my number one cheerleader during this entire process. When I thought I had gotten in over my head, he

had endless words of encouragement. He tirelessly proofread many papers, numerous times, providing constructive feedback. Chipo and Alfie, and Farai my 3 children, have demonstrated flexibility and understanding during this period. I have witnessed a change of attitude about education from watching them as I embarked on this path. My daughter graduated from college last spring with over a 3.0 GPA, a son is currently working hard towards a film degree in Johannesburg and another son, Farai who has a strong career as an actuary in Johannesburg, who lives with his lovely family while looking out for his younger brother. I am so proud of them all! It is clear that they all view learning as a life-long experience that helps us grow. I am blessed to have such a lovely family, including my extended Zimbabwe family here in the United States, and in Zimbabwe. I love you, and I thank all of you for your support.

ABSTRACT

Purpose

The purpose of this dissertation was to explore the facilitators of, and barriers to, neonatal resuscitation to identify areas for improvement. First, an integrative review of measurement instruments for delivery room neonatal resuscitation simulations was conducted, followed by a qualitative study examining interprofessional neonatal resuscitation team member perceptions of facilitators and barriers to delivery room neonatal resuscitations. The first qualitative study informed the second qualitative study, an examination of the enablers and barriers to effective bag-mask ventilation as perceived by labor and delivery nurses.

Problem

Birth asphyxia continues to remain a cause of neonatal deaths worldwide (Te Pas, Somotka, & Hooper, 2016). Simulation is a potentially powerful means of maintaining competence in individual neonatal resuscitation skills and team performance (Halamek, 2016). However, a review of the literature revealed a lack of standardized measurement of outcomes related to simulation-based training (Clary-Muronda & Pope, 2016). Moreover, a paucity of research has been conducted to link simulation-based education programs, often costly to implement, with neonatal outcomes.

The specific aims of this dissertation were:

- **Aim1:** To conduct an integrative review of measurement instruments for delivery room neonatal resuscitation simulations

- **Aim 2:** To examine the facilitators of, and barriers to, delivery room neonatal resuscitation from the perspectives of interprofessional neonatal resuscitation team members
- **Aim 3:** To explore the barriers and enablers of bag-mask ventilation from the perspectives of labor and delivery nurses

Design

This research employs qualitative methodology to explore the barriers and enablers of effective delivery room neonatal resuscitation, using two qualitative studies, with the first study informing the second. The Theoretical Domains Framework (TDF), an intuitive guide to examine the barriers and enablers to implementation of best practices, was used to frame this research.

Findings

This two part qualitative study examining facilitators of, and barriers to, delivery room neonatal resuscitations revealed a skills deficit for labor and delivery nurses in bag-mask ventilation skills. Several contextual factors affected the ability of labor and delivery nurses to implement best practices in delivering bag-mask ventilation to newborns in the delivery room, ranging from individual factors such as comfort with skills, practice, and ability to use the algorithm to guide action in a timely fashion, to organizational factors such as staffing, equipment, and logistics.

Conclusion

The TDF provided a comprehensive guide to frame enablers and barriers to best practices in this understudied population. Standardized guidelines do not take into account the contextual factors that may impede the implementation of best practices.

Prior to intervention implementation, assessment of organization and population specific factors and consideration of such factors in designing interventions is more likely to promote a sustainable improvement in clinician practices and adherence to the Neonatal Resuscitation Program algorithm.

Keywords: neonatal, resuscitation, delivery room, interprofessional, team, qualitative, Theoretical Domains Framework

1. INTRODUCTION

1.1. Overview of Dissertation

Birth asphyxia continues to remain a cause of neonatal deaths worldwide (Te Pas, Somotka, & Hooper, 2016). Most neonates transition to life outside the uterus with little intervention at the time of birth; however 4-10% will require some assistance with establishing respirations (AAP, AHA, 2015). Delivery room neonatal resuscitations require prompt, well-coordinated interventions for optimal outcomes. While the importance of timeliness is well documented in the literature, evidence suggests that most delivery room neonatal resuscitations do not occur in accordance with the recommended timeline (McCarthy et al., 2013; McKinsey & Perlman, 2016). Simulation is a potentially powerful means of maintaining competence in neonatal skills, however, a review of the literature revealed a lack of standardized measurement instruments to determine clinician competence. Moreover, few studies have been conducted to link simulation-based education programs, often costly to implement, with neonatal outcomes.

The specific aims of this dissertation were:

- **Aim1:** To conduct an integrative review of measurement instruments appropriate for interprofessional neonatal resuscitation simulations
- **Aim 2:** To examine the facilitators for, and barriers to, delivery room neonatal resuscitation from the perspectives of interprofessional neonatal resuscitation team members to determine areas for improvement
- **Aim 3:** To qualitatively explore the barriers and enablers of bag-mask ventilation from the perspectives of labor and delivery nurses for the purpose of developing an intervention that will promote the enablers and minimize the barriers

The overall objective of this research was to identify the facilitators for, and barriers to, effective clinical practices in delivery room neonatal resuscitations to develop a targeted simulation-based intervention with the goal of improving neonatal outcomes. The overarching questions driving this research are*: (1) What do interprofessional neonatal resuscitation team members believe to be facilitators for, and barriers to, effective delivery room neonatal resuscitations? (2) What specific areas can be targeted for intervention to minimize the barriers and enhance the enablers of delivery room neonatal resuscitations?* The results of this research provide the foundation for the development of a multifaceted approach to intervention implementation, one that takes into account the multifactorial enablers and barriers to the implementation of best practices in delivery room neonatal resuscitations. The long-term goal of this research is to refine approaches to neonatal resuscitation education by using a theory-informed strategy to assess existing enablers and barriers for consideration in intervention development.

2. BACKGROUND AND PROBLEM STATEMENT

Neonatal resuscitation requires teams with a diverse set of skills to process large amounts of information quickly while working through complex algorithms to provide timely, case-appropriate care (Yamada, Yaeger & Halamek, 2015). Although the neonate represents the smallest, most fragile population in the hospital setting, retrospective observational studies have shown that errors in resuscitation in this population are common (Yamada, et al., 2015). Errors of commission in completing tasks such as positive pressure ventilation, intubation and chest compressions, are among the more common errors, and are potential sources of harm (Bennett, Finer, Halamek, Mickas,

Bennett, et al., 2016). In 1987, the American Academy of Pediatrics and the American Heart Association (AAP & AHA) developed standardized neonatal resuscitation training, the Neonatal Resuscitation Program (NRP). Although there has been an improvement in neonatal mortality rates, studies have shown that the error rate associated with adherence to the NRP algorithm still ranges from 16-55% (Fuerch, Yamada, Coelho, Lee, & Halamek, 2015). The American Academy of Pediatrics suggests more frequent training to ensure competency for interprofessional team members responding to delivery room neonatal resuscitations, but there is no specific recommendation for the frequency of such training (Bellini, 2016).

Simulation-based education is a prominent tool in medical education, and has been adopted for use in hospital-based continuing education programs to improve interprofessional team functioning (Cheng, Lang, Starr, Pusic, & Cook, 2014; Michael et al., 2014). Despite the increasing use of simulation in hospital-based education (Halamek, 2016), the benefits of such training in relation to outcomes are not well supported in the literature (Dadiz, et al., 2013; Finan et al., 2012; Rakshasbhuvankar and Patole, 2014). A concise understanding of the underlying problems surrounding delivery room neonatal resuscitations is necessary for the development of effective interventions aimed at improving team processes and patient outcomes (Yamada, et al., 2015). Sustainable improvements in team processes and patient outcomes are more likely to occur with specific targeted interventions that consider the barriers to best clinical practices (Michie, van Stralen, & West, 2011).

3. GAPS IN KNOWLEDGE

Although evidence supports an environment conducive to a culture of teamwork and collaboration, barriers exist to optimal team functioning, especially in situations where team members are diverse in knowledge and skill sets. A retrospective study by Yamada et al. (2015) examining 250 real-time neonatal resuscitations in the operative delivery room showed that 149 tasks (23%) were completed incorrectly, with 42 (28%) errors of omission, and 107 errors of commission (72 %). Although no systematic retrospective studies have been conducted to examine the relationship between neonatal resuscitation skills and clinical outcomes, existing evidence shows that errors during neonatal resuscitations, particularly in very low birth weight infants, can be devastating with poor neurodevelopmental consequences (Yamada et al., 2015).

The Neonatal Resuscitation Program has been instrumental in improving neonatal outcomes (Berger, 2012). However, studies have shown that individuals completing the course experience skill decay in only three to six months, although participants are only required to demonstrate competence through renewing certification every two years (Surcouf et al., 2013). A longitudinal cohort study by Mosley and Shaw (2013) revealed a deterioration of neonatal resuscitation skills three months after the NRP course. However, participants who participated in bi-yearly booster sessions retained both knowledge and skills (Mosley & Shaw, 2013). Simulation-based training, a central component of the NRP, can be an effective method of reinforcing individual skills, collaborative team skills, and overall team performance.

A prospective observational study by Trevisanuto et al. (2016) examined the perceived time of intervention in simulated delivery room neonatal resuscitations. The

research revealed an underestimated timing of key resuscitation interventions (Trevisanuto et al., 2016). Experts in neonatal resuscitation stress that aeration of the lungs is the most important step in neonatal resuscitation; yet, little attention is given to this crucial skill in neonatal resuscitation training. Notwithstanding the importance of bag-mask ventilation, the procedure is not without challenges such as difficulty obtaining an adequate seal, inconsistent tidal volumes, and airway obstruction, which can complicate or prolong resuscitation (Wilson, O'Shea, Thio, Dawson, & Boland et al., 2014). Wood et al. (2008), in a small study evaluating the effectiveness of improving technique with bag and mask neonatal ventilation, suggested that additional training in bag-mask ventilation will likely reduce the incidence of failed bag-mask resuscitation, simplifying some neonatal resuscitations. Since the Wood et al. (2008) study, there have been few studies focusing on the simple task of bag-mask ventilation. However, emerging evidence suggests that bag-mask ventilation is a skill for which both experienced and novice practitioners require frequent practice, outside of routine NRP training (Schilleman, et al., 2010; van Vonderen, Witlox, Kraaij & Pas, 2014; Wilson, O'Shea, Dawson, Boland, & Davis, 2014). Despite this evidence, standardized neonatal resuscitation training places little emphasis on establishing and maintaining competency in this skill. Deficits in bag-mask ventilation have the potential to complicate the simplest of delivery room resuscitations. However, targeted training in bag-mask ventilation skills may improve outcomes in delivery room resuscitations. Furthermore, a needs assessment identifying knowledge or skills deficits, followed by self-paced learning, is likely to enhance group learning in the larger NRP course (Meguerdichian et al., 2016).

4. DESIGN AND METHOD

This research employs qualitative methodology to identify the barriers to, and facilitators for, effective delivery room neonatal resuscitations from the standpoints of interprofessional team members for the purpose of targeting specific areas for improvement. A two-phase qualitative study, the first study investigated the problem of neonatal resuscitation broadly, from the perspectives of interprofessional team members. Findings from the first study informed the second study, narrowing the focus to labor and delivery nurses and positive pressure ventilation skills. Information from this qualitative research can be used as a guide to identify specific needs that may easily be improved with simulation-based training with a focus on targeted skills deficits. This research used a theory-informed approach, facilitated by the Theoretical Domains Framework (TDF), to identify the most salient issues encountered in clinical practice in neonatal resuscitation teams. Identification of existing barriers and enablers to implementing the best evidence-based practices is integral for sustainable improvements in clinical practices. A systematic method to examine the rationale of current practices, the TDF provides an intuitive approach to address key clinician behaviors to develop specific, targeted interventions to improve practice and patient outcomes (Boet et al., 2017; Craig et al., 2015; Debono et al., 2017).

5. KEY CONCEPTS/TERMS AND DEFINITIONS

5.1 Bag-Mask Ventilation

Bag-mask ventilation describes one method of ventilating the lungs by providing positive pressure ventilation when assistance with breathing is required. There are three

types of devices that can be used to deliver positive pressure ventilation, a self-inflating bag, a flow-inflating bag, or a t-piece resuscitator (AAP/AHA, 2015).

5.2. Cognitive Intrinsic Load

Cognitive intrinsic load is interactive material that contributes to a particular learning activity. The reduction of intrinsic load is associated with learning theories that emphasize enhancing the authenticity of learning by scaffolding learning task from simple to complex for long term memorization (Paas, Renkl, & Sweller, 2004).

6. THEORETICAL FRAMEWORK

An implementation science framework with evidence-based underpinnings for tailoring clinical interventions to meet the specific needs of the clinician, the TDF provided an intuitive guide to frame this research. The importance of evidence-based practice is well emphasized in the literature, however, behavior change in the clinical arena is a challenging and complex process affected by numerous variables (Cane, O'Connor, & Michie, 2012). Many individual and organizational change theories exist and have been applied in healthcare research however, no one theory has been identified as most suitable for behavior change (French et al., 2012). Developed by a team of health psychologists, health care researchers, and psychological theorists, the TDF was designed specifically for implementation behavioral research. Specifically created for use by interdisciplinary researchers, the Theoretical Domains Framework (TDF) creates a means to bridge the knowledge-practice gap by using theory to guide intervention implementation (Michie et al., 2005). The TDF addresses an extensive range of potential barriers and enablers that may impede or facilitate such interventions (French et al., 2012). The implementation of the TDF to achieve the desired clinician behavior changes

is systematic and transparent, involving a four step process of identification of the following: (a) targeted behaviors for change, (b) barriers and enablers to the proposed change, (c) change techniques or models of behavior to use, and (d) measurement and implementation of the change (French et al., 2012). Cane, O'Connor, and Michie (2012), conducted additional research to test the validity of the TDF using behavioral experts to sort theoretical constructs of the TDF resulting in a refined framework with a strong empirical base. A literature review by Francis, O'Connor and Curran (2012) identified 17 studies that used the TDF in empirical studies to guide health care clinician behavior changes. Moreover, transparency and the repeatability of the TDF process in behavior change implementation are identifiable strengths to the TDF, further supporting its use in this research.

7. BRIEF OVERVIEW OF MANUSCRIPTS

Manuscript Description

The first manuscript is an integrative review of the current literature to determine measurement instruments appropriate for measuring neonatal resuscitation team performance in simulations. Since a long-range goal of this research is developing an intervention that uses simulation as a means to improve care delivery and neonatal resuscitation skills, finding a well-established instrument to measure the effect of such training was necessary. However, most measurement instruments identified were not applicable to the neonatal population, lacked a team focus, or were specifically for use by physician-only teams (Clary-Muronda & Pope, 2016). Furthermore, few instruments were identified for use in delivery room neonatal resuscitation simulations, a unique, dynamic setting with team members with varying levels of skill sets. Even fewer

instruments were identified with adequate psychometric documentation. One instrument was identified that underwent appropriate psychometric testing, however the instrument was developed in 2006, requiring an update of the instrument (Lockyer at al., 2016).

The second manuscript described a qualitative study in which interprofessional team members were interviewed, following the TDF as a guide, to determine the facilitators for, and barriers to, effective delivery room neonatal resuscitations. According to the TDF, identification of targeted behavior for change is the first step. The behavior for change was assessed by the following question: Who needs to change what behavior? Answering this specific question facilitated the identification of a specific crucial skill with potential to improve clinical outcomes, positive pressure ventilation. Information from this study revealed a recurrent theme of a need for targeted positive pressure ventilation practice for labor and delivery nurses, often first responders to neonatal resuscitations. As stipulated by the TDF, the next step involved an exploration of the enablers and barriers to effective delivery of positive pressure ventilation, which laid the foundation for the third manuscript.

The third manuscript describes a qualitative study in which the enablers and barriers of effective positive pressure ventilation were examined from the perspectives of labor and delivery nurses. Using qualitative description, with a direct content analysis approach, the perceptions of labor and delivery nurses were explored in focus group interviews. The goal of the focus group interviews was to provide the foundation for a specific, targeted intervention that promotes the enablers for, and minimizes the barriers to, effective positive pressure ventilation by these crucial neonatal resuscitation team members.

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JOGNN

REVIEW

Integrative Review of Instruments to Measure Team Performance During Neonatal Resuscitation Simulations in the Birthing Room

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Keywords
birthing room
interprofessional
measurement
neonatal
resuscitation
simulation
social ecological model

ABSTRACT

Objective: To identify instruments appropriate to measure interprofessional team performance in neonatal resuscitation (NR), describe the validity and reliability of extant NR instruments, and determine instruments for use in interprofessional birthing room NR simulations.

Data Sources: The Cumulative Index to Nursing and Allied Health Literature, Ovid MEDLINE, Proquest, ScienceDirect, PubMed, and Scopus databases were searched.

Study Selection: We used inclusion and exclusion criteria and screened 641 abstracts from January 2000 through December 2014 for relevance to the research question. We reviewed 78 full-text primary research publications in English and excluded 37 publications not specific to pediatrics or neonatology. After in-depth review of the 41 studies that remained, we excluded additional studies if they did not have an interprofessional focus, include psychometric information, or include a measurement instrument. Ten publications met the inclusion criteria.

Data Extraction and Synthesis: Studies were reviewed, categorized, and scored to identify instruments to measure interprofessional team performance in simulations of birthing room NR. A social ecological model was used as a guide framework to identify multiple influencing factors at various levels that affect team performance. Ten instruments with documentation of validity and reliability for technical competence and team processes in interprofessional birthing room NR teams were identified.

Conclusion: Extant instruments rarely address the multiple factors that may impede interprofessional team performance in birthing room NR. It is necessary for researchers to engage in rigorous psychometric testing of measurement instruments to ensure their validity and reliability for interprofessional NR teams and consider tests or updates (if necessary) of extant instruments rather than the development of new instruments.

JOGNN, 45, 684–698; 2016. http://dx.doi.org/10.1016/j.jogn.2016.04.007

Accepted April 2016

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(Continued)

The authors report no conflict of interest or relevant financial relationships.

Most neonates will transition normally with little intervention and promotion of skin-to-skin contact and bonding (Dani et al., 2015). However, more than 400,000 neonates per year in the United States require assistance to establish ventilations at birth; less than 1% of all neonates require extensive resuscitation (Nahidi, Tavafian, Haidarzade, & Hajizadeh, 2014; Rich, Leone, & Finer, 2010). The first minutes of life are crucial for compromised neonates and necessitate timely intervention, team cohesion, and coordinated efforts for the best outcomes. Researchers demonstrated that effective teamwork improves quality of care in neonatal resuscitation (NR; Sawyer, Laubach, Hudak, Yamamura, & Pocrnich, 2013). Unfortunately, an effective team needs more than just a group of NR experts (Miller, Riley, Davis, & Hansen, 2008). A team that functions well in NR events in the birthing room requires an orchestration of skills from diverse team members, each with various skill levels and knowledge. Multiple factors affect team cohesion and can serve as facilitators or barriers to NR team functioning.

After the 2004 Joint Commission recommendation for improved collaboration and communication in perinatal teams, the Neonatal Resuscitation Program (NRP) developers identified a need to integrate behavioral skills and

teamwork into the NRP curriculum (Katakam, Trickey, & Thomas, 2012). To answer the call for better perinatal outcomes, many hospitals are developing simulation-based educational programs with the aim to improve care delivery. However, there are few effective measurement instruments with evidence of reliability and validity to assess team functioning and performance, especially in diverse interprofessional teams (Thomas et al., 2010). Although technical performance or team processes are evaluated in most studies of interprofessional teams, it has become apparent that both qualities together are required for better outcomes (Schmutz & Manser, 2013). In interprofessional NR, team performance and proficiency are highly dependent on social interaction among team members, which is in turn influenced by interpersonal, environmental, and organizational factors (Masiello, 2012). Although effective team competency in the management of NR events in the birthing room involves technical skills critical for optimal patient outcomes, measures to assess interprofessional team processes such as team performance and interaction are inconsistent (Masiello, 2012). Furthermore, reliability and validity have not been documented for many of the extant published measurement instruments for interprofessional team performance in resuscitation (Kardong-Edgren, Adamson, & Fitzgerald, 2010).

Purpose

The purposes of this integrative review were to (a) identify measurement instruments that are currently used to assess interprofessional teamwork technical functioning and team performance in NR in the birthing room, (b) describe the reliability and validity of the extant instruments, and (c) determine which of these instruments are appropriate for use in simulations of NR in the birthing room. To effectively address multiple factors in the health care setting, we used the McLeroy, Bibeau, Steckler, and Glanz (1988) application of a social ecological model (SEM) as the theoretical framework to guide this integrative review (Golden & Earp, 2012).

Background

Patient safety initiatives can benefit from an enhanced understanding of team processes and how to develop team functioning to improve performance. In 1999, the Institute of Medicine (IOM) identified the need for interprofessional training in the formative education of health care professionals with continued interprofessional education throughout team members' careers.

Measures to assess interprofessional team processes such as team performance and interaction are inconsistently reported in the literature.

In 2003, the IOM strongly suggested that interprofessional education initiatives would improve patient outcomes; however, health professional education remains discipline specific. Subsequently, Congress amended Title IX of the Public Health Service Act to designate the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research with the goal to improve patient safety and outcomes (IOM, 1999). In response to this directive, interprofessional educational programs that use simulation-based learning activities are in development in hospitals. Although the number of measurement tools for technical performance has increased exponentially, there are few instruments to appropriately measure interprofessional teamwork processes and team performance because of the lack of reliability and validity of these measurements (Jeffcott & Mackenzie, 2008).

Although evidence shows that simulation-based NR exercises improve team performance in simulation settings, the effect of simulation-based learning on interprofessional NR team performance during actual real-time resuscitations remains unknown. Furthermore, because of inconsistent determination of outcomes, little support of the effectiveness of simulation-based training exists in the literature (Dadiz et al., 2013; Rubio-Gurung et al., 2014). More research to explore the effects of interprofessional simulation-based education on interprofessional team processes is necessary to refine this educational strategy for translation of skills to the clinical area and improvement of patient outcomes. Clinical simulations are rapidly becoming central to interprofessional efforts to improve patient outcomes. In a meta-analysis of technology-enhanced simulation in pediatric educational studies, researchers found that few studies included an interprofessional learner group and patient care–related outcomes (Cheng, Lang, Starr, Pusic, & Cook, 2014). Moreover, most research on simulation-based learning in the various professions occurs in silos specific to the respective profession, and the authors of many of these studies rely on measurement instruments with minimal or no documented psychometric properties.

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Few measurement instruments can be used appropriately to measure interprofessional teamwork processes and interprofessional team performance because of the lack of reliability and validity of these measurements.

Despite the lack of psychometric documentation or psychometric testing in interprofessional populations, these studies form the foundation for simulation-based educational programs. Consequently, educational programs designed for an interprofessional population might not address the multiple factors that serve as barriers to effective teamwork functioning and therefore might not have a significant effect on patient outcomes. Although the need for rigorous instrument development processes and psychometric testing is apparent, researchers continue to develop measures with little attention to validity and reliability testing (DeVellis, 2012). NR is a high-stakes intervention that requires effective interprofessional teamwork based on the best current evidence for optimal patient outcomes (Jukkala & Henly, 2009). Currently, there are few extant measurement instruments with which to assess interprofessional team performance in quality improvement training initiatives and even fewer in NR (Sigalet et al., 2013).

Theoretical Framework

Although theoretical frameworks have not been consistently applied to simulation-based research, findings have been linked by the use of theory to guide the research process (Jeffries, 2014). Various components of health care systems can serve as barriers to effective teamwork and affect patient outcomes (Jeffcott & Mackenzie, 2008). With the application of a SEM, we were able to take a multifactorial approach to address individual, interpersonal, environmental, organizational, and policy factors that affect interprofessional NR team collaboration and performance (Weller, Boyd, & Cumin, 2014). It is especially important to consider multiple-level factors in birthing rooms, where the environment is often noisy, chaotic, and complex (Halamek, 2008).

Methods

Integrative reviews allow for inclusion of experimental and nonexperimental research to create a comprehensive understanding of a particular phenomenon (Whittemore & Knafl, 2005). Chosen for its comprehensiveness, the Whittemore and Knafl (2005) methodology was used to guide this integrative review. Stages include problem identification, literature search, data evaluation, and data analysis. Data were extracted and systematically ordered and summarized by categories in a matrix. After data evaluation, we used the McLeroy et al. (1988) variation of the SEM to compare the data and guide the examination of the findings. See Figure 1 for a presentation of the review process.

We searched PubMed, the Cumulative Index to Nursing and Allied Health Literature, Scopus, ScienceDirect, ProQuest, and Ovid Medline for the following keywords: *simulation, neonatal, team, resuscitation,* and *measurement.* Inclusion criteria consisted of the following: original and primary research analyses written in English in which nurses were part of the interprofessional team, more than one discipline was included, teamwork and performance were measured during a code or a simulation, measurement instruments were used in neonatal or pediatric populations, teamwork or team performance were evaluated quantitatively, and evidence of instrument psychometric testing was provided. Titles were reviewed for content, and abstracts of publications with relevant titles were selected for review. After review of the abstracts, publications were retained if the inclusion criteria were met. We used the Oxford Centre for Evidence-Based Medicine (2011) Levels of Evidence tool to guide this review and score publications in a matrix (see Table 1).

Results

After we screened for inclusion criteria, we were left with 10 studies with 10 instruments for review. We found an abundance of measurement instruments that may be used for neonatal and pediatric resuscitation simulations; however, for most of the instruments, comprehensive psychometric characteristics were not documented. For those modified from extant instruments, the psychometric characteristics of the revised instrument were not documented. Additionally, most studies were conducted within a single profession, and most occurred with physician teams. We used studies in which nurses were acknowledged in the development of the instruments. However, studies that included NR teams reflect actual team composition in the clinical area and may render results that are more likely to be applicable to birthing room NR teams.

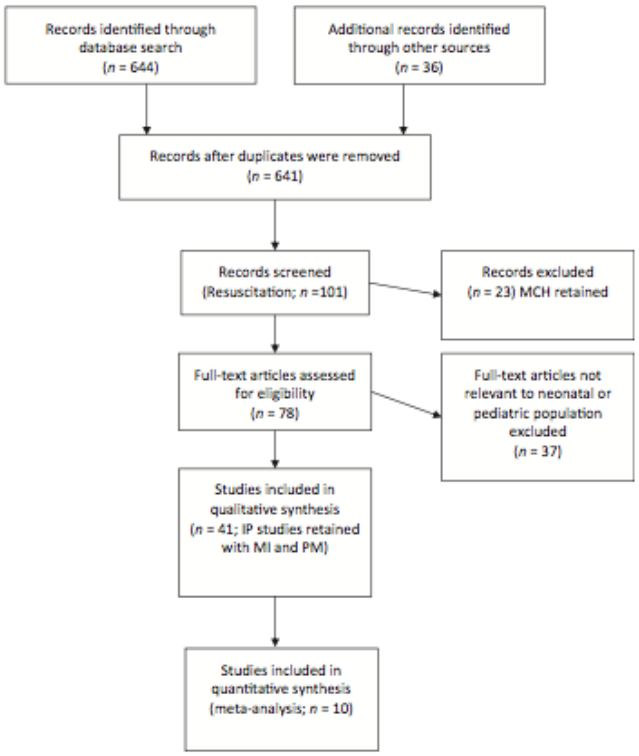

Figure 1. Search results. IP = interprofessional; MCH = maternal child health; MI = measurement instrument; PM = psychometrics.

Review of Instruments

We identified 10 instruments used to measure interprofessional team performance in NR simulations:

- Scoring Instrument for the Assessment of Neonatal Resuscitation Skills (van der Heide, van Toledo-Eppinga, van der Heide, & van der Lee, 2006)
- Neonatal Resuscitation Experience Index (Jukkala & Henly, 2007)
- Performance Checklist to Assess Neonatal Resuscitation Megacode Skill (Lockyer et al., 2006)
- Neonatal Resuscitation Simulation Self-Assessment Questionnaire (Amin, Aziz, Halamek, & Beran, 2013)
- Team Performance During Simulated Crisis Instrument (Calhoun et al., 2011)
- KidSIM Team Performance Scale checklist (Sigalet et al., 2013)
- Communication Item Performed by Obstetric and Pediatric Teams During Simulated Deliveries (Dadiz et al., 2013)
- TeamSTEPPS Teamwork Perceptions Questionnaire (T-TPQ; AHRQ, 2014)
- Collaboration and Satisfaction About Care Decisions (Baggs, 1994)
- Neonatal Resuscitation Index (Jukkala & Henly, 2009)

Five instruments were observer-rating checklists for team performance, and five were self-rating checklists for team performance.

Table 1: Instruments Used to Measure Team Performance During Neonatal Resuscitation Simulations

Instrument Name	Concept Measured/ SEM Level Addressed	Number of Items	Item Scaling	Instrument Scoring	Validity/Reliability Quality Score[a]
Scoring Instrument for the Assessment of Neonatal Resuscitation Skills (van der Heide et al., 2006)	Neonatal resuscitation skills in a team setting/individual	44	Binary options: *Yes/No* *Yes* = 2 points, *No* = 0 points 8 subscales	2 points for every correct decision/proper procedure Points awarded for subheadings of bag/mask ventilation, intubation, chest compressions, drugs, and volume expansion, multiplied by 3 Sum of awarded points divided by maximum possible points and multiplied by 100 for score as percentage Maximum possible sum score: 100%	Validity: face/content validity Construct validity: pre-/posttest scores Reliability: rated twice by same rater in 2-week intervals Reliability sum score: intrarater = 0.95, interrater 0.77 Kappa coefficients below 0.50 for 18 items Quality score: 2b
Neonatal Resuscitation Experience Index (Jukkala & Henly, 2007)	Comfort with resuscitation skills and estimation of frequency of performance of specific NR skills during previous year/ individual	19	5-point Likert-type scale ranging from 1 to 5	Scoring of skills on a 5-point scale 1 = *Very uncomfortable*, 5 = *Very comfortable* Frequency measured using 3-point scale: 0 = *Never*, 1 = *Occasionally* (1–3 times), 2 = *Often* (4 or more times)	Validity: content validity assessed by panel of four expert advanced practice nurses/ university faculty Reliability: Cronbach's α = .95. Corrected item total test correlations ranged from .30 to .82. One item with corrected item total score correlation < .50 was removed from instrument Quality score: 2b
Performance Checklist to Assess Neonatal Resuscitation Megacode Skill (Lockyer et al., 2006)	Neonatal resuscitation skills during simulated neonatal code/ individual, interpersonal, organizational, societal	20	Thurston scaling; 0 = *Not done*, 1 = *Partially done*, 2 = *Correctly done*	Raw scores for each item ranged from 0 to 2 Scores converted to value between 0 and 1 Total converted Megacode score = sum of raw scores across all 6 lessons and divided by the highest possible score per lesson Total summed Megacode scores ranged from 7 to 40, with a mean of 36.02 (*SD* = 4.68)	Validity: checked for content validity by Neonatal Resuscitation Program Steering Committee members and by 822 interprofessional volunteers recruited online Criterion-related validity: correlation of Megacode scores with Megacode questionnaire

(Continued)

Table 1: Continued

Instrument Name	Concept Measured/ SEM Level Addressed	Number of Items	Item Scaling	Instrument Scoring	Validity/Reliability Quality Score[a]
				Total converted Megacode scores ranged from 0.35 to 1.00, with a mean of 0.94 (*SD* 0.09).	Construct validity: linear regression Reliability: internal consistency Cronbach's α in lesson scores ranging from .63 to .70, with an overall Cronbach's α of .70. Grouped by lessons, low but significant correlations found with converted subscale scores of the MCQ (lessons 1–4: $r = 0.23$, $p < .01$; lessons 1–5, $r = 0.24$, $p < .01$; lessons 1–6, $r = 0.24$, $p < .01$; lessons 1–7, $r = 0.25$, $p < .01$) Quality score: 1b
Neonatal Resuscitation Simulation Self-Assessment Questionnaire (Amin et al., 2013)	Respondent perceptions about the degree of knowledge skills and confidence in neonatal resuscitation skills/individual, interpersonal	18	Likert-type 5-point scale ranging from *Strongly agree* to *Strongly disagree*	Scoring of instrument not reported Perceptions of teamwork did not significantly increase $t(28) = 1.64$, $p = .11$	Validity: content validity based on input from content experts Using pretest data,18 items were subjected to principal component factor extraction with rotation (type not specified) reliability reported high Reliability: internal reliability Cronbach's α of .75 Quality score: 3b
Multi-rater Team Performance During Simulated Crisis Instrument (TPDSCI; Calhoun et al., 2011)	Resuscitative competency and self-appraisal using multirater and gap analysis/individual	5	Likert-type scale ranging from 1 to 5	1 = *Poor*, 2 = *Fair*, 3 = *Good*, 4 = *Very good*, 5 = *Excellent* Competency-specific scores calculate individual faculty scores for each competency	Validity: content validity assessed by 2 experts Reliability: interrater reliability Overall Cronbach's α of .72 Cronbach's α for averaged scores ranged between .72 and .87

(Continued)

Table 1: Continued

Instrument Name	Concept Measured/ SEM Level Addressed	Number of Items	Item Scaling	Instrument Scoring	Validity/Reliability Quality Score[a]
				Overall score determined by first averaging the individual competency scores for each faculty rater and then averaging this score among all faculty raters Average scores of 3 (*Good*) or greater were defined as meeting/exceeding expectations; scores of less than 3 (*Poor* or *Fair*) were defined as needing improvement Gap analysis calculated by subtracting the self-score for each competency and for the overall resuscitation from the corresponding average score Gap of 0.5 cut-off for significance; gap of 0.5 or greater was defined as self-underappraisal, and a gap of -0.5 or less was defined as self-overappraisal	ICC for professional domain = 0.22 Overall ICC for TPDSCI = 0.82 Gap analysis showed significant gaps among all competencies Quality score: 3b
KidSIM Team Performance Scale checklist (Sigalet et al., 2013)	Team performance, leadership, roles, responsibilities, communication, situational awareness, resource use, and patient-centered care/individual, interpersonal	12	5-point behavioral indicator scale 3 subscales: Roles, Communication, Patient-Centered Care	5 = *Optimal performance* Maximum possible score = 60	Validity: exploratory factor analysis Subscales developed based on factor analysis: communication (6 items, 27%–6% variance, α = .84); roles and responsibilities (5 items, 27.4% variance, α = .86); and patient-centered care (1 item, 10.5% variance) Reliability: Overall α = .90 Quality score: 3b

(Continued)

Table 1: Continued

Instrument Name	Concept Measured/ SEM Level Addressed	Number of Items	Item Scaling	Instrument Scoring	Validity/Reliability Quality Score[a]
Interdisciplinary simulation-based training to improve birthing room communication (Dadiz et al., 2013)	Communication between obstetric and pediatric teams in the delivery room: individual, interpersonal, organizational	20	5-point Likert-type scale	Scores reported as medians with the interquartile range as medians	Validity: content validity, 5-member expert team Construct validity per standards for educational/psychological testing Reliability: Cronbach's α = .80, .85, .81, and .82 for years 1, 2, 3 and all, respectively For rater ICC, values and 95% confidence intervals in each year: 0.88 in Year 1 [0.85, 0.95], 0.96 in Year 2 [0.91, 0.98], 0.96 in Year 3 [0.89, 0.99], and 0.95 in all years [0.91, 0.97] Quality score: 2b
TeamSTEPPS Teamwork Perceptions Questionnaire (Agency for Healthcare Research and Quality, 2014)	Individual perceptions of group-level team skills and behavior: individual, interpersonal, organizational	20	Likert-type scaling 5 subscales with 4 items each: Team Structure, Team Leadership, Mutual Support, Situation Monitoring, and Communication	Subscale item responses coded as following: 5 = *Strongly agree*, 4 = *Agree*, 3 = *Neutral*, 2 = *Disagree*, and 1 = *Strongly disagree* Two items testing discriminant validity, perceptions of self-esteem and control over practice, were scored as 3 = *High*, 2 = *Medium*, and 1 = *Low*	Validity: Content validity review by expert team; cognitive interview testing and divergent validity tested by correlating to another validated instrument, the Hospital Survey on Patient Safety (r = 0.60–0.81) Construct validity: factor analysis Reliability: Cronbach's α for 5 constructs with 7 items per construct ranged from .89 to .95; construct intercorrelations ranged from .57 for team structure and communication to .79 for situation monitoring/mutual support Quality score: 1b

(Continued)

Table 1: Continued

Instrument Name	Concept Measured/ SEM Level Addressed	Number of Items	Item Scaling	Instrument Scoring	Validity/Reliability Quality Score[a]
Collaboration and Satisfaction About Patient Care Decisions (CSPCD; Messmer, 2008; original developer: Baggs, 1994)	Nurse–physician collaboration in making patient care decisions/ interpersonal, organizational	7	7-point Likert-type scale ranging from 1 to 7; 1 = *Strongly disagree*, 7 = *Strongly agree*	7-point-scale Total possible scores range from 7 (lowest possible) to 49 (highest possible)	Validity: Criterion-related validity: large correlation (r = 0.87) of global collaboration question with other 6 critical attribute items Quality score: 1b
Neonatal Resuscitation Index (NRI; Jukkala & Henly, 2009)	Knowledge about neonatal resuscitation/individual, organizational	26	Descriptive correlational comparison design	Scored as a classroom test *Unsure* responses coded as incorrect Item difficulty calculated as proportion of responses answered correctly Indexed using correct item/total score—point biserial correlations Item responses calculated and tallied and corrected item total test score correlations estimated	Validity: Classical Test Theory (Allen & Yen, 1979) NRI content validity, convergent validity Internal consistency reliability: Cronbach's α of .73 in prior sample (where psychometric testing was conducted), .74 in current sample Interrater reliability reported as exemplary, no data provided Nurses: correlations with knowledge and experience greater than correlations with knowledge Physicians: knowledge moderately correlated with comfort, not recent skill performance Quality Score: 2b

Note. ICC = intraclass correlation coefficient; MCQ = multiple choice questionnaire; SD = standard deviation; SEM = social ecological model.
[a]The Oxford Centre for Evidence-Based Medicine (2011) Levels of Evidence tool was used to score publications.

Scaling and Scoring

The 10 instruments contained Likert-type scales, semantic differential scales, or Guttman scales with binary options (DeVellis, 2012). The number of items in each instrument ranged from 9 to 20. Two instruments were used to measure team behaviors in NRs (AHRQ, 2014; Jukkala & Henly, 2009), two instruments were used to measure individual competencies in NR (Lockyer et al., 2006; van der Heide et al., 2006), two instruments were used to measure self-appraised performance in NR (Calhoun et al., 2011; Jukkala & Henly, 2007), one instrument was used to measure NRP instructor perception of debriefing for NR in simulations (Amin et al., 2013), one instrument was used to measure communication in NR (Dadiz et al., 2013), and one instrument was used to measure collaboration during life-threatening emergencies in pediatric resuscitation simulations (Baggs, 1994; Messmer, 2008). In most studies, researchers used the instruments as originally developed. In one instance, however, researchers used an instrument that was modified for use in the study (Messmer, 2008). In another, researchers combined eight items from two previously published instruments and added four new items (Sigalet et al., 2013).

Methods of scoring varied from the calculation of raw scores for the entire instrument to calculation of scores for subcategories. Van der Heide et al. (2006) discussed several limitations in the scoring of the instrument used in their study, such as the need to adjust the items for a simulation setting, variance in scenarios, and low fidelity of the simulator. These limitations required an adjustment of the scoring with the elimination of seven items. Other variables that affected instrument scoring included poor visualization of skill performance, use of only one rater, and changes in checklist scores (Dadiz et al., 2013; van der Heide et al., 2006).

Validity

All of the studies contained information about validity; face and content validity were most commonly addressed. Some researchers used systematic methods to determine content validity (AHRQ, 2014; Baggs, 1994; Dadiz et al., 2013; Lockyer et al., 2006). Factor analysis was used to support construct validity by some researchers (AHRQ, 2014; Amin et al., 2013; Baggs, 1994; Sigalet et al., 2013). In one study, a principal component extraction was performed during the development of the Neonatal Resuscitation Simulation Self-Assessment Questionnaire on predata, which resulted in five factors with total explained variance of 87.02% (Amin et al., 2013). Baggs (1994) performed a principal component factor analysis in the development of the Collaboration and Satisfaction About Care Decisions instrument to confirm that the factors supported the critical aspects of collaboration. The factor analysis confirmed the presence of one factor regarding collaboration that explained 75.0% of the variance and factor loadings that ranged from 0.83 to 0.93 (Baggs, 1994).

Sigalet et al. (2013) supported construct validity of the KidSIM Team Performance Scale checklist by performing an exploratory factor analysis, which resulted in a three-factor solution that accounted for 65.5% of the variance. The findings of Sigalet et al. (2013) supported the measure as a two-dimensional instrument to measure team structure and communication as underlying constructs of team performance. The AHRQ (2014) supported convergent validity of the TeamSTEPPS instrument by comparing it with the AHRQ Hospital Survey on Patient Safety (Henriksen, Battles, Keyes, & Grady, 2008) in addition to factor analysis. Lockyer et al. (2006) used criterion-related validity by correlating scores of the Performance Checklist to Assess Neonatal Resuscitation Megacode Skill during the developmental stages of the instrument with the Megacode questionnaire, using a linear regression to determine if sociodemographic characteristics had a significant effect on findings. The linear regression analysis showed that ratings were not significantly affected by the demographic characteristics, which supported the use of the instrument across settings (Lockyer et al., 2006). Baggs (1994) supported concurrent validity by using criterion-related validity to correlate the instrument with a similar measure and additionally used predictive validity to assess the ability of the instrument to measure the same construct reliably in the future.

Reliability

Nine of the studies reviewed contained an explanation of how reliability of the instrument was supported, and authors reported acceptable reliability values. Most reported internal consistency, with Cronbach's alpha values that ranged from .72 to .95 (AHRQ, 2014; Amin et al., 2013; Calhoun et al., 2011; Dadiz et al., 2013; Jukkala & Henly, 2007; Lockyer et al., 2006; Messmer, 2008; Sigalet et al., 2013; van der Heide et al., 2006). Cronbach's alpha values of greater than

.70 are considered acceptable (Tavakol & Dennick, 2011). Most of the researchers supported interrater reliability with values of .70 or greater, which is considered acceptable. Values of greater than .80 indicated good agreement (Hallgren, 2012). Cohen's kappa coefficients ranged overall from .70 to .90. Van der Heide et al. (2006) reported significantly lower Cohen's kappa coefficients, with values less than .50 for 18 items. They reported difficulty in the assessment of certain items on videotape, such as medication doses, correct mask size choice, and adequacy of ventilations, as potential cause for the lower interrater reliability values (van der Heide et al., 2006).

Discussion

Although some instruments were identified with well-documented psychometric properties directly applicable to NR, these instruments were developed in 2006 and 2007 before major changes in NR guidelines and do not reflect important aspects of these recent changes (Jukkala & Henly, 2007; Lockyer et al., 2006; van der Heide et al., 2006). However, these instruments were included in this review because they comprise the few instruments found with adequate psychometric data created specifically for use in NR simulations. Some of the authors used checklists to assess performance (Katheria, Rich, & Finer, 2013; van der Heide et al., 2006), but these checklists only show whether a task was initiated rather than the quality of performance. Because simulation-based training activities are used to improve team performance, more emphasis is needed on the degree to which the task is performed correctly and how the team works collaboratively to deliver the best care possible (van Schaik, Plant, Diane, Tsang, & O'Sullivan, 2011).

Of the instruments reviewed, the T-TPQ has undergone the most rigorous testing; however, The T-TPQ does not address the unique challenges of interprofessional NR, because it is a universal instrument with a global approach to team functioning (AHRQ, 2014). Use of this instrument is supported by extensive validity and reliability testing, and it has been deemed generalizable in many different settings, including the neonatal setting (AHRQ, 2014; Sawyer et al., 2013). Despite the strengths of this instrument, the T-TPQ rates only perceptions of teamwork. Another TeamSTEPPS instrument designed for observer ratings, the Team Performance Observation Tool, is used to rate the overall team, rather than individual team members, but it has not undergone the same extensive testing and use in the neonatal population as the T-TPQ (AHRQ, 2014; Sawyer et al., 2013).

The Dadiz et al. (2013) instrument was developed for use in NR; however, it addresses one aspect of birthing room NR: communication of vital information to the neonatal team in high-risk births. Although this aspect is important, other components of interprofessional NR affect neonatal outcomes in the birthing room and necessitate a broader view of interprofessional teamwork and collaboration during births.

Few NR measurement instruments addressed the unique challenges of NR in the birthing room, such as the variety of NR interprofessional team composition. Continuous changes in the composition of team leadership in a complex and dynamic environment, with pressure intensified by emotional family members, can produce high levels of stress in interprofessional team members (Anderson & Warren, 2011; Manser, 2009).

Some of the instruments in the studies reviewed used a crisis resource management framework (Calhoun et al., 2011; Sigalet et al., 2013). Although this framework has proven successful in industries such as aviation, this theoretical approach to interprofessional teams often involves assessments that are labor intensive and that focus on the skills of the leader (van Schaik et al., 2011). An important limitation of the crisis resource management framework is the omission of important human factors that impede teamwork and collaboration, such as team membership, varied skills, stress, and familiarity with environment (e.g., knowledge of where supplies are located; Norris & Lockey, 2012). Alternatively, researchers who design studies to examine multiple potential factors that affect interprofessional team performance should also consider human factors in addition to leadership and technical skills (Norris & Lockey, 2012).

Of the instruments reviewed, the Lockyer et al. (2006) instrument had the most extensive psychometric testing specific to the neonatal population, including review by 822 NR experts in addition to members of the NRP Steering Committee. Additionally, Lockyer et al. (2006) addressed the multidimensional needs of the diverse interprofessional team by including nurses, physicians, and respiratory therapists in the process of the creation of the instrument. However,

the instrument was created based on guidelines that are now obsolete because updates in evidence-based guidelines were released by the American Academy of Pediatrics and the American Heart Association in 2015.

Updates to extant instruments are needed to include current evidence-based practices in addition to further psychometric testing to support continued use.

Application of a SEM to Interprofessional Education in Neonatal Resuscitation

Consideration of multiple factors in planning interprofessional team education programs is essential for the development of sustainable interventions that may improve patient safety and outcomes (van Schaik et al., 2011). The McLeroy et al. (1988) variation of the SEM provides a framework to systematically address multiple-level factors that depend on interprofessional teamwork and could impede the status of the neonate: the individual factors, interpersonal processes, organizational factors, societal factors, and public policy.

Individual. Individual-level factors that affect NR team collaboration and performance include personal beliefs about hierarchical relationships within health care teams, individual skill competence, knowledge, and experience level. Simulation-based mock NRs provide an opportunity for skill review and practice for infrequently encountered scenarios and thereby address individual-level factors.

Interpersonal. Interprofessional teams that respond to NRs in the birthing room undergo continuous changes in composition and consist of interprofessional team members of diverse backgrounds and cultures. In such diverse teams, one barrier to effective collaboration is the lack of familiarity with the various skill levels of individual team members (Ostergaard, Dieckmann, & Lippert, 2011). Factors that impede teamwork and collaboration of an interpersonal nature include hesitation to stop incorrect behavior, lack of effective communication skills, incomplete or insufficient handover report to interprofessional team members, and psychological barriers (Weller et al., 2014). Preconceived notions, varied interpretations, cultural differences, and environmental distractions can further hamper communication in interprofessional teams and render teamwork less effective (Gephart & Cholette, 2012).

Organizational. Organizational factors that affect interprofessional team performance include barriers to communication and information sharing, equipment issues, lack of interface of electronic health record software, and frequent changes in primary nurse assignment (Weller et al., 2014). These organizational shortfalls can be improved with regularly scheduled interprofessional simulation-based training sessions across departments, team-based debriefings to compare perceptions with practice, and interdepartmental collaboration to improve team processes.

Societal. Societal-level factors include the stereotyping of professional roles that occurs in media such as television and entertainment. More realistic portrayals of interprofessional teams in media that include team approaches to the management of patient care will likely affect policy formation, because legislative decisions about health policy are decided by political leaders with little background in health care.

Policy. In a study to examine barriers to simulation in continuing medical education for anesthesiologists, one need expressed was the creation of policy to promote simulation-based learning activities in the practice setting (Savoldelli et al, 2006). Since then, the IOM has recommended the development of well-designed research studies with interprofessional groups that are linked with patient outcomes, particularly in continuing education (IOM, 2015). Such research requires measurement instruments with well-documented psychometrics that are appropriate for use in interprofessional teams (IOM, 2015). Advocacy for policies to support interprofessional continuing education aligns with IOM recommendations for improvements in interprofessional collaboration, and simulation-based learning promotes a culture of safety.

Limitations

In this review, we examined only measurement instruments with documented psychometric properties in interprofessional NR teams. However, numerous instruments were identified that may be appropriate for use by NR teams if appropriately tested and deemed psychometrically sound.

Implications

Although many hospitals and health care organizations are initiating simulation-based interprofessional NR education programs, it is necessary to first determine the appropriateness of the instrument to measure educational outcomes and the transferability to neonatal outcomes. Interprofessional studies focused on the improvement of current patient care processes require measurement instruments that address the unique challenges of complex, diverse, interprofessional team members. Measurement instruments with well-documented psychometric characteristics in one particular profession may not be generalizable to diverse interprofessional team members. We recommend an update to the Lockyer et al. (2006) instrument using a systematic, interprofessional approach to include the newest evidence-based guidelines to answer the call for a well-designed NR instrument for interprofessional use. Furthermore, psychometric testing of any instrument proposed for use in NR is critical to determine the usefulness of the instrument to measure the construct under examination (DeVon et al., 2007). Ultimately, the goal is an improvement in patient outcomes, which can be determined only by reliable, appropriate instruments that are related to outcomes.

Conclusion

The objectives of this review were to identify instruments appropriate to measure interprofessional team performance in NR, describe validity and reliability of existing NR instruments, and determine instruments for use in interprofessional birthing room NR simulations. We identified several potential instruments for use in birthing room NR simulations; however, most of the instruments that have undergone the most vigorous psychometric testing are outdated. Extant instruments need to be updated to include current evidence-based practices in addition to further psychometric testing to support continued use. Development of a new instrument is an alternative option to provide a more comprehensive assessment that encompasses the multiple SEM factors that may affect interprofessional team functioning. However, vigorous reliability and validity testing of newly developed instruments is necessary to ensure that the instrument meets the diverse needs of interprofessional NR teams. In addition, outcomes research can provide useful information about the effects of simulation-based education on neonatal outcomes.

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1.2. Interprofessional team member perceptions of delivery room neonatal resuscitations

A qualitative descriptive study

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Call outs:

To achieve optimal neonatal outcomes, a concise understanding of the underlying problems surrounding delivery room neonatal resuscitations is necessary (page 4)

An overarching theme identified in this study was the importance of timely implementation of positive pressure ventilation in the newborn (page 14)

Labor and delivery nurses should be adequately prepared to initiate positive pressure ventilation to avoid a more complex, prolonged resuscitation (page 17)

Keywords: neonatal, resuscitation, delivery room, interprofessional, team, qualitative

Abstract

Objective: To explore interprofessional team member perceptions of facilitators of, and barriers to, effective neonatal resuscitations in the delivery room setting using the Theoretical Domains Framework and the McLeroy et al. variation of the Social Ecological Model.

Design: Qualitative research; qualitative description.

Setting: Community Hospital in the northeastern United States.

Methods: Semi-structured interviews were conducted and the data were analyzed using a direct content analysis approach using the McLeroy et al. (1988) version of a social ecological model as a guide.

Participants: Purposive sampling of 12 interprofessional delivery room neonatal resuscitation team members comprised of nurse midwives, neonatal nurse practitioners, neonatologists, nurses, and respiratory therapists.

Results: Several factors were identified as critical to optimal team performance in delivery room neonatal resuscitations such as remaining calm, defining clearly established roles, engaging in clear communication and adhering to established neonatal resuscitation guidelines. An overarching theme that emerged was the importance of establishing effective and timely bag and mask ventilation. Several labor and delivery nurse participants reported a skill deficit in positive pressure ventilation of the neonate.

Conclusion: Continuing education in neonatal resuscitation skills for team members may improve team confidence and competence in tasks essential for effective resuscitation of the neonate. An intervention specifically for labor and delivery room nurses aimed at

improving positive pressure ventilation skills may be beneficial. Additional research is necessary to link educational initiatives to patient outcomes.

Precis: Findings from this qualitative study identify a targeted area for behavior change, bag-mask ventilation for labor and delivery nurses.

Introduction

Interprofessional (IP) teams respond to neonatal resuscitations in the delivery room on a daily basis. While most newborns will require little or no intervention at the time of birth, approximately 10% will require some assistance, with 1% requiring extensive resuscitation at birth (American Academy of Pediatrics, 2016). Neonatal resuscitation requires teams with a diverse skill set to process large amounts of information in a short amount of time while working through complex algorithms providing case-appropriate care (Yamada, Yaeger & Halamek, 2015). Although the neonate represents the smallest, most fragile patient in the hospital setting, retrospective observational studies have shown that errors in resuscitation in this population are common (Yamada et al., 2015). Errors of commission in completing tasks such as positive pressure ventilation, intubation and chest compressions, are among the more common errors, and are potential sources of harm (Bennett et al., 2016). Moreover, management of the care of the neonate in the delivery room setting is difficult to audit during resuscitation due to the fluidity of the resuscitation team and the chaotic environment (Halamek, 2008). To achieve optimal neonatal outcomes, a concise understanding of the underlying problems surrounding delivery room neonatal resuscitation is necessary for the development of effective interventions aimed at improving team processes and patient outcomes (Yamada et al., 2015).

In 1987, the American Academy of Pediatrics and the American Heart Association (AAP & AHA) developed a standardized neonatal resuscitation training program (NRP). While neonatal mortality rates have improved since the implementation of NRP training, studies have shown that the error rate associated with non-adherence to

the NRP algorithm ranges from 16-55% (Fuerch, Yamada, Coelho, Lee, & Halamek, 2015). Extremely preterm infants requiring chest compressions in the delivery room have an increased risk of intra-ventricular hemorrhage, poor neurodevelopmental outcomes, and mortality (Fuerch et al., 2015; Yamada et al., 2015). Although the AAP suggests frequent training to ensure competency for IP team members responding to delivery room neonatal resuscitations, there is no specific recommendation for the frequency of such training (Bellini, 2016). While simulation-based training is rapidly being adopted and implemented in hospital-based continuing education programs, the evidence supporting the impact of such training on clinical practice is lacking. Additional research is necessary to determine neonatal team training priorities and preferred strategies for simulated NRP training (Rubio-Gurung et al., 2014). The purpose of this study was to investigate IP team members' perceptions of the facilitators of, and the barriers to, effective IP team collaboration during delivery room neonatal resuscitations.

Theoretical Frameworks

Theoretical Domains Framework

This line of research is informed by the Theoretical Domains Framework (TDF). The importance of evidence-based practice is well described in the literature; however, behavioral change is a challenging and complex process determined by numerous variables and factors (Cane, O'Connor, & Michie, 2012). Many individual and organizational change theories exist and have been applied in healthcare research. However, no single theory has been identified as the most suitable for behavior change intervention implementation (French et al., 2012). Specifically created for use by interdisciplinary researchers, the TDF creates a means to bridge the knowledge-practice

gap by using theory to guide intervention implementation (Michie et al., 2005). Designed to answer a need for an explicit, methodological, theory-informed guide for intervention implementation, the TDF was developed to address an extensive range of potential barriers and process enablers that may impede or facilitate such interventions (French et al., 2012). Selected as a transparent and evidence-based approach to intervention development, the TDF encompasses the everyday challenges of the bedside practitioner for the purpose of developing an intervention that may facilitate sustainable behavior change. Use of the TDF for intervention implementation involves a four-step process for identification of the following: (a) targeted behaviors for change, (b) barriers and enablers to the proposed change, (c) change techniques or models of behavior to use, and (d) measurement and implementation of the change (French et al., 2012). This study addresses the first two steps in the TDF process, identification of the targeted behaviors for change, and the identification of potential barriers and enablers through the lens of the Social Ecological Model.

Social Ecological Model

McLeroy et al.'s (1986) Social Ecological Model for Health Promotion, a highly adaptable model to explore factors influencing behavior, posits that patterned behavior is determined by the following five factors: (a) intrapersonal factors which include individual characteristics such as attitudes, behaviors, skills, and knowledge, including individual developmental history; (b) interpersonal processes which involve informal and formal social groups and social support systems including family, work groups, and friendships; (c) institutional level factors that encompass institutions with organizational characteristics with both formal and informal rules for operation; (d) community level

factors which include the relationships within organizations within the institution, including informal networks with defined boundaries; and (e) public policy level factors which include laws on the local, state, and national levels. Multiple variables within health care organizations can serve as barriers to effective care delivery, adversely affecting patient outcomes (Jeffcott & Mackenzie, 2008). The SEM facilitates a multifactorial approach to the various levels of care delivery (Weller, Boyd, & Cumin, 2014). The results from this study may help inform the development of interventions to promote collaborative IP teamwork behaviors during delivery room neonatal resuscitations and integrate specific strategies to address barriers and enablers to these behaviors.

Methods

Setting and Participant Recruitment

Following IRB approval, we recruited labor and delivery room nurses, neonatal intensive care nurses, neonatologists, neonatal nurse practitioners, and respiratory therapists with the minimum one years experience working in the study setting. Individuals who met the inclusion criteria were recruited from a community hospital (approximately 6000 births/year) in the Northeast region of the United States using purposive sampling to represent an IP population consisting of 12 IP team members. Participants were recruited in person and given a study information sheet describing the study and the required time commitment.

Data Collection and Analysis

Semi-structured, key informant interviews were conducted and analyzed using methods of qualitative description, as described by Sandelowski (2000). Selected for its

naturalistic underpinnings, qualitative description is a valuable method that presents the facts by remaining close to the surface of the words rather than delving into the more interpretive realms of other methodologies such as grounded theory, phenomenology, and ethnography (Sandelowski, 2000). Semi-structured interview questions (see Table 1) were used to ask participants to describe IP team collaboration, as well as facilitators for and barriers to, team functioning in delivery room resuscitations. Key questions were used to facilitate the elicitation of data with probing questions for clarification. The interviews ranged from 20 minutes to 40 minutes in length, and were conducted in a private location at the preference of the participants or by phone. Interviews were audiotaped and transcribed verbatim with concurrent memo writing to facilitate the data analysis process. Qualitative content analysis, a method of visual representation of the data for the purpose of summarization of the data, is typically the data analysis strategy of choice in qualitative description (Sandelowski 2000). A directed content analysis approach provided structure to our data analysis by using existing theory or prior research to organize and categorize the data (Hsieh & Shannon, 2005). The McLeroy version of the Social Ecological Model guided the coding and categorization of the data in this study (1988).

Data were organized in the following SEM levels: individual, interpersonal, organizational, societal, and policy. The direct quotes were organized using the various SEM levels, with the quotes representing the verbatim words of the participants.

Results

An ethnically diverse population comprised the study sample (see Table 2). Twelve neonatal resuscitation team members consented to participate in the interview

process, including six labor and delivery nurses, two neonatal nurse practitioners, one neonatal nurse, two nurse midwives, and one neonatologist.

Individual Level Factors

Individual level factors affecting IP team performance included personal perceptions of responsibilities and roles in neonatal resuscitation, individual stress responses to the urgency of neonatal resuscitation, and fear of performing positive pressure ventilation incorrectly. Participants from all professional groups stressed the importance of following the standardized steps of neonatal resuscitation emphasizing timeliness and the correct execution of tasks. Four labor and delivery nurses discussed the importance of performing the steps of neonatal resuscitation correctly, timely, and efficiently. One nurse described her perception of why positive pressure ventilation is often not performed early enough by some labor and delivery nurses: "*...people are afraid to give PPV in resuscitation because they don't do it that often."* Most respondents acknowledged the importance of early and effective positive pressure ventilation in delivery room neonatal resuscitations; however, several labor and delivery nurse described a lack of comfort with positive pressure ventilation: "*I don't feel like my skills are as good six months after the class as they were right after I just took the class… let alone, a year later."* Many of the IP team members described the need to have more hands-on experience in a practice setting to enhance skill performance in actual resuscitations, as stated by one team member: "*I wish that there were more easy drills, so that it is like second nature, because its just we do it so infrequently, it's just not second nature"* (nurse midwife 2). Two team members describe channeling the stress of the emergency to help them focus on paying attention to detail and remaining calm: "*There's*

that whole like adrenaline rush of making sure that you do everything possible for this baby and figuring out what is the cause, and why is this happening right now (labor and delivery nurse 2*). Your adrenaline is flowing, you heart rate is up, and you have to stay calm to be a team member"* (respiratory therapist).

Interpersonal Level Factors

Most participants interviewed discussed teamwork as a major component of interpersonal level factors that contributed to a positive outcome. Team members who worked mainly in the NICU such as the nurse practitioners, neonatologists, and neonatal nurses had positive statements regarding team interactions in delivery room resuscitations. Some team members with a home base outside of the NICU, such as labor and delivery nurses and midwives, described a lack of cohesion in neonatal resuscitations due to the constantly changing team members and the fluidity of the team. Three labor and delivery nurses expressed frustration regarding situations when team members entered a resuscitation repeating steps that had already been initiated and delayed positive pressure ventilation, which is necessary in apneic neonates. One nurse's perception was that some people delay providing positive pressure ventilation: "*People are afraid to give PPV in resuscitation because they don't do it that often … that's the easiest way to get the baby to come around..."*(NICU nurse 1)

Organizational Level Factors

Potential organization levels factors included staffing ratios, policies, and required certifications. Identified organizational factors included the need for a second person who can participate in the resuscitation at the time at delivery: "*Need to have that second person, even if they are only there for a few minutes, if they do nothing else, they are just*

there as a second pair of hands to do things…" (labor and delivery nurse 4). *There should always be, able to be 2 nurses, if you don't need them, if its that crazy, then they walk away"* (labor nurse 5). *"Have the policy in place that you need 2 RNS in the room in each delivery so that you have enough people"* (midwife 3). Another organizational level factor identified by labor and delivery nurses (often the first responders to an unanticipated neonatal resuscitation) was the location of the NICU emergency button summoning additional assistance: *"It is like a 5 second delay to try to get to that button" (labor nurse 5).*

Societal Level Factors

Societal level factors focused on having the patient and family understand what is going on when a neonate requires resuscitation. "*How do you tell them nicely that you need to, you are ripping the kid out of her arms, cause you see that its not doing something right?"* (labor nurse 6).*"I realized that the baby didn't look like it was breathing and I couldn't really tell with the dad holding the baby, so I kind of went over without trying to upset him and just kind of shook the baby, and then realized that the baby was limp…and I took the baby over to the warmer, and hit the button, and there was another nurse in the room and so I asked her for help and she came over. We immediately started PPV, the heart rate was still good, we had caught it in time that it hadn't gone into that secondary apnea where it needed chest compressions but it was not breathing and it was limp*…" (labor nurse 4). One labor nurse participant described experiences dealing with families during situations in which the neonate, although once stable, later became apneic requiring immediate attention while being held by family members. In these situations, the neonate had to be rushed to the infant care center and

resuscitated immediately: *"As I was doing what I was doing I was just explaining, you know, quickly, and giving a very quick explanation of what was going on with the baby so that they wouldn't be like… oh my gosh what is going on …"* (labor nurse 2).

Discussion

Several behaviors were identified as key to efficient team performance in neonatal resuscitations, such as remaining calm, having clearly established roles, communicating clearly, and adhering to established NRP guidelines. These key behaviors are now central components in the newly restructured NRP course, with the emphasis on positive team behaviors, debriefing, and structured, closed loop communication. Despite these changes, delivery room neonatal resuscitations still present unique challenges such as varying skill level, a stressful chaotic environment, and team dynamics that remain difficult to address in a bi-yearly course (Niles et al., 2017). While NRP guidelines are the basis of neonatal resuscitation actions there continues to be a lack of adherence to the NRP algorithms as evidenced by a delay in initiating positive pressure ventilation, not using the correct sequence, and other actions/lack of action which are likely to affect outcomes negatively (McCarthy et al., 2013; Niles et al., 2017; Sharma et al., 2015). This study addressed the first two steps of the TDF process for developing an intervention in the clinical practice setting: the identification of a specific area to target for behavior changes, and the associated barriers and enablers. The rationale for employment of the TDF in this study stems from the need to develop interventions that are likely to promote sustainable changes in clinical behaviors. Removing obstacles to employing best practices while providing support to reinforce best practices requires an assessment of supports and barriers at various levels from the clinician standpoint.

Positive Pressure Ventilation

An overarching theme identified in this study was the importance of timely implementation of positive pressure ventilation in the neonate. This theme was most prominent in the labor and delivery nurse participants. Key barriers associated with bag-mask ventilation specific to labor and delivery nurses were comfort levels with bag-mask skills due to lack of practice, inefficient teamwork, and not having a second person to assist in an unanticipated resuscitation. SEM levels most associated with these barriers were the intrapersonal, interpersonal, and organizational levels. While no policy level factors were identified in this study, mandatory IP team education may have a positive impact on patient outcomes. Although the importance of bag-mask ventilation is well documented in the literature, the focus of targeted education is directed to primarily physician and medical students (Deindl et al., 2014; Pearlman et al., 2016). Labor and delivery nurses are often the only individuals with NRP training in low-risk deliveries and must be prepared to provide ventilation support effectively within evidence-based NRP guidelines to avoid hypoxic injury (Niles et al., 2017). These first responders may benefit from training directly targeted at improvement of bag-mask ventilation skills, a critical step in the NRP algorithm.

Potential interventions to improve this skill may include respiratory monitor use to determine the effectiveness of ventilation (Binder et al., 2014; Schmolzer et al., 2012), instructional videos, and video recording of actual resuscitation for debriefing and review by the resuscitation team (Shivananda et al., 2017). While these strategies have been implemented in the training of medical students, residents, and advanced practice nurses, few studies have targeted the most frequent responders to unanticipated delivery room

resuscitations, labor and delivery nurses. Furthermore, few existing studies have linked interventions with neonatal outcomes (Rakshasbhunankar & Patole, 2014). The lack of studies linking interventions to neonatal outcomes is also an area for future research, since improvement of neonatal outcomes is the ultimate goal. A systematic review examining the benefits of simulation-based training for neonatal resuscitation revealed a lack of well-designed studies with adequate sample sizes and variable methodology (Rakshasbhuvankar & Patole, 2014). Although challenging to design, adequately powered interventional studies that link findings with patient outcomes are necessary to determine if simulation-based interventions improve outcomes (Rakshasbhuvankar & Patole, 2014).

While the findings of this study may not be generalizable to other populations, the creation of pertinent interventions addressing specific individualized learning needs of the population under study may prove beneficial. Training designed to specifically meet the needs of the learner may prevent skill deterioration and provide clinicians and practitioners with current up-to-date information prior to the next biyearly NRP course. Targeting simulation-based education to improve labor and delivery nurse performance of positive pressure ventilation is an example of a low cost, low fidelity, simple simulation-based intervention that may improve outcomes. Consideration of cognitive load theory may prove helpful in designing targeted interventions as the approach focuses on segmenting information and reducing tasks to more manageable tasks for practice (Fraser, Ayres, & Sweller, 2015). This method of instruction may be particularly useful in reinforcing best practices in bag mask positive pressure ventilation by labor and delivery nurses.

Development of an intervention that addresses the barriers and enablers of neonatal resuscitation from the standpoints of frontline clinicians is a systematic, intuitive approach to improving clinical practices, while validating the use of the TDF. Findings from this qualitative study address the first step two steps in the TDF process, identification of the barriers to and facilitators of effective neonatal resuscitation, and the identification of targeted behavior change, bag-mask ventilation for labor and delivery nurses. The next step in the process is to identify barriers and facilitators to effective bag-mask ventilation from the standpoints of these key interprofessional team members to develop a strategy to enhance the enablers and eliminate the barriers for implementing best practices in bag-mask ventilation.

Limitations

The number of labor and delivery nurses in this study is a limitation since this factor may have skewed the findings in this study. A sample with more participants from the other professions may have yielded data of a broader scope. Nearly half of participants were labor and delivery nurses. Since most unanticipated neonatal resuscitations are initiated by labor and delivery nurses, this sample serves the purpose of this study.

Conclusion

Timely and correct administration of positive pressure ventilation was identified by labor and delivery nurses as a behavior for improvement for this professional group. Other team members did not indicate positive pressure ventilation as a necessary area for review. Frequent opportunities to practice positive pressure ventilation skills for labor and delivery nurses in the study setting would be beneficial since prompt ventilation of

the lungs is the most important and effective action in neonatal resuscitation (AHA/AAP, 2016; Sharma, Lakshminrusimha, Carrion, & Mathew, 2015). Often the first responders to neonatal resuscitations, labor and delivery nurses should be adequately prepared to initiate positive pressure ventilation to avoid a more complex, prolonged resuscitation. Such preparation of labor and delivery nurses warrants focused training and practice in the specific skill of delivering positive pressure ventilation. Neonates are the most vulnerable population of all. Significant improvements in outcomes may be achievable with specific, targeted neonatal training specific to the learning needs of the particular population that are linked to the measurement of outcomes.

Table 1

Interview Guide

Interview Guide

- *Can you describe your role in neonatal resuscitations in the delivery room?*
- *What can you tell me about what happens in the delivery room when a baby cannot breathe?*
- *Can you describe a memorable neonatal resuscitation in the delivery room that you were involved with? Walk me through what happened…*
- *If you had to come up with an improvement plan for neonatal resuscitations in the delivery room, how would you make the process better?*

Secondary prompts to elicit narrative:

Tell me more about that.
Can you tell me how that happened?
Yes…
Ummhmm…
Interesting.
Can you describe what you mean by that?
Really?
How do/did you feel about that?
In your experience, does it often happen like that? (for generalizations)

Table 2

Participant Demographics

Profession	Participant	Race/Sex	Years of experience	Role
Nurse	Labor Nurse 1	White/Female	30 years	Initial responder
Physician	Neonatologist	White/Female	10 years	Initial responder
Nurse	Labor Nurse 2	Black/Female	7 years	Initial responder
Nurse Midwife	Midwife 1	White/Female	7 years	Second assist
NICU Nurse	NICU Nurse	White/Female	5 years	Second assist
Nurse	Labor Nurse 3	White/Female	16 years	Initial responder
Respiratory therapist	Respiratory Therapist	White/male	30 years	Respiratory support
Nurse Midwife	Midwife 2	White /Female	30 + years	Secondary support
Nurse	Labor Nurse 4	Black/Female	30 years	Initial responder
Nurse	CRNNP 1	White/Female	6 years	Initial responder
Nurse	CRNNP 2	White/Female	15 years	Initial responder
Nurse	Labor nurse 5	White/Female	25 years	Initial responder

Table 3
Categorization of qualitative evidence using the Social Ecological Model

SEM Category	Descriptive Evidence
Individual	"*There's that whole adrenaline rush of making sure that you do everything possible for this baby and figuring out what is the cause, and why is this happening right now…I want to make sure I get every single thing…it actually givens me a better chance to focus cause I think the worse thing that can happen in emergent situations is when you get so nervous and you forget to do things"* (labor nurse 2) *"Because your adrenaline is flowing, your heart rate is up, and you have to stay calm to be a team member."* (respiratory therapist) *" I think that's one of the biggest problems is that people are afraid to give PPV in resuscitation because they don't do it that often."* (labor nurse 4) *"I wish that there were more easy drills, so that it is like second nature, because its just that we do it so infrequently, its just not second nature."* (midwife 2) *I don't' feel like my skills are as good six months after the class as they were the first six months after I just took the class, let alone a year later."* (labor nurse 2)
Interpersonal	*"I think that there is a shortcoming in this nursery that not everybody is as proficient in the delivery room as possible because there are so many people on that there are other people that can step up and take over so people are not getting up to where they need to be."* (neonatal NP 2) *"Even though we were not in our own forum we didn't have everything where we expected it to be, still the team still came together." (Neonatologist)* *"We want absolutely no flaws, so what we do, is that many times we will get our heads together after, and make comments, what could we have done better?"* (Respiratory therapist) *"I think the most important thing is for people to establish roles, to get help right away"*(labor nurse 4) *"Sometimes people come in to help you and they bring their nervous energy in there and they start doing things that are out of the steps that we've been taught to do."*(labor nurse 2)
Organizational	*"Need to have that second person, even if they are only there for a few minutes, if they don nothing else, they are just there as a second pair of hands."*(labor nurse 3)…*"Have the policy that you need 2 RNs in the room in each delivery."*(midwife 2)
Societal	"*…how do you tell them nicely that you need to, you are ripping the kid out of her arms, cause you see that its not doing something right."* (Nurse 6) *"I realized that the baby didn't look like it was breathing and I couldn't really tell with the dad holding the baby, so I kind of went over without trying to upset him and just kind of shook the baby, and then realized that the baby was limp…and I took the baby over to the warmer, and hit the button, and there was another nurse in the room and so I asked her for help and she came over we immediately started PPV the heart rate was still good, we had caught it in time that it hadn't gone into that secondary apnea where it needed chest compressions but it was not breathing and it was limp…"(labor and delivery nurse 4)* *"As I was doing what I was doing I was just explaining, you know, quickly, and give a very quick explanation of what was going on with the baby so that they wouldn't be like… oh my gosh what is going on…" (labor and delivery nurse 2).*

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1.3. A Theoretical Domains Framework perspective of barriers and enablers to bag-mask ventilation of the newborn in the delivery room: A qualitative descriptive study

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Abstract

Purpose: The purpose of this study was to explore labor and delivery nurses' perceptions of enablers and barriers to bag-mask ventilation of the newborn in the delivery room using the Theoretical Domains Framework.

Method: Using qualitative description, we conducted 6 focus groups with 24 labor and delivery nurses. Methods of directed content analysis using the Theoretical Domains Framework guided the data analysis.

Results: Barriers and enablers were identified during focus group interviews with the participants. Themes were identified and categorized within the domains of the TDF. Most of the barriers identified were within the TDF domains of Skills and Environmental Context/ Resources. Skills barriers included lack of practice, inadequate skill, and variance of skill level among nurses and obstetric providers. Environmental Context/Resources barriers included lack of comfort with current bag-mask equipment, staffing, supplies, and multiple nursing responsibilities.

Clinical Implications: Labor and delivery nurses may benefit from a multi-faceted targeted intervention to improve bag-mask ventilation skills. Low fidelity, individualized, simulation-based education in combination with other strategies such as short instructional videos, and continuing education in-services, and interprofessional neonatal resuscitation simulations may improve individual skill execution and interprofessional team processes. The TDF provides nurse educators with a systematic method of assessing deviation from best practices for the purpose of developing an intervention that is sustainable, making optimal use of resources.

Introduction

Labor and delivery nurses are often the first responders to delivery room neonatal resuscitations, particularly in low-risk deliveries. While many deliveries requiring neonatal resuscitation can be anticipated with the presence of antepartum and intrapartum risk factors, newborns requiring resuscitation can be born in the absence of risk factors. Early aeration of the lungs is key in preventing the development of asphyxia, a complex combination of respiratory and metabolic acidosis, which can lead to decreased cerebral flow, neurological injury, and even death (de Pas, Sobokta & Hooper, 2016; van Vonderen, Roest, Siew, Walther, Hooer et al., 2013). The process of aerating the lungs is complex due to different types of ventilation equipment, different types of masks, clinician hand size, gestational age of the newborn, and other factors (van Vonderen, Witlox, Kraaij & Pas, 2014). A challenging skill to master, effective positive pressure ventilation (PPV) can be obscured by leakage of air around the mask, difficulty holding the mask, delivery of inadequate or excessive tidal volumes, or poor technique (Wood & Morley, 2013). To address these issues, in 1985 the American Academy of Pediatrics (AAP) and the American Heart Association (AHA) developed national neonatal resuscitation guidelines based on a compilation of the most recent and best evidence (AAP/AHA, 2010). Interventions aimed at improving neonatal outcomes in delivery room resuscitations are based upon Neonatal Resuscitation Program (NRP) algorithms, which serve as a guide to clinician decision-making (AAP/AHA, 2015). Although the NRP guidelines are the gold standard in NRP training, in actual neonatal resuscitations, a lack of adherence to NRP guidelines persists (Niles et al., 2017; Trevisanuto et al., 2016).

Theoretical Domains Framework

Clinical practice in nursing is informed by both, nationally and internationally established evidence-based guidelines (Atkins, Kelly, Littleford, Leng and Michie, 2017). Unfortunately, the implementation of evidence-based guidelines is often challenged by unidentified contextual barriers in the clinical environment (Michie et al., 2005). A plethora of literature exists describing interventional studies aimed at changing clinician practices; however, the interventions vary in effectiveness, warranting a change in approach to influencing clinician behaviors (French et al., 2012). Change may not effectively occur without a preliminary analysis of the contextual issues that may interfere with intervention implementation (Grol, 2001). Identification of existing enablers and barriers prior to intervention implementation is a novel approach that may allow nurse leaders to create a more favorable environment to sustain best practices.

The Theoretical Domains Framework (TDF) provides a systematic approach to the development and implementation of behavior-change interventions targeting clinicians, as the TDF bridges the knowledge-practice gap by using theory to guide interventions (Michie, 2005). Designed for use by interdisciplinary researchers, the TDF addresses the need to examine existing barriers and enablers to best practices (French et al., 2012). Developed by a team of 18 psychological theorists, 16 health services researchers, and 30 health psychologists, the TDF integrates several behavior change theories into a framework to increase accessibility and use by health care professionals (Michie et al., 2005). Since its inception in 2005, the TDF has been used to guide

numerous intervention implementation studies and systematic reviews (Cane et al., 2012; Srigley et al., 2015; Tuti et al., 2017).

Creation of the TDF stemmed from a need to develop implementation studies designed to promote positive behavior changes in the clinical setting, taking into consideration the existing conditions that impede the implementation of the best, evidence-based practices. The TDF has undergone rigorous construct validity testing further strengthening it for use in implementation studies (Cane et al., 2012). Refinement of the original TDF involved an iterative three-step validation process resulting in a final framework with a total of 14 domains, integrating several psychological theories, such as social cognitive theory, self-determination theory, and goal theory, for a comprehensive assessment of potential implementation problems (Cane et al., 2012; Michie et al, 2005). Final domains of the refined TDF are: Knowledge, Skills, Social/Professional Role and Identity, Beliefs About Capabilities, Optimism, Beliefs About Consequences, Reinforcement, Intentions, Goals, Memory, Attention and Decision Processes; Environmental Context and Resources, Social Influences, Emotions, and Behavior Regulation (Cane, O'Connor, & Michie, 2012).

Purpose

The purpose of this study was to examine labor and delivery nurse perceptions of barriers and enablers to bag-mask ventilation of the newborn in the delivery room using the TDF as a guiding framework. Findings from this study will inform an intervention to improve bag-mask ventilation skills of labor and delivery nurses that will take into consideration the enablers and barriers to this crucial skill. The usefulness of the TDF in the identification of barriers and enablers to the implementation of best practices is well

documented in the literature (Craig et L., 2016; Kirk et al., 2016; Mosavianpour et al., 2016; Debono, et al., 2017). A good fit, the TDF was used to guide both arms of this study.

This study is the second part of a two-phase qualitative study examining the facilitators and barriers of delivery room neonatal resuscitations. The first qualitative study examined the enablers and barriers to delivery room neonatal resuscitations from the perspective of interprofessional neonatal resuscitation team members. Informing the second arm of the study, the first study revealed a need for further exploration of the nuances of bag-mask ventilation skills in labor and delivery nurses. Positive pressure ventilation, the most important step in resuscitation of the newborn, is an essential skill for first responders (AAP, AHA, 2016). Although this step is paramount in neonatal resuscitation, there is no current mechanism for assessing competency and accuracy in this skill (Pearlman, Zern, Blackson, Ciarlo, Mackley, et al., 2016). A paucity of information exists regarding the bag-mask ventilation skills of labor and delivery nurses, although these individuals are present for most hospital deliveries and as a result, often administer bag-mask ventilation to newborns requiring it (Ades & Lee, 2016).

Methods

A qualitative descriptive approach was used to explore participant perceptions of enablers and barriers of bag-mask ventilation of neonates in the delivery room (Sandelowski, 2000).

Setting and Sample

Following IRB approval, we recruited labor and delivery nurses from a community hospital located in the North Eastern part of the country. The inclusion

criteria for participation were current experience as a staff labor and delivery nurse in the study setting and experience of one year or greater. Signed informed consent was waived for this study. Participants were provided with an information sheet that contained the elements of informed consent, the study purpose, procedures, time commitment, risks, and benefits of study participation.

Data Collection

An interview guide was formed to explore factors acting as enablers and barriers of bag-mask ventilation from the perspectives of the participants (Boet et al., 2017). The first author conducted six face-to-face semi-structured focus group interviews with participants. The focus group interviews were preceded by a short questionnaire related to years of clinical experience, education level, and age. Participants were de-identified and assigned numbers for anonymity purposes. To minimize risk of participant embarrassment, prior to each focus group interview, participants were reminded of the privacy of the information gained from the interviews. Ground rules were reviewed with participants and included refraining from discussing interview information outside of the focus group. All focus group interview data was transcribed verbatim.

Data Analysis

Direct content analysis using the TDF domains, guided analysis of the transcripts and provided the key themes used to organize the data (Hsieh & Shannon, 2005). The transcripts were read line-by-line several times and text was highlighted and categorized into TDF domains. Some participants made several references to a particular domain in different contexts over the course of the interview. Inductive themes emerged from the data and were allocated to TDF domains as sub-categories for the data. Statements were

examined and categorized into the sub-categories, and under the broader TDF domain categories (Power, Kiezebrink, Allan, & Campbell, 2017). Data were then analyzed using a descriptive approach to determine if statements indicated barriers or enablers to bag-mask ventilation. Perceived barriers and enablers to bag-mask ventilation were categorized into TDF domains with the frequency of categories in each domain facilitated by *Nvivo 10* software. The TDF was deemed comprehensive enough to capture the full breadth of participant perceptions for the study. An independent coder analyzed a portion of the interview data to determine consistency of the coding scheme. Exemplar statements were excerpted from highlighted text to represent categories and subcategories.

Results

(See Table 1)

Twenty-four labor and delivery nurses comprised the study population. Ages of participants ranged from 28-67 (mean = 47). Six focus groups were completed with 2-6 members per group. Education level for participants included Diploma (n = 4), Associate Degree (n = 9), BSN (n = 10), and Masters degree (n = 1). Participant level of experience in the current role ranged from 7 years to 40 years (mean = 22 years). All participants were female and had administered PPV to a neonate on more than one occasion in the delivery room.

Barriers to PPV

Barriers are identified in the TDF as factors that inhibit the implementation of evidence-based practice (Michie et al., 2005). Eleven of the 14 domains were used to categorize the data in this study. We will describe the data in the order of frequency of

categorization to the domains. The majority of the barriers to the implementation of PPV by labor and delivery nurses were identified in the TDF domains of Skills (34 quotation frequencies) and Environmental Context/Resources (27 frequencies).

Skills. According to the TDF, the domain of skills includes the constructs of skill development, competence in skills, ability, interpersonal skills, practice, and skill assessment (Cane et al., 2012). Skills were overwhelmingly perceived as a barrier to bag-mask ventilation. Many nurses expressed doubt about their personal technical PPV skills:

"I don't have a comfort level that I am ventilating correctly to get the air in there, is it really going in or is not going in?"

"I feel like I can brush up on things…"

Nurses expressed frustration when providers not current or competent in their neonatal resuscitation skills insist on "helping" although they are not aware of current guidelines:

"If the other person is not skilled, they actually get in your way and not help you, they will hinder you."

Environmental context and resources. The domain of Environmental Context and Resources is inclusive of any situation or environmental issues that either encourages or discourages the development of a skill, independence, and competence (Cane et al., 2012). Factors in this domain included supplies, equipment, systemic issues, and staffing. Environmental context was second only to skills (27 frequencies) as an area that nurses perceived as having a significant negative impact on their ability to provide bag-mask ventilation to a newborn. One reason mentioned was having the right supplies:

"When the equipment is missing or the oxygen isn't working."

Several participants discussed the difficulty working with the bag-mask equipment, stating that it is difficult to work with:

"I feel that the bag and mask is not a good bag and mask."

"I don't like the new ambu bags we have because it sound like you have a leak."

"The present equipment, terrible, terrible."

Location of the button used to contact the NICU for a neonatal resuscitation was discussed as a barrier:

"The emergency button should be right next to the warmer."

Increasing responsibilities and having more things to do in the same amount of time was also revealed as a barrier:

"There is a lot of stuff we do now. It's a lot more responsibility on us, just the paper work alone, to get through it all."

While many participants sought the opportunity to practice with simulation, some participants believed that simulation was not very helpful:

"I don't feel inhibited during practice."

"Even the best manikins don't feel the same."

"The first time I did chest compressions on a baby I thought, wow, this is not what baby Annie felt like…"

Social/professional role and identity. Eight participant quotations were allocated to the Social/Professional Roles/Identity domain. Social/Professional Role and Identity are defined by the TDF as a set of behaviors and personal qualities of a person in a work or social setting (Cane et al., 2012). Data that included descriptions of professional roles and boundaries were allocated to this domain. Nurses stated that they were the first to

respond to neonatal resuscitations, particularly in cases where there were no pre-identifiable risk factors. Lack of clarity of roles, was discussed as a detriment to neonatal resuscitations requiring bag-mask ventilation:

"You walk in…and everyone is in the way, but not everyone is doing something." One focus group discussed having to complete multiple tasks concurrently when their focus should be completely on the resuscitation at hand:

"…a needy doctor asking you for things when you are trying to take care of a baby, while you are resuscitating."

Emotions and Behavior Regulation. The domains of Emotions, and the domain of Behavior Regulation follow, with 7 quotations allocated to each domain.

Emotion. According to the TDF, the domain of emotion encompasses a complex reaction involving psychological elements by which the person copes with a personally significant event. Participants discussed the psychological response to the thought of providing PPV for a neonate, suggesting that the emotions related to providing PPV might prevent many nurses from doing so:

"There is real anxiety about giving PPV for a lot of people."

"People are afraid to do it."

Some expressed profound anxiety when called on to deliver PPV:

"On the inside, your heart is pounding."

Behavior regulation. Behavior regulation is defined by the TDF as anything aimed at changing behavior that is measurable or objectively observable. Participants discussed the effects of their emotions on their actions, stating that emotion affected their behavior and actions when there is a need to provide bag-mask ventilation. Several nurses

stated that anxiety affected their perception of time, making them work faster than NRP guidelines suggest when they have to deliver PPV:

"I think the biggest thing is your own stress anxiety and you tend to work faster than you should."

"When you are in that situation, it's hard to slow yourself down."

"I start bagging, I don't know if it has been 10 seconds or a minute and a half…you are supposed to reassess every couple of seconds but I rarely look at the Apgar timer…"

Social Influences and Beliefs About Consequences. The domains of Social Influences and Beliefs About Consequences follow with four quotations allocated to each domain.

Social influence. Social influences, according to the TDF, include the processes between individuals that cause people to change adaptive behaviors, thoughts, or feelings. Several factors emerged as barriers in this category, such as the peer pressure dissuading some of the more novice nurses from calling for assistance in a delivery:

"There are some nurses who don't put their call lights on for assistance, but I always do."

Nurses expressed a need to have a second person in the room for a delivery just in case an infant might need resuscitation:

"I never want to be by myself."

Some nurses expressed anxiety of being watched nervously by family members and the provider, "The parents are watching me, everyone is watching me."

Optimism/belief about consequences/goals/ reinforcement. The domains of Optimism, Belief About Consequences, Goals, and Reinforcement were combined in this analysis to account for the overlapping of data in these domains. Optimism, in the TDF, is described as confidence that the desired goals will be achieved; while acceptance of the truth and validity about behavior outcomes describes the domain of Beliefs About Consequences (Cane et al., 2012). The TDF describes goals as intended outcomes that an individual would like to achieve. Statements allocated to these domains described actions by one particular participant, describing that troubleshooting continues until the desired result is achieved (the baby cries or initiates breathing). Reinforcement, according the TDF, is the likelihood a response will occur as the outcome of a particular action, or that a stimulus will create a certain response:

"I just keep doing things to try to fix it until the baby responds."

Cost. One group believed that the cost of having a neonatal team attend a delivery would be reflected in the patient's bill, and stating they have been discouraged by the provider to call for assistance to prevent the additional charge to the patient:

"A doctor says they get charged $600…somebody told me not to call because of that consideration whereas I never thought of it before."

The domains of Knowledge and Intentions have two quotations allocated to each domain.

Knowledge. The TDF stipulates that the domain of "Knowledge" is inclusive of knowledge of a particular condition, procedural knowledge, or knowledge of a specific task or environment (Cane et al., 2012). While most of the data indicated skills as an enabler, one barrier noted by 2 nurses was the mid-cycle changes of the NRP protocol or

changes of practice occurring between NRP training sessions. Neonatal health care providers receive evidence-based updates regarding best practice on a regular basis. NRP courses are held only bi-annually; therefore updates are not communicated to NRP course participants until their certification is updated. Changes in neonatal resuscitation management prior to the next course should be discussed as a part of continuing education to ensure consistency in care. One participant stated that the NICU team might be aware of protocol changes that are not always communicated to labor and delivery nurses, contributing to confusion:

"You have the changes that happen mid cycle…Sometimes they change their protocols in how they do things on NICU but we don't know it downstairs so even though we prep our beds…they are redoing what we already did."

Intentions, Reinforcement, and Memory, Attention and Decision Processes. One quotation was allocated to each of the 3 domains, the domains of Intentions, reinforcement, and Memory, Attention and Decision Processes.

Intentions. The TDF describes the domain of Intentions as a conscious decision to perform an action to act in a certain way. Data allocated to this domain described specific actions that nurses take to explain neonatal resuscitative actions to a frightened parent or family member. Some nurses discussed the importance of keeping the family informed of what is happening, since the family may not understand why their baby is being whisked away from them:

"You need to be able to look at the mom and dad and say its okay and that this is going on, I think that goes a long way when they are lying there." "They just see: 'they just took my baby!'"

Memory, attention, and decision processes. The Memory, Attention and Decision Processes domain expresses the ability of an individual to move through important information to focus on a task at hand, choosing between one or more alternatives, as in the NRP algorithm (Cane et al., 2012). Participants discussed the importance of remaining calm, although it might be difficult if the primary nurse has bonded with the patient and family. The importance of having a second nurse in the room that could be more focused was stressed:

"I find if I'm the second person, it's much easier for me to keep calm and be objective and do what I have to do…Sometimes it's easier if you are the helper that comes in to focus on the baby."

While one nurse expressed a need for more practice to get to used to the timing of interventions: "Because we don't do it that often, I feel like I can do it but I feel like I don't often keep track of time."

TDF Domain Enablers

Knowledge. Knowledge was the most frequently cited enabler, with 12 quotations allocated to the domain. Participants take an NRP bi-yearly course, and believed that the course provides adequate information about neonatal resuscitation and bag-mask ventilation. Most participants perceived themselves as comfortable with their knowledge regarding bag-mask ventilation:

"You just kind of look at the general look of the baby, you know if a baby is going to need more or less depending on the tone."

Knowledge was followed in frequency by the domains of Social Professional Roles/Identity, Beliefs About Capabilities; Beliefs About Consequences, Reinforcement, and Environmental Context and Resources, with 4 quotations allocated to each domain.

Social/professional roles/identity. Establishment of clear roles and appropriate delegation was identified as an enabler.

"Everyone should know their role, who's going to check the pulse, who's going to bag, who's going to suction, who's going to hit the NICU button…"

Belief About Capabilities. Some nurses were very confident in their PPV skills, and did not hesitate to provide PPV when they believed was necessary.

"There's no doubt in my mind if I have a baby that has not come around through stimulation that I bring the baby right over and start PPV."

Optimism, Memory attention and decision processes, and Social Influences follow with 2 quotations allocated to these domains.

One quotation was allocated to the domain of intentions and goals.

Optimism, belief about consequences, goals, reinforcement

Two nurses expressed amazement of the impact of positive pressure ventilation on an apneic infant, stressing the importance of delivering it promptly:

"What's amazing is that when you do it…it's amazing how fast these babies turn around with just a couple of puffs…"

"I just figure, why not? I don't want to wait too long to do it."

Several nurses discussed the good feeling following a successful bag-mask neonatal resuscitation as a reinforcement to move towards PPV quickly as instructed in NRP training if initial brief stimulation does not facilitate breathing:

"And all of a sudden, you hear the baby go "brr", and oh, I did a good job! I did it! Everything worked!"

"That's a nice feeling to think, okay, this worked and I did this."

Several nurses expressed a need to be prepared to resuscitate an infant at all times, and to call for extra help when risk factors exist. These nurses discussed having the equipment checked, ready, and turned on, even if no risk factors are present:

"I think being prepared is the best thing to prevent barriers."

"I turn the heater up on the warmer, I turn on the O2. I turn everything on because you never know…"

"One of my mindsets is to check that ICC (infant care center) before I even think about pushing with a patient…"

Environmental context/resources. Nurses believed there was adequate back up from the neonatology team in emergencies:

"I think our neo gets there really quick, I think they are outstanding at getting there."

Discussion

The TDF was used to examine the enablers and barriers to effective bag-mask ventilation as perceived by labor and delivery nurses in this study. NRP training is a standardized approach to update labor and delivery nurses regarding the best practices in neonatal resuscitation and stabilization. However, standardized training does not take into account the various contextual factors that interfere with the implementation of best practices. Lack of adherence to practice guidelines may be secondary to implementation difficulties that are likely specific to the particular target population (Grol, 2001). While

distinct differences are obvious in practice settings, most clinical practice guidelines are designed for implementation across settings without consideration of such contextual variables (Grol, 2001). Using a systematic approach such as the multidimensional TDF affords the opportunity to examine in detail the complexity of variables that interfere with adherence to evidence-based guidelines. Moreover, performing a periodic assessment of the contextual barriers within the specific setting may uncover barriers that impede best practices that may be easily corrected (Debono et al., 2017).

TDF Barriers

This study revealed numerous barriers to bag-mask ventilation in delivery room neonatal resuscitations as experienced by labor and delivery nurses. The TDF domains of Skills and Environmental Context/Resources encompassed the majority of the barriers to implementing best practices in delivering PPV. Key barriers perceived by labor and delivery nurses included deficient bag-mask skills, lack of comfort with current bag-mask apparatus and inadequate staffing and personnel resources. Additional barriers perceived by participants were lack of role clarity in neonatal resuscitations, working too fast or losing track of time due to anxiety, and lack of up-to-date knowledge regarding best practices. A comprehensive understanding of the enablers and barriers to best practices is necessary to design an intervention that meets the needs of the individuals in that particular setting.

Labor and delivery nurses overwhelmingly perceived factors within the Skills domain as having a negative affect on ability to perform bag-mask ventilation. Skill related factors ranged from technical skill in handling the ambu bag and mask to interpersonal skills in implementing evidence based practice. Although positive pressure

ventilation is an essential skill in neonatal resuscitation, there is no current standardized mechanism to assess this skill. Development of a targeted intervention for the specific purpose of addressing the learning needs of individual labor and delivery nurses is an approach that may offer an opportunity to enhance the specific skill set of bag-mask ventilation, and to practice. Simplifying simulation-based education to meet the needs of the learner is a practical approach in improving bag-mask ventilation skills by integrating concepts of cognitive load theory. Cognitive load theory can be applied to simulation based education by reducing the focus to bag-mask ventilation to meet the needs of the individual labor and delivery nurse (Meguerdichian, Walker, & Bajaj, 2016). In addition, other modes of instruction such as short video instructions, periodic updates of new evidence-based practices, and task-appropriate simulation can augment these simple teaching strategies (Haji et al., 2015).

The domain of Environmental Context encompassed many broad categories barriers from staffing to equipment. Consistency across all of the environmental context domain themes would eliminate several of the barriers identified. Standardized checklists have been instituted in other areas such as the operating room where evidence-based standards guide practices, and being implemented in delivery room settings (Brown, Ty, Profit, Gupta, & Lee, 2016). Checklists may improve environmental contextual barriers, and can be individualized to meet the needs of the specific institution.

The domain of social influences addressed social interactions between nurses, providers and families. Potential solutions to mitigate the barriers of this domain include standardization of care and continuing education to ensure that practices meet evidence-based standards. The NRP guidelines stipulate that two individuals attend deliveries with

one having the care of the newborn as the primary responsibility (AAP/AHA, 2015). Adherence to staffing guideline in deliveries can improve social support during delivery room resuscitation, and provides assistance when it is warranted. The parents and family are present during delivery room resuscitations, which can be a particularly frightening experience. A brief explanation of what is happening, followed by a debriefing can help cultivate an atmosphere of transparency and trust with the family (Sawyer et al., 2015). Focus on parental involvement in resuscitation care is important, and should be considered in delivery room neonatal resuscitations.

Several overlapping themes emerged from the Memory, Attention and Decision Processes domains, the Emotions domain, and the Behavior Regulation domains, including difficulty tracking time, anxiety, and working too fast. Potential solutions to variance in time perception in neonatal bag-mask ventilation is appointing a team member as a recorder to document any resuscitative action with closed-loop communication and use of a metronome as guidelines suggest (Cocucci et al., 2015; Trevistanuto et al., 2016).

Quarterly interprofessional neonatal resuscitation simulations, either scheduled or unscheduled, can also provide a forum where clinicians can discuss updates and improvements in techniques. Interprofessional neonatal resuscitation simulation may also serve as a means to address social/professional role ambiguity factors that often arise in actual resuscitations. Well-planned interprofessional simulations that emphasize team behaviors, closed-loop communication, and clarification of roles, can promote best practices in actual neonatal resuscitations. However, simulations that authorize learners to practice outside of their normal roles in simulated resuscitations can be detrimental to

team functioning, contributing to role ambiguity and confusion in the clinical setting (Jnah et al., 2016).

Some institutions have moved toward video documentation of actual resuscitations to provide an accurate record of events and interventions and an opportunity for learning geared at improving practices (Konstantelos et al., 2016; Schilleman et al., 2014). Video documentation of resuscitations provides an objective record of the events while providing a means to assess the resuscitation from multiple aspects. Video documentation is a potential means of evaluating adherence to the NRP algorithm, examine techniques, and provide constructive feedback for the purpose of improving quality of care.

TDF Enablers

While the barriers identified exceeded the enablers, one of the advantages of the TDF is the identification of the enablers so that they might be enhanced. The most frequently cited enabler was within the Knowledge domain. Labor and delivery room nurses believed they had an adequate knowledge regarding the steps of bag-mask ventilation and the importance of initiating it. However, there was a lack of congruence of knowledge and skills. Video instruction combined with short low-fidelity instruction could enhance knowledge, while strengthening skill weaknesses. Other enablers that were commonly cited were within the domains of Social Professional Roles/Identity, Beliefs About consequences, Beliefs About Capabilities, Reinforcement, and Environmental Context/Resources. The themes from the Knowledge domain overlapped with themes from these areas were associated with effective team dynamics, having competent resources available in an emergency, being adequately prepared for a resuscitation in

every delivery, and working knowledge of the NRP algorithm. These enablers may be enhanced with the proposed interventions to address the barriers.

Limitations

One significant limitation to this research is the lack of generalizability of the findings. While generalizability is not typically a goal in qualitative research, contextual application is more appropriate. As qualitative research evolves, qualitative research synthesis may provide a means for researchers to aggregate qualitative findings in a systematic manner, enhancing the utility of qualitative research (Sandelowski, Barroso & Voils, 2007; Ludvigsen, Hall, Meyer, Fergran, &Aagaard et al., 2016). Use of the TDF in systematic reviews examining enablers and barriers to the employment of best practices by health care professionals is an emerging area of health care research (Craig et al., 2016; Liang et al., 2017; Mosavianpour et al., 2016; Crayton et al., 2017; Tuti et al., 2017). As the body of evidence becomes larger in this understudied population, bag-mask ventilation interventions may be developed for a larger-scale intervention targeting specific areas for improvement. Another limitation of this study was the investigator relationship to the study participants. To mitigate this factor, one focus group interviewed was from another hospital within the same hospital system. Secondly, a second independent researcher analyzed and coded a portion of the interviews to support validity and credibility of the findings.

Implications for Nursing Practice

Potential solutions that might bridge the gap between knowledge and technical skills in bag-mask ventilation are short video updates of bag-mask ventilation, the use of checklists and pre-briefing prior to delivery, frequent practice sessions in bag-mask

ventilation, and short, low fidelity simulation-based instructional sessions aimed at reviewing the skill (Wood et al., 2008; Brown et al., 2015; Rubio-Gurung et al., 2014; & Sharma et al., 2015). Short, focused practice sessions with either low-fidelity simulation or high-fidelity simulation to improve bag-mask skills may be most effective with the integration of cognitive load theory concepts. Cognitive load theory bases instructional design on knowledge of human cognition (van Merrienboer & Sweller, 2005).

Conclusion

Evidence-based practice is a gold standard that guides nursing and medical care, but not without limitations. The linearity of the research to practice pipeline does not address the innumerable contextual issues that are individual to distinct populations, clinicians, and practitioners (Atkins et al., 2017). Benefits of using a theory-based approach to better understand the existing conditions of the setting under study are many. Use of the TDF to assess current behaviors enhances understanding of the real-life challenges present in day-to-day practice, enhancing the ability to target resources appropriately to specific areas to meet those challenges. This study used the TDF to examine labor and delivery nurse perceptions of enablers and barriers to bag-mask ventilation of newborns. Results from this study suggest that while the labor and delivery nurse is often the first responder to neonatal resuscitation emergencies, the factors that affect their ability to implement best practices are multifaceted and may require changes on many levels. Interventions to improve practices in labor and delivery nurses must address a complex mix of challenges for the best results. The next step in this process is to develop an intervention aimed at improving the targeted skill of bag-mask ventilation in labor and delivery nurses that encompasses the factors unveiled in this research.

Table 1

Barriers and enablers to bag-mask ventilation in order of frequency

TDF Domain	Subtheme	Exemplar Quotation
Skills as a barrier (n = 34) Incudes the constructs of skill development, competence in skills, ability, interpersonal skills, practice and skill assessment	PPV skills PPV not performed often	"I don't have a comfort level that I am ventilating correctly to get the air in there. Is it really going in or is it not going in?'
	Need for more practice	I feel like I can brush up on things…"
	Practice is not like reality	"I don't feel inhibited during practice…" "Even the best manikins don't feel the same…"
Skills as an enabler (n = 0)	First responders	"The delivery room nurse" "The charge nurse"
Environmental contexts and resources Any situation or environmental issues that either encourages or discourages the development of a skill, independence, and competence	Equipment	"I don't like the new ambu bags we have because it sounds you have a leak. "The present equipment, terrible terrible."
Environmental context and resources as a barrier (n = 27)	Logistics	"The emergency button should be right next to the warmer "There's a lot of stuff we do not. It's a lot more responsibility on us, just the paper work alone, to get through it all."
Environmental context and resources as an enabler (n = 4)	Staff	"I think our neon gets there really quick, I think they are outstanding at getting there very fast…" "I've never been, knock on wood, when no one shows up…"
Social/Professional Role and Identity set of behaviors and personal qualities of a person in a work or	Labor nurse making decision to do PPV	"Knowing it's an acceptable practice for the nurse in the delivery room to initiate bag and mask …and that no one is going to say, "why did you do that?"" "You walk in…and everyone is in the way, but not everyone is doing something." "a needy doctor asking you for things when you are trying to take care of a baby, while

social setting		you are resuscitating…"
Social Professional Role Identity as a barrier (n = 8)		
Emotional and Behavior Regulation/ Emotion (n = 7) encompasses a complex reaction involving psychological elements by which the person copes with a personally significant event Emotion as a barrier (n = 7) Emotion as an enabler (n = 0)	Anxiety	"There is real anxiety about giving PPV for a lot of people…" "On the inside, your heart is pounding…"
	Fear	"People are afraid to do it…"
Behavior Regulation describes anything aimed at changing behavior that is measurable or objectively observable Behavior Regulation as a barrier (n = 7) Behavior Regulation as a enabler (n = 0)	Anxiety affecting actions	"I think the biggest thing is your own stress anxiety and you tend to work faster than you should…" "When you are in that situation, it's hard to slow yourself down…" "I start bagging; I don't know if it has been 10 seconds or a minute and a half…"
Social Influences/Beliefs about consequences/Optimism/Goals/ Reinforcement	Peer pressure	"There are some nurses who don't put their call lights on for assistance, but I always do"
Social Influences include the processes between individuals that cause people to change adaptive behaviors, thoughts or feelings Social influences as a barrier (n = 4)	Being watched by the family	"The parents are watching me, everyone is watching me…"
Social influences as a enabler	Easier for the	"I find that if I'm the second person, it is not really my responsibility so I find that it's

(n = 2)	second person in the delivery to remain calm	much easier to be calm and objective and do what I have to do…" "…sometimes its easier if you are the helper that comes in, to focus on the baby…"
Beliefs about consequences is the acceptance of the truth and validity about behavior outcomes Beliefs about Consequences as a barrier (n = 4) Beliefs about Consequences as a enabler (n = 4)	Prevention of extra charges to patient	"A doctor says they get changed $600…somebody told me not to call because of that consideration whereas I never thought of it before…" "I think being prepared is the best thing to prevent barriers…that's one of my mindsets, to check that ICC before I even think about pushing…" "I turn the heater up on the warmer, I turn on the O2, I turn everything on because you never know…"
Optimism is confidence that the desired goals will be achieved Optimism as a barrier (n = 0) Optimism as a enabler (n = 4)	Positive effects of PPV	"If you are willing to do it(bag mask ventilation)…that's our problem for a lot of people…is that initial step to do it, they don't want to go to that step…but if you do it makes such a difference…"
Goals are intended outcomes that an individual would like to achieve Goals as a barrier (n = 0) Goals as an enabler (n = 4) Reinforcement	Troubleshooting	"I reposition the baby, I reposition the mask, because I keep thinking until the baby starts responding to me…" "I just keep doing things to try to fix it until the baby responds…"
Knowledge includes knowledge of a particular condition, procedural knowledge, or knowledge of a specific task or environment Knowledge as a barrier (n = 2)		"You have the changes that happen mid cycle…sometimes they change their protocols in how they do things on NICU but we don't know it downstairs so even though we prep our beds…they are redoing what we already did…"
Knowledge as an enabler (n = 12)		"You just go through the motions and you just do it because that's what you are trained to do…"

Intentions are a conscious decision to perform an action to act in a certain way	Keeping the family updated regarding the baby's status	"You need to be able to look at the mom and dad and say it's okay and that this is going on, I think that goes a long way when they are lying there…they just see, "They just took my baby!""
Beliefs about capabilities		"Even if I think I have a secondary apnea…or it I have a baby that has not come around through stimulation there is no doubt in my mind that I bring that baby right over and start PPV

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SUMMARY OF MANUSCRIPTS

Overview of Manuscripts' Contribution to the question of Interprofessional Teamwork and Performance in Delivery Room Neonatal Resuscitations

Manuscript one was a review of the existing literature to examine measurement instruments appropriate for use in interprofessional neonatal resuscitation simulations. While a plethora of research regarding interprofessional teamwork in resuscitation was identified, most of the studies had an adult focus and were used primarily in medicine, and not useful in interprofessional teams. In fact, a paucity of literature exists supporting the use of simulation and the effects of such training on patient outcomes. Moreover, most of the measurement instruments identified in the review had little supporting psychometric data (Clary-Muronda & Pope, 2016). One instrument by Lockyer et al. (2006) deemed appropriate for use in neonatal resuscitation simulations had extensive psychometric testing in interprofessional groups. However, the instrument was developed in 2006 and neonatal resuscitation guidelines have been updated twice since the instrument was developed. The updating of the Lockyer et al. (2006) instrument is beyond the scope of this research.

Manuscript two described a qualitative descriptive analysis using the TDF and the McLeroy et al. (1988) version of the Social Ecological Model to examine the facilitators of, and barriers to, effective delivery room neonatal resuscitations from the perspectives of interprofessional neonatal resuscitation team members. The study results unveiled team processes that facilitated teamwork, and some team and individual behaviors that impeded team functioning. Data from the first qualitative study answered the first overarching question: "What do interprofessional neonatal resuscitation team

members believe to be facilitators for, and barriers to, effective delivery room resuscitations?" Several recurrent themes emerged from the data such as the need for practice, the need for enough assistance in all deliveries, and the need to act quickly for the best outcomes. Information from this study revealed several barriers and facilitators for consideration in intervention design.

One approach that may support the implementation of best practices is frequent simulation-based continuing education in interprofessional teams (Rubio-Gurung et al., 2014). Other potential solutions include use of standardized pre-resuscitation checklists and video debriefing of actual resuscitations (Brown et al., 2016; Pearlman et al., 2016; Rubio-Gurung et al., 2014). This study also answered the second overarching question, "What specific areas can be targeted for intervention to eliminate the barriers and enhance the enablers of delivery room resuscitations?" One consistent theme emerged for further exploration, bag-mask ventilation as an area for a targeted intervention specifically for labor and delivery nurses.

The first qualitative study informed the next arm of the study, a qualitative analysis of enablers for, and barriers to, effective bag-mask ventilation as experienced by labor and delivery nurses, who are often first responders in neonatal resuscitations. Using the 14 domains of the TDF, barriers and enablers of bag-mask ventilation were systematically explored for areas for improvement. While a dearth of studies focus specifically on the bag-mask skills of labor and delivery nurses, the literature supports interventions that focus on assessing competency in bag-mask ventilation (Pearlman, Zern, Blackson, Ciarlo, Mackley et al., 2016). Evidence from this research suggests there is a need for frequent practice of skills in addition to standard NRP training. A

combination of approaches to address the multiple factors in delivery room neonatal resuscitations may promote the enablers and minimize the barriers for best practices. Interventions such as individualized short, instructional videos in bag-mask ventilation and self-directed low fidelity simulation sessions reinforce best practices. Assessment of intervention impact in relation to neonatal outcomes is essential since improvement of outcomes is the goal, requiring the development of measurement instruments to assess learning and clinical outcomes.

Limitation of Dissertation Research

As with most qualitative research, findings of this research may not be generalizable to all similar populations. However, the intent was to use a theory-informed method to develop an intervention in the specific study setting that might be sustainable and have a positive impact on clinician practices and patient outcomes. The rationale for qualitative description provides an insight to participant perceptions that is difficult to assess with quantitative and the more interpretive qualitative realms (Hsieh & Shannon, 2005).

While limitations of qualitative research are well documented in the literature, inherent limitations are also present in quantitative research as it fails to address the individual experiences of participants, and in effect, generalizes those experiences. Qualitative research provides an additional dimension to data with a degree of depth that is impossible to capture with strictly quantitative methods. Yet, this wealth of data is underutilized in application to intervention implementation (Ludvigsen, Hall, Meyer, Fegran, Aagaard, et al., 2015). Relatively new in qualitative research, qualitative research synthesis (QRS) is similar in approach to quantitative meta-synthesis. A methodological

secondary analysis of previous studies, QRS uses the findings from previous qualitative studies to support themes, categories, hypotheses, or theories that extend beyond the findings of the primary analysis. QRS is not without challenges; the process involves delving into large amounts of data, requiring expert knowledge in both the qualitative and quantitative realms of research. Despite these challenges, QRS can provide a means for compilation of qualitative data in a manner that supports validity and enhances the transferability to other populations. As the emerging body of qualitative evidence grows in the area of enablers and barriers to neonatal resuscitation, QRS may be of use in secondary analyses of the larger body of data for the purpose of transferability to other populations. (Ludvigsen, Hall, Meyer, Fegran, Aagaard, et al., 2015).

Lessons Learned

This research was revised due to the difficulty obtaining an interprofessional sample to participate in originally proposed neonatal resuscitation simulations. While support was evident from the study setting stakeholders, organizing interprofessional activities is a complex task due to participant scheduling issues, clinician availability, and in-situ space availability. Interprofessional educational activities are relatively new in the study setting, and have not been fully implemented, further complicating the initially proposed simulation arm of the study. Furthermore, the lack of a current measurement instrument to use for the study created an additional challenge. The focus of the study was redirected to develop a comprehensive understanding of the contextual factors that might impede the implementation of best practices. The TDF provides a systematic guide for the development of a multipronged intervention that may have an optimal impact by addressing existing enablers and barriers.

Importance of theory, model or framework to guide overall findings

Health care researchers continuously strive to discover ways to improve clinical practices by conducting research to discover the best evidence-based practices for implementation. Various problems exist in clinical settings that may be specific to the particular setting, and may complicate proposed practice changes, minimizing their effectiveness (Grol & Grimshaw, 2003). Less than 10% of implementation researchers use a theoretical rationale to guide interventions (Gagliardi et al., 2016; Grimshaw et al., 2004). As a result, evidence-based guidelines are inconsistently applied to practice (Gagliardi et al., 2016). Recognizing the various challenges of clinical practice, this research used a theoretical approach to assessing current practices and the barriers and enablers of best practices in delivery room neonatal resuscitations. A comprehensive understanding of the challenges can make it possible to create a favorable environment for the implementation of best practices. Michie et al. (2005) propose using theory to inform practice by using an integrative theoretical framework to address the contextual factors that might impede best practices. The Theoretical Domains Framework has been used successfully to unveil barriers to best practices that have been overlooked (Kirk et al., 2016).

Central to the study, the TDF provided a methodological transparent process that was instrumental in guiding each part of this research. The challenges of bridging the knowledge-practice gap in nursing and the other health professions are well documented in the literature. The reliability and validity of the TDF are well documented, making the TDF an ideal framework to guide similar interventions that require sustainable changes in clinician behaviors (Cane, O'Connor, & Michie, 2012).

Simulation-based neonatal resuscitation scenarios are central to the 7th Edition Neonatal Resuscitation Program (AAP, AHA, 2015), However, emerging evidence suggests that such complex scenarios may overwhelm participants, impeding learning (Meguerdichian, Walker, & Bajaj, 2016). Meguerdichian, Walker, and Bajal (2016) suggest simplifying simulation-based learning by identifying knowledge gaps by a needs assessment to provide an opportunity for learner-paced practice of skills. The TDF provides a validated, systematic means to assess the specific learning needs of the population of the study.

To address some of the contextual issues involving the larger interprofesssional team, high fidelity simulation-based learning, videotaping of actual resuscitations for debriefing, and standardized pre-delivery checklists may remove some of the barriers identified by participants (Brown et al., 2016; Pearlman et al., 2016; Shivananda et al., 2016). Yamada et al. (2016) suggests using a toolkit combining multiple strategies delivered in combination to strengthen implementation of best practices. The Yamada et al. (2016) approach aligns well with the TDF as it integrates several strategies to address existing barriers and enablers to implementing best practices.

An ideal approach that may address the learning needs identified in the second study is smaller, learner paced, training specific to the area of bag-mask ventilation for labor and delivery nurses. Shifting the approach to identifying specific learner knowledge deficits can optimize learning, enhancing long-term memory (Meguerdichian et al., 2016). Improving this basic skill can contribute to improvements in team functioning in the larger, team-based simulation, and in execution of bag-mask ventilation in real-time actual resuscitations. Lastly, evaluation of outcomes, a component missing from most

simulation-based studies in neonatal resuscitation, is an important component to be integrated with interventions, since improved neonatal outcomes is the overall goal.

Research Trajectory

This research identified several areas that warrant further investigation: (a) the development of a new or the updating of an existing measurement instrument using current neonatal resuscitation guidelines to use for continuing education in simulation-based training for interprofessional teams in neonatal resuscitation, (b) the development of targeted bag-mask ventilation practice sessions for labor room nurses as a refresher between NRP courses to improve this crucial skill, and (c) use of a theory-based framework to provide the foundation for interventions in neonatal resuscitation aimed at improving clinician practices.

Contribution of Research to Science and Nursing

This research used the TDF as a guiding framework to understand the existing contextual barriers that prevent adherence to clinical practice guidelines in delivery room neonatal resuscitations. As a result, this is the only research identified by this investigator that addresses bag-mask skills, one of the most crucial skills, specifically for labor and delivery nurses, a population who must draw upon those skills in a stressful environment. Additional research is necessary to develop and refine this specific skill set for labor and delivery nurses and to improve the team behaviors of the larger interprofessional team so that teams can function with improved efficiency. Use of video to record actual neonatal resuscitations for audit and teaching purposes is an emerging strategy to create an objective assessment of interventions and outcomes (Schilleman et al., 2014; Shivananda

et al., 2017). Video data of actual and simulated resuscitations may provide instrumental data to measure the effect of learning on patient outcomes.

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List of Appendices

Appendix A MUSC IRB Approval Letters (Initial and second protocol)

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00059012** entitled:
Using Simulation to Assess Inter-professional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

submitted by: **Valerie Clary-Muronda**
Department: **Medical University of South Carolina**
Sponsor:

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved. In accordance with 45 CFR 46.101(b)(2), the referenced study is exempt from Human Research Subject Regulations. No further action or Institutional Review Board (IRB) oversight is required, as long as the project remains the same. However, you must inform this office of any changes in procedures involving human subjects. Changes to the current research protocol could result in a reclassification of the study and further review by the IRB.

Because this project was determined to be exempt from further IRB oversight, consent document(s), if applicable, are not stamped with an expiration date.

Research related records should be retained for a minimum of three years after termination of the study.

Approval Date: **8/31/2016**

Type: **Exempt**

Chairman, **IRB-I - Medical University of South Carolina**
Mark Hamner•

•***Electronic Signature***: *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

MUSC
MEDICAL UNIVERSITY
of SOUTH CAROLINA

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00063463** entitled:
Study Title: Bag-Mask Ventilation of the Neonate in Labor and Delivery: The Perspective of the Labor and Delivery Nurse: A Qualitative Descriptive Study

submitted by: **Valerie Clary-Muronda**
Department: **Medical University of South Carolina**

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved. In accordance with 45 CFR 46.101(b)(2), the referenced study is exempt from Human Research Subject Regulations. No further action or Institutional Review Board (IRB) oversight is required, as long as the project remains the same. However, you must inform this office of any changes in procedures involving human subjects. Changes to the current research protocol could result in a reclassification of the study and further review by the IRB.

Because this project was determined to be exempt from further IRB oversight, consent document(s), if applicable, are not stamped with an expiration date.

Research related records should be retained for a minimum of three years after termination of the study.

Approval Date: **2/4/2017**

Type: **Exempt**

Chairman, **IRB-I - Medical University of South Carolina**
Mark Hamner•

•***Electronic Signature***: *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Virtua

TITLE OF RESEARCH: Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

Study Information Sheet: Part 1: Interview

PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this form carefully and take your time making your decision. As your study staff discusses this form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this research study is to identify the facilitators and barriers to interprofessional collaboration in neonatal resuscitation teams in the delivery room and to compare self-ratings of team performance in neonatal resuscitations to observer ratings of team performance to determine areas for improvement. You are being asked to join the study because you are an interprofessional team member and your perspective of interprofessional teamwork and performance in neonatal resuscitation is important if substantial improvements in team processes are to be made. This study has 2 parts, one consisting of a 30-45 minute interview, and one consisting of observation of your NRP simulation. You may participate in one or both parts of the study. This sheet explains the interview part of the study. This study involves research consisting of an interview either in person or by phone and the observation of simulation and debriefing sessions. You will also be asked to fill out a brief demographic questionnaire where you will be asked information about your background. The study is a dissertation study requirement for the researcher. The investigator in charge of this study is Valerie Clary Muronda, MSN, a labor and delivery nurse at Virtua Voorhees. The study is being done at Virtua Health, at the Voorhees Campus. Up to 25 people will take part study-wide.

PROCEDURES

- You will have an in-depth interview with the researcher. In the interview, you will be asked questions about your perceptions of team performance and potential areas for improvement in neonatal resuscitations in the delivery room. This interview will be audio recorded, then transcribed and given a code so that your interview responses will be unable to be identified. You will also be asked to fill out a a questionnaire with brief background questions such as profession, years experience, etc.

DURATION:

The interview will take approximately 30 minutes to 45 minutes and will be conducted in person or by phone. The maximum time commitment for this portion of the study is 1 hour.

MUSC
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IRB Number: 47681«ID»
Date Approved
3/2/2016«ApprovalDate»

Virtua

RISKS/DISCOMFORTS:

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. However, the researcher will maintain confidentiality by removing identifying information from study data and assigning numeric codes to prevent loss of confidentiality. Furthermore, the research data will only be accessible to the study researcher and her supervisor and will only be used for research purposes. You can discontinue participation in this study at any point, however, data collected until that point will be retained for analysis for the study.
BENEFITS: There is no direct benefit to you for participating in this study. However, it is expected that the findings may provide useful information to guide educational activities geared at improving team processes and interprofessional collaboration, particularly during delivery room resuscitations occurring in the study setting.

COSTS:

There is no associated charge for participation in this study.

PAYMENT TO PARTICIPANTS:

Those who choose to participate in the study will receive a $5 gift card for each part of the study as a token of appreciation.

EMPLOYEE PARTICIPATION: This study is strictly voluntary. Participation in this study is not a requirement of employment. Your participation in this study is not mandatory.

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this institution. For further questions please contact Valerie Clary Muronda at clarymur@musc.edu; or by cell at 609-636-3712. If you have any concerns about your rights please contact the Virtua IRB at (856) 761-3844.

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA
IRB Number: 47681«ID»
Date Approved
3/2/2016«ApprovalDate»

TITLE OF RESEARCH: Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

Study Information Sheet: Part 2: Simulation

PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this form carefully and take your time making your decision. As your study staff discusses this form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this research study is to identify the facilitators and barriers to interprofessional collaboration in neonatal resuscitation teams in the delivery room and to compare self-ratings of team performance in neonatal resuscitations to observer ratings of team performance to determine areas for improvement. You are being asked to join the study because you are an interprofessional team member and your perspective of interprofessional teamwork and performance in neonatal resuscitation is important if substantial improvements in team processes are to be made. This study has 2 parts, one part consisting of a 30-45 minute interview, and one part consisting of observation of your NRP simulation. You may participate in one or both parts of the study. This information sheet describes the second part of the study, the observation of simulation and debriefing sessions. You will also be asked to complete a brief demographic questionnaire where you will be asked some information about your background. The study is a dissertation study requirement for the researcher. The investigator in charge of this study is Valerie Clary Muronda, MSN, a labor and delivery nurse at Virtua Voorhees. The study is being done at Virtua Health, at the Voorhees Campus. Up to 25 people will take part study-wide. You will also be asked to fill out a questionnaire.

- You will be asked to complete a demographic questionnaire that asks a few brief questions about your job responsibilities, experience level, and background.
- You will participate in simulations of neonatal mock codes that are part of your standard NRP training. These mock codes are routine scenarios used for NRP training purposes and will not be controlled or manipulated by the researcher. The simulations will be subject to real-time observation by the researcher and two objective raters for study purposes. Raters will rate team member performance using an updated neonatal resuscitation skills checklist for comparison to your ratings of skill performance. No names or identifiers will be attached to any checklist. Additionally, the recorded debriefing session will be observed by the researcher for study purposes to identify information that may provide additional insight regarding participant perspectives and team processes. You will also be asked to fill out a a questionnaire with brief background questions such as profession, years experience, etc.
- Lastly, you will be asked to complete a questionnaire about your perceived performance in neonatal resuscitation during your NRP simulation.

DURATION:

Participation in this portion of the study will take approximately 2 hours, but no longer than 4 hours, approximately 15-20 minutes longer than participation in NRP training. The data collection for this portion of the study will occur with previously scheduled NRP activities. Completion of the surveys will take approximately 10-15 minutes.

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Virtua

RISKS/DISCOMFORTS:

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. However, the researcher will maintain confidentiality by removing identifying information from study data and assigning numeric codes to prevent loss of confidentiality. Furthermore, the research data will only be accessible to the study researcher and her supervisor and will only be used for research purposes. You can discontinue participation in this study at any point, however, data collected until that point will be retained for analysis for the study.

BENEFITS: There is no direct benefit to you for participating in this study. However, it is expected that the findings may provide useful information to guide educational activities geared at improving team processes and interprofessional collaboration, particularly during delivery room resuscitations occurring in the study setting.

COSTS:

There is no associated charge for participation in this study.

PAYMENT TO PARTICIPANTS:
Those who choose to participate in the study will receive a $5 gift card for each part of the study as a token of appreciation.

EMPLOYEE PARTICIPATION: This study is strictly voluntary. Participation in this study is not a requirement of employment. Your participation in this study is not mandatory.

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this institution. For further questions please contact Valerie Clary Muronda at clarymur@musc.edu; or by cell at 609-636-3712. If you have any concerns about your rights please contact the Virtua IRB at (856) 761-3844.

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MEDICAL UNIVERSITY OF SOUTH CAROLINA
IRB Number: 47681«ID»
Date Approved
3/2/2016«ApprovalDate»

TITLE OF RESEARCH: Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: Bag and Mask Ventilation of the Neonate in Labor and Delivery: The Perspective of the Labor and Delivery Nurse.

Study Information Sheet: Part 2: Part II Focus Group Interviews

PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this form carefully and take your time making your decision. As your study staff discusses this form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this research study is to identify the facilitators and barriers to to effective bag and mask ventilation of the neonate in the delivery room. You are being asked to join the study because you are a labor and delivery nurse who responds to delivery room neonatal resuscitation. As a labor and delivery nurse, your perspective is an important aspect of addressing the existing barriers to effective bag-mask ventilation and developing a plan to address the barriers and facilitate improvement of this crucial skill. This study has 2 parts, one consisting of a 30-45 minute one-on-one interview, and one consisting of focus group interviews. This information sheet describes the second part of the study you are being asked to participate in, the focus group interviews. Focus groups will be comprised of labor and delivery nurses who will be interviewed as a group and asked to identify enablers and barriers to effective ventilation of the neonatal in labor and delivery. This sheet explains the focus group interview part of the study. This portion of the study involves group interviews of 6-8 labor and delivery nurses per group. Participants will be asked questions about unexpected delivery room resuscitations in which labor and delivery nurses are first responders. The information will be used to guide an intervention aimed at improving the essential skill of bag-mask ventilation for labor and delivery nurses. The study is a dissertation study requirement for the researcher. The investigator in charge of this study is Valerie Clary Muronda, MSN, a labor and delivery nurse at Virtua Voorhees. The study is being done at Virtua Health, at the Voorhees Campus. Up to 24 people will take part study-wide.

PROCEDURES

You will participate in a focus group interview with the researcher. The interviews will last approximately 60-90 minutes. In the interview, you will be asked questions about your perceptions of bag-mask ventilation and potential areas for improvement in the specific skill of bag mask ventilation for labor and delivery nurses. The interview will be audio recorded, then transcribed and given a code so that your interview responses will be unable to be identified.

DURATION

The interview will take approximately 60 minutes to 90 minutes and will be conducted in person in a group of 6-8 labor and delivery nurses. The maximum time commitment for this portion of the study is 60 to 90 minutes.

RISKS/DISCOMFORTS

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. However, the researcher will maintain confidentiality by removing identifying information from study data and assigning numeric codes to prevent loss of confidentiality. Furthermore, the research data will only be accessible to the study researcher and her supervisor and will only be used for research purposes. You can discontinue participation in this study at any point, however, data collected until that point will be retained for analysis for the study.

BENEFITS

There is no direct benefit to you for participating in this study. However, it is expected that the findings may provide useful information to guide educational activities geared at improving bag mask ventilation skills for the delivery room nurse, particularly during delivery room neonatal resuscitations resuscitations occurring in the study setting.

COSTS

There is no associated charge for participation in this study.

PAYMENT TO PARTICIPANTS

Those who choose to participate in the study will receive a $50 gift card for participation in the focus group as a token of appreciation.

EMPLOYEE PARTICIPATION

This study is strictly voluntary. Participation in this study is not a requirement of employment. Your participation in this study is not mandatory. Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this institution.

For further questions please contact Valerie Clary Muronda at clarymur@musc.edu; or by cell at 609-636-3712. If you have any concerns about your rights please contact the Virtua IRB at (856) 761-3844.

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Appendix C IRB Approval Letters Virtua Health

Virtua

Medical University of South Carolina
IRB Board
19 Hagood Avenue
Suite 601
MSC 857
Charleston, SC 29425

August 24, 2016

To: The MUSC IRB:

I am writing to express my support of the research study entitled "Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study" submitted by Valerie Clary Muronda. Valerie currently works as a staff nurse on the labor and delivery unit at Virtua in Voorhees New Jersey. I have been working collaboratively with Valerie and the Virtua IRB board as this study proposal has been created and revised to address the concerns that the Virtua IRB board and I have expressed. The original protocol was approved by the Virtua IRB February 12, 2016, and an amendment to the original protocol was approved July 15, 2016.

Sincerely,

Amy Glasofer DNP
Director for Nursing Research
Virtua Health
Center For Learning

General Institutional Review Board
1200 Howard Boulevard, Suite 100
Mt. Laurel, NJ 08054
Phone: (856) 761-3844
Fax: (856) 761-3834

July 15, 2016

Valerie Clary Muronda, MSN-Ed
409 Tanforan Drive
Cherry Hill, NJ 08002

Re: IRB G16003, Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

Dear Val,

The Virtua General Institutional Review Board (IRB) has reviewed and approved, through an expedited process, the amendment which relocates the study related simulations from the simulation lab to the labor and delivery unit. Approval for this study expires on February 11, 2017. If you need to continue your research beyond that time, a letter must be sent to the Chairperson of the IRB indicating your intent to continue research. At that time, an interim report discussing your progress is required.

If you have any questions, please feel free to contact me at (856) 761-3844.

Sincerely,

Amy Glasofer, DrNP, RN, NE-BC
IRB Administrator

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Licensed Content Title	Integrative Review of Instruments to Measure Team Performance During Neonatal
Licensed Content Author	Valerie Clary-Muronda,Charlene Pope
Licensed Content Date	September–October 2016
Licensed Content Volume	45
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BACK

Appendix E IRB Approval Interview Guides

Interview Guide

- Can you describe your role in neonatal resuscitations in the delivery room?
- What can you tell me about what happens in the delivery room when a baby cannot breathe?
- Can you describe a memorable NR in the delivery room that you were involved with? Walk me through what happened…
- If you had to come up with an improvement plan for NRs in the delivery room, how would you make the process better?

Secondary prompts to elicit narrative:

Tell me more about that.

Can you tell me how that happened?

Yes…

Ummhmm…

Go on…

Oh my…

Interesting.

Can you describe what you mean by that?

Really?

How do/did you feel about that?

In your experience, does it often happen like that? (for generalizations)

Other prompts such as echo wording, following up on overly broad generalizations by suggestion exceptions, playing devils advocate to present a counter position and clarifying confusing or contradictory statements may be used.

Focus Group Interview Guide

1. *Who are the first responders when you have to provide bag-mask ventilation for a neonate?*
2. *How often would you say you have to provide bag-mask ventilation for a neonate?*
3. *Can you describe the process and what typically happens?*
4. *What do you perceive as barriers to providing effective bag-mask ventilation for a neonate?*

(Any environmental factors?)

5. *What do you perceive as enablers to providing effective bag-mask ventilation for a neonate?*
6. *If you had to improve your resuscitation skills, what area would you like to work on?*

The interviewer will use prompting word and phrases such as "Go on," "Tell me more," "What did you mean by that," "Interesting," and "How did you feel about that?"

Appendix F Study Protocols

Medical University of South Carolina
Protocol

PI Name: Valerie Clary Muronda, MSN-Ed

Study Title: Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

Once protocol is complete, save it as a Word document. Go back to the IRB application and upload the protocol.

TABLE OF CONTENTS – *Prepare a table of contents based on the following outline, including page numbers, and insert here.*

A. SPECIFIC AIMS

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Need: Childbirth seems a miraculous event to expectant parents who welcome the newest addition to their family. Although most neonates make the transition to the extra-uterine environment without much intervention, a small number of neonates will require assistance with breathing at birth. Even the slightest error in resuscitative efforts can result in permanent injury or death. To address the needs of this uniquely vulnerable population, a readily available interprofessional (IP) team with well-coordinated skills is necessary at all times. Until recently, neonatal resuscitation (NR) instruction focused on task completion, usually in educational forums within the individual professions. However, in the delivery room, respiratory therapists, neonatal nurses, labor nurses, neonatologists, and nurse practitioners, with a diverse range of skills and expertise, comprise the typical NR team. Research studies addressing teamwork and collaboration are well documented in the literature in multiple patient situations across the lifespan, however few studies address the challenges of team diversity that are unique to delivery room NR teams and the multiple barriers to their effective functioning. Furthermore, few measurement instruments exist that adequately measure IP team functioning in NR. The goal of this mixed methods study with an exploratory sequential approach is to explore IP team functioning in simulations routinely used for educational and training purposes to update skills involved in NR to identify areas for improvement. Results will generate hypotheses and areas for intervention for better IP team coordination, beyond neonatal tasks, while updating a well-validated instrument that assesses NR performance. This mixed methods study will explore perceptions of facilitators and barriers to NR as experienced by individual IP team members (qualitative

data from a prior study) , and compare their self-ratings of a NR simulation with external rater observations of simulated NR performances. Findings will also provide a preliminary foundation for future validity and reliability testing of the updated NR instrument.

Specific Aims:

Aim 1. Assess and compare individual post hoc self-ratings of perceived team performance with external observer quantitative assessments of team performance during NR simulations to determine variations pertaining to patient safety using an updated version of a previously validated measurement instrument for NR.

Aim 2. Use a matrix to identify and organize themes across qualitative data from a previous study and quantitative data from this study to integrate findings to determine areas for improvements in team processes for future intervention.

Aim 3. Update and perform preliminary testing of an established, validated NR instrument during NR simulations to incorporate recent Neonatal Resuscitation Program (NRP) of the American Academy of Pediatrics guideline changes and the perspectives of IP NR team members for continuing validation.

B. BACKGROUND AND SIGNIFICANCE

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this protocol by relating the specific aims to the broad, long-term objectives. If the aims of the study are achieved, state how scientific knowledge or clinical practice will be advanced.

A Joint Commission review of root cause analyses of sentinel events related to perinatal death or permanent disability involving NR found that 72% of these events acknowledged communication breakdown, and 55% cited organizational culture barriers to teamwork and communication (Joint Commission, 2004). Increasingly, researchers propose simulation training to improve NR (Halamek, 2013); yet, the role of such simulation training in improving teamwork in subsequent clinical practice for effects on clinical outcomes requires further study, according to systematic reviews (Finan et al., 2012; Rakshasbhuvankar and Patole, 2014). Although evidence supports an environment conducive to a culture of teamwork and collaboration, barriers exist to optimal team functioning, especially in situations where team members are diverse in knowledge and skill sets. Raab et al. (2013) reported on an observational three-hospital case study to improve patient safety and IP collaborative efforts among obstetrics, high-risk obstetrics, and neonatal providers that excluded NR with provider self-reported outcomes. This lower level evidence identified a need for objective measures that relates IP collaborative efforts to better teamwork, better clinical performance, and improved patient outcomes. The Neonatal Resuscitation Program (NRP) certification process for those responding to NR emergencies has been instrumental in improving neonatal outcomes (Berger, 2012). The NRP is jointly sponsored with the American Heart Association (AHA) and the American Academy of Pediatrics (AAP) to teach evidence-based NR to multidisciplinary hospital staff. Introduced in 1987, the NRP 6th Edition, updated in 2011, and more recently in May 2016, uses simulation methodology and advocates leadership, communication and teamwork skills. However, studies have shown that individuals taking the required formal NR course experience skill decay in only three to six months, while participants are required to renew these certifications every two years (Surcouf et al., 2013). While IP educational programs are challenging due to diverse educational backgrounds and learning needs, it is necessary to improve collaborative efforts for better outcomes, especially in the context of NR, which typically occurs in teams. Research addressing teamwork and collaborative efforts are documented in the literature in general practice, operating rooms (Nguyen et al., 2015), labor and delivery (Dadiz et al., 2013), and overall (Rigall & Smith, 2015). Few studies of NR address the challenges of IP team diversity, the complexities of organizational culture, barriers to IP collaboration, and the multiple levels of support necessary to sustain changes.

While some studies use measurement of self-assessment of performance, these measures are often inaccurate, necessitating external assessment of team functioning and performance, as shown in a randomized control trial of a simulated hospital emergency (Siassakos, et al., 2011). Few studies compare the observations of individual team behavior and self-perceived individual performance jointly. Results of a pretest/posttest interventional study in which 216 physicians and nurses were trained in post neonatal resuscitation stabilization skills suggested a need for well-developed evaluation instruments to asses learner outcomes (Singhal, Lockyer,

Fidler, Aziz, McMillan, Qui, Ma, Du & Lee, 2012). Currently, according to Nalini Singhal, MD, a content expert in NR, no existing instrument adequately addresses important aspects of team functioning such as timeliness, sequence, and organization, although these aspects are directly related to neonatal outcomes (N. Singhal, personal communication, February 19, 2015). As aptly stated by John J. Schaefer III, MD, professor of anesthesiology at the Medical University of South Carolina (MUSC), pioneer in simulation development, and content expert in simulation-based education and research, existing measures fail to address the fluidity of team dynamics in resuscitations that has a direct effect on patient outcomes (J. Schaefer, personal communication, July 21, 2014; MUSC, n.d.). Studies that compare individual self-ratings of skills with observations of performance can provide useful information to guide simulation-based, evidence-based continuing education programs (Jukkala & Henly, 2009). Both, the improvement of team behaviors and better execution of skills work jointly to enhance care delivery, thereby improving patient outcomes, according to a prospective observational simulation-base study by Dadiz et al. (2013). According to a randomized control trial of 34 interns testing the 2-hour NRP, video recorded observations of NR events raise questions about the role of teamwork behaviors and errors and how to best deliver training to improve collaboration and patient safety (Thomas et al., 2010). Literature review of patient safety and dynamic events, such as NR, identifies the need for more research focusing on healthcare provider perceptions of team performance and their attitudes toward team behaviors associated with patient safety (Manser, 2009). A preliminary study of NR in a simulation setting suggested improvements in some teamwork behaviors (Sawyer et al., 2013), but did not account for provider perceptions of team performance. Hence, there remains a need to investigate how simulation training in NR changes perceptions and behaviors associated with patient safety. A prospective pre-test/post-test study by Sawyer et al. (2013) examined teamwork during NR after teamwork training using the TeamSTEPPS course curriculum. TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) is a program designed by the AHRQ and the Department of Defense to improve collaboration in health care teams (AHRQ, 2006). However, performance was not measured. More research examining both perceived teamwork and recorded and measured skill performance is necessary to improve IP continuing education programs with a team focus. Yuan et al. (2012) conducted a meta-analysis of evidence on improving skills and knowledge using high fidelity simulation in English and Chinese. Twenty-six studies, 16 RCTs, one non-RCT and nine quasi-experimental studies were reviewed. Most of the evidence was found to be of poor quality due to small sample size and insufficient power to detect effect, lack of description of randomization procedures, and lack of attention to validity and reliability of the instruments used in the studies (Yuan et al., 2012). Only one of the studies reviewed by Yuan et al. (2012), had a neonatal focus, and this study had a sample size of 45 and the results were not statistically significant. Clearly, a need exists for well-designed studies that have an IP team focus, measures with well-established psychometric properties, and are translatable to clinical practice. The following research question guides this study: In IP NR teams, how can variations related to patient safety be identified in a comparison of qualitative individual perceptions of current IP team practices (from a prior study) to quantitative self-ratings of team performance and external observer ratings of team performance during NR simulations and be integrated in the update of a previously validated measurement instrument for performance in NR simulations?

This proposed study addresses the need to explore the facilitators for, and barriers to, effective NR, and a need to establish appropriate, current, measures to assess team functioning in IP NR teams to develop a scientifically - driven intervention to improve patient outcomes. Application of a mixed methods research approach allows the researcher in the proposed study to identify the facilitators for and barriers to collaborative efforts from the standpoints of individual IP team members from diverse perspectives in contrast to the identification of gaps between self-perceived performance and actual performance for quantitative analysis in a safe simulation environment. Integration of qualitative methods (from a prior study) allows for an expansive view of the challenges present in IP collaboration that may remain undiscovered in a strictly quantitative approach as Creswell and Plano Clark describe (2011).

Simulation

While simulation-based education is rapidly becoming a standard in healthcare professional education, there is a lack of literature discussing the best approaches to improve patient outcomes (Knight et al., 2014). A review of the literature by Schaefer et al. (2011) suggested that many of the simulation-based studies reviewed lacked rigor due to inappropriate research design and methodology, lack of attention to validity and reliability, and lack of

translational generalizability. A narrative review sorting types of simulation education also suggests that the use of simulation for mandatory training of IP teams may improve neonatal outcomes; however studies have shown mixed results in the transference of skills to the clinical area (Griswold et al., 2012). For example, a study by Finan et al. (2012) in which pediatric residents completed a two-hour training session did not reveal significant improvements in clinical performance. Alternatively, emerging evidence from a review suggests the use of simulation as a frequent refresher for skill practice for educational teams may improve operational team functioning and skill performance, though desired outcomes of safer patient care and better outcomes will require more rigorous studies (Griswold et al., 2012). A single-group pre and post-intervention study was conducted by Meier et al. (2012) to determine the effectiveness of a TeamSTEPPS-based curriculum on medical student team skills, though not in an IP setting, results of the study showed improved self-evaluation and team skills post-intervention. Conflicting findings such as the Meier et al. study (2012) and the Finan et al. study (2012) suggest a need for further research exploring simulation-based education on IP education, particularly in NR, an area that has been underexplored.

Simulation and Teamwork in NR

Given the prominence of simulation in the continuing education of licensed clinicians, additional research needs to explore the effectiveness of IP collaborative neonatal resuscitative efforts using simulation. In a study by van de Ven et al. (2010) involving an IP training program for obstetrical emergencies, the investigators noted the lack of literature supporting simulation as an educational method for these situations. Many studies claiming a team focus to NR have only a physician focus. A quasi-experimental study conducted by Cordero et al. (2013) emphasized team approaches to NR. However, study participants were all pediatric residents. In clinical practice at the bedside, NR rarely consists of only physicians, necessitating a broader team focus to NR, one that takes into consideration the diversity of the IP team (Cordero et al., 2013). Implementation of similar simulation-based activities with IP team members would add the challenge of working with diverse teams, as they exist in clinical practice, strengthening this educational approach.

C. PRELIMINARY STUDIES

Provide an account of the principal investigator's preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

An integrative review conducted by this author provided information about measurement instruments for assessing teamwork and collaboration in delivery room neonatal resuscitations. This review found that few studies with well-documented psychometrics assess IP collaboration and teamwork in neonatal teams with diverse skills. Moreover, many of the existing studies have been done within the discipline of medicine, although most neonatal resuscitations occur in IP teams, often without a physician team member or with physicians of differing specialties. Even fewer of the studies reviewed considered the multiple level factors influencing neonatal resuscitative efforts in the delivery setting. Consultation with members of the team that developed one of the few instruments found with supporting psychometric data led to a collaborative effort to update the 2006 instrument to include the most recent NRP guidelines in the instrument.

D. RESEARCH DESIGN AND METHODS (including data analysis)

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Explain sequentially the study procedure, including all the visits, contacts, and interactions if the study will be designed in phases and each phase will require separate IRB approval, please specifically indicate this in the description. Include how the data will be collected, analyzed, and interpreted and specify what statistical methods will be used. Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. For well-known, established valid and reliable test instruments the detail here can be brief. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or

materials that may be hazardous to personnel and the precautions to be exercised.

This study is made possible because the health system, Virtua Health System, has granted permission for the use of the Virtua Voorhees site for this study. The simulations will occur in situ, in a labor and delivery suite for a realistic assessment of the facilitators and barriers of team functioning in delivery room resuscitations The neonatal resuscitation simulations are for research purposes only and are not related to training. Participation is voluntary and consenting interprofessional team members will comprise the neonatal resuscitation teams. Eligible study candidates will be approached in person and given an information sheet about the study. The information sheets will state the purpose of the study, research-related tasks and procedures, reinforce that participation is voluntary with the ability to withdraw from the study at any time without loss of benefits or penalty and provide PI contact information. The PI will obtain verbal consent from study participations and assign a code to individual participants for de-identification purposes. Participants may give verbal consent to participate in neonatal resuscitation simulation in the delivery room. Neonatal resuscitation simulation will occur at scheduled times. The PI will work with the labor and delivery management team and the neonatal intensive care unit management team to determine appropriate times to run the simulations.

This mixed methods study is non-experimental observational research with an exploratory sequential approach. An exploratory sequential approach is often employed in instrument refinement and is useful in providing vital information that can be incorporated in later revision of an instrument. Particularly useful in research that seeks to hear the voices of the participants, a mixed methods study design is a suitable choice to answer the research questions in this study, because of the combination of qualitative data (from a prior study) and quantitative data (Creswell & Plano Clark, 2011). The study compares qualitative data from a previous study with quantitative measures of skills and team processes to determine areas for improvement in interprofessional neonatal resuscitations.

Upon IRB review and approval, Neonatal resuscitation simulations will occur in the labor and delivery unit for volunteer interprofessional participation for research purposes. A standardized neonatal resuscitation simulation scenario will be used for consistency, and simulations will be video recorded for later analysis by 2 observers. Quantitative data collection will occur via participant post hoc ratings and external observer ratings of teamwork during a simulation of a NR using an updated version of the Performance Checklist to Assess Neonatal Resuscitation Megacode Skills (PCANRMS) (Lockyer et al., 2006). After the completion of aims 1, and 2, the data will be integrated. After reducing both quantitative and previously collected qualitative data in a matrix, the data will be examined for relationships and identifiable themes with the assistance of *NVivo* 10 software. Although the original instrument has well-established reliability and validity, updates are necessary to reflect important changes to the NRP guidelines. The updated instrument incorporates these changes with the addition of 7 new items with no changes to the 3-point scale and original content. The updates of this instrument will include the NRP guideline changes with the updated instrument undergoing reliability testing in addition to face and content validity testing with a consensus of a 12-person IP expert panel. For the proposed study, the updated version will be used for the purpose of preliminary testing since it most appropriately addresses the current standard of care in NR.

Aim #1 (Quantitative): Assess and compare individual post hoc self-ratings of perceived team performance with external observer quantitative assessments of team performance during NR simulations to determine variations pertaining to patient safety using an updated version of a previously validated measurement instrument for NR. ***Significance.*** Many studies have examined perceptions of teamwork, however there is a dearth of studies examining both perceptions of teamwork and performance in diverse IP teams. An observational study of 22 IP providers by Robertson et al. (2009) evaluated crisis team training for obstetrical emergencies and found that individual perceptions and attitudes of team performance improved after a 4-hour training session, yet the perceptions of improvements were not compared to actual performance. More research examining interpersonal dynamics among team members is necessary to develop continuing educational programs that improve IP collaborative efforts while eliminating barriers to team functioning (Beebe et al., 2012). The *objective* of this aim is to determine if there is a variation between perceptions of team performance and observations of team performance, two measures that have been examined interchangeably in simulation-based studies. The research null hypothesis for testing is: *There are no differences between self-evaluation and external observer ratings. To attain the objective of this aim* the researcher will use a Bland - Altman Analysis to compare both quantitative assessments, the rater assessments, and the self-appraisal assessments to determine if the methods are comparable to the extent that the methods might be used interchangeably (Bland & Altman, 1983). The *rationale* of this objective is that concurrent examination of both

measures can provide useful information about how interchangeable each measures is, and to what extent the measures differ.

Data Collection. For aim 2, Neonatal resuscitation simulations will occur "in situ" with consenting interprofessional team members within the labor and delivery suite for research purposes. Willing participants will receive a pre-numbered packet with a self-rating and demographic questionnaire. 3-4 individual team members will comprise each neonatal resuscitation team. Video recorded neonatal resuscitations and debriefings will be analyzed to capture event for quantitative and grounded theory data analysis and review by raters. Scenarios will take 15-20 minutes to complete including debriefing sessions. The neonatal resuscitation simulations will consist of standardized neonatal resuscitation scenarios for consistency. The PCANRMS updates will incorporate the recent NRP guideline changes. Two raters will use the updated version of the PCANRMS to rate performance.. Additionally, participants will complete self-assessment of NR skills by completing the same updated PCANRMS immediately following each simulation session. To gain further information regarding the generalizability of results, a brief demographic questionnaire (in the participant packet) will facilitate the (an instrument developed by the researcher) examination of the effect of demographics on study results. All surveys will be kept in a locked cabinet in the office of the PI with key access only. The demographic instrument will be completed by each participant for examination of following demographic variables: profession, years of experience, NRP certification, age, position, level of education, race/ethnicity, gender, and primary language. The participants and raters will complete the questionnaires on paper and the data will be subsequently exported for analysis in IBM SPSS 22.

Descriptive statistics will be computed using the demographic data of the study participants. Frequencies will be reported for each categorical variable. Frequencies will also be reported on ordinal variables such as years of experience. For continuous variables such as age, the central tendency measures of mean, median, and standard deviation will be computed.

Statistical Analysis.

While many similar studies use the product moment correlation coefficient to compare two measures, there are several issues with this approach: (a) *r* measures the strength of the relationship between variables rather than the extent of agreement between them; (b) significance of a relationship between the two measures is not the same as agreement between two measures; (c) data that shows poor agreement can produce high correlations, making a correlation coefficient an inappropriate measure for the purposes of this study; and (d) the correlation will increase if the variability of subjects increases (Altman, & Bland, 1983; Bland & Altman, 2010).Chosen for its ability to detect the degree to which the measurements agree, the Bland - Altman Analysis most appropriately addresses the research aims in the proposed study. While it is unlikely that both methods of measurement will be identical, the Bland - Altman analysis will provide information regarding how much the self-ratings will agree with the observer ratings and if the difference between the two ratings is insignificant enough for the methods to be used interchangeably (Bland & Altman, 2010). The method of analysis that will be used in this study is the Bland - Altman comparison of methods approach, in which the two methods will be directly compared, with the observer rating method serving as the gold standard, and the self-ratings as the alternative method (Bland & Altman, 1983). The Bland - Altman method is a calculation of the mean differences (bias) between the two methods. The standard deviation of the difference of a single measurement between the two methods is necessary to determine the extent of agreement between the two methods. To compare each quantitative measure, data from both measurements, the self-ratings and the observer ratings, will be visually inspected on the Bland-Altman plot with the observer ratings on the *x*-axis and the self-ratings on the *y*-axis. While this plot will reveal a visualization of the relationship, the greater the range of measurements, the better the agreement will appear. Thus, another plot displaying the differences between the methods ((A-B) against (A + B)/2) is necessary and will provide a visualization of the magnitude of disagreement, display outliers, and display data trends (Bland & Altman, 1983). In this plot, the average of the methods will comprise the *x*-axis, and the difference between the methods will comprise the *y*-axis.

Instrumentation

The rationale for updating the instrument in this study was the lack of appropriate instrumentation to measure perceptions and observations of team performance that are inclusive of items that are specific to current NR guidelines and appropriate for diverse IP team members.

Original Performance Checklist to Assess Neonatal Resuscitation Megacode Skill (PCANRMS)

Validity

Content validity of the original instrument was assessed by the NRP steering committee and the instrument was placed on the NRP website for review by other NRP providers (Lockyer et al., 2006). In the initial version, 822 responders provided feedback and modifications were made based upon this feedback. Criterion validity was established through assessment of correlations between the megacode scores and the megacode exam scores and between the total converted megacode scores and student perception scores. The final checklist contained 20 items that were then tested on 468 students and 148 instructor volunteers and the data was analyzed using descriptive statistics. The updated version of the instrument will be inclusive of recent NRP guideline changes. Changes in the instrument reflect the new NRP guidelines, and are currently under review for content and face validity by a panel of 12 IP content experts. The updated instrument will likely be an early version of the revised PCANRMS, and will later undergo standard psychometric testing similar to the original instrument in future studies.

Reliability

The original Performance Checklist to Assess Neonatal Resuscitation Megacode Skills (PCANRMS) is a checklist that was developed by the Neonatal Resuscitation Program Steering Committee of the American Academy of Pediatrics as an abbreviated instrument for NRP skill performance (Lockyer et al., 2006). The original version of the Performance Checklist to Assess Neonatal Resuscitation Megacode Skills (PCANRMS) is a final version of the 77 NRP item checklist that underwent psychometric testing in 3 phases ending in a 20-item checklist with a 0-2 point scale. The internal consistency reliability was tested for each of the megacode sub scores and the overall Cronbachs alpha was 0.70 (Lockyer et al., 2006).

Expected Results, Interpretation, Possible Pitfalls. It is expected that the information gained from this aim will provide useful information regarding educational needs of team members so IP team educators can target weak areas of teamwork, collaboration and performance. The quantitative instrument employed in this study is an update of the original instrument. Although assessment of validity and reliability of the updated instrument is ongoing and psychometric support has not been fully established, the psychometric testing of the instrument in its original form provides a dependable baseline for assessment. Preliminary content validity will be assessed using a 12-person expert interprofessional panel. Consistent with the original instrument, a three-point scale ranging from 0-2 will comprise the response range for each item. Cronbachs alpha will be calculated for internal reliability, in addition to interrater reliability using two raters to assess performance. Further validity and reliability testing are necessary to support the use of the updated instrument. Construct validity and criterion-related validity are among other types of validity and are beyond the scope of this preliminary study; however, establishment of other types of validity of the instrument would provide additional psychometric support for subsequent studies. Additionally, systematic problems with collection methods can complicate quantitative data collection and analysis result in systematic errors in data processing. The researcher will look over paper surveys for completion and provide standardized instructions for questionnaire completion to reduce the likelihood of missing data and systematic errors. Other limitations include the small sample size in this preliminary study. This limitation will be considered in the discussion of the results. Data will be displayed in the following format:

Participant	PCANRMS Item	Self Assessment	Observer Rater Assessment	Effect on Patient Safety Positive/Neutral/Negativ

Aim 2: (integration) Use a matrix to identify and organize themes across data sets to integrate findings from qualitative (from a prior study) with quantitative data (from this study) to determine areas for improvements in team processes for future intervention. ***Significance.*** The integration phase, integral to mixed methods studies, is the point where the researcher combines the data, using both sets of data to provide a more enhanced view of the research problem than either method alone (Creswell & Plano Clark, 2011). Providing an opportunity for IP NR team members to express views about NR IP team functioning can elucidate complex

team problems that require consideration when developing an intervention. Employment of mixed methods in this study enhances understanding of IP team functioning from various points of view within the context of a complex, multi-level system. The *objective* of this aim is to link findings from the individual data strands into an integrative description of the bridging of both data sets (meta inferences). To attain the objective of this aim, the data will be examined from both the qualitative(from a prior study) and quantitative data strands from this study to determine the potential effect of the identified facilitators for, and barriers to, IP team performance and to determine gaps between observations and perceptions of team performance. Additionally, this aim addresses the following components of triangulation as identified by Greene et al (1989): triangulation, which involves the convergence of both data strands; complementarity, which allows the researcher to enhance the description of a particular phenomenon with both qualitative and quantitative data respectively, and expansion, in which the researcher seeks to broaden the range of inquiry by integrating the two research methods (Green et al., 1989). The *rationale for this aim* is the enhanced understanding of IP team functioning elucidated by the combination of both, the qualitative and quantitative methods, when compared to each individual method alone. Information from this aim will provide a comprehensive, multidimensional, understanding of barriers and facilitators to IP teamwork and performance in NR that can be instrumental in intervention development.

Integration. After independently analyzing data as described by the first two aims, the data will be examined and integrated to draw on the strengths of both data sets (Creswell, 2012. Qualitative responses will be quantitatively displayed with simple frequencies by profession in the matrix for comparison with quantitative data. Additionally, previously collected qualitative data will be systematically organized by themes to determine if there is a relationship with quantitative variables (Creswell & Plano Clark, 2011). The process of preparing qualitative data for integration with quantitative data consists of the following steps: data reduction, data display, data transformation, data correlation, data consolidation, data comparison, and data integration (Creswell & Plano Clark, 2011). To prepare data for analysis, data reduction will occur by writing summaries of qualitative findings, and identifying categories, codes, and themes in qualitative data and subsequently transforming this data into quantitative data as simple frequencies with the assistance of *NVivo 10* software (Creswell & Plano Clark, 2011). Data will then be examined for similarities and differences within and between the different professions. Themes will be matched with the corresponding quantitative items to elucidate better understanding of facilitators and barriers to effective NR as they relate to patient safety from the standpoints of the participants. These findings will be displayed in the integration matrix to facilitate the bridging of both data strands and the drawing of meta-inferences through side-by-side comparison. The PI will use the findings to generate hypotheses that will form the foundation for an implementation model with the goal of improving team processes.

Integration matrix. A mixed methods matrix will be used to examine data during the integration phase of data analysis to study the relationship between themes (and similarities and differences) identified in the qualitative interviews (from data obtained in a previous study)

and quantitative data. Quantitative and qualitative data (from a prior study) will be placed in the following matrix. Qualitative themes will be matched with corresponding quantitative items and the associated affect on patient safety (positive, negative, or neutral).

Profession	Qualitative Theme/ frequency	Corresponding quantitative item(s)	Item self-participant rating /observer rating	Effect on patient safety (positive/negative/neutral)/Rationale

Integration Procedure

1. Compare results from Aim 2 for the identification of similarities and differences, especially where patterns of participant perceptions parallel with individual quantitative scores (low or high performance, low or high teamwork, etc.), specific patient safety issues, or wide intervals between self and external observer ratings.

2. If similarities are evident in data strands, compare similarities in data to reveal any relationships between the data.

3. If differences are evident in data strands compare differences in data to generate hypotheses that explain the incongruence.

4. Draw meta inferences and validate with inferences from individual data strands.

5. Consolidate the findings from Aim 3 using the new hypotheses for the development of an implementation model for IP neonatal resuscitation simulations..

Mixed Methods Study Design Overview (Creswell & Plano Clark, 2011)

Quantitative Data Analysis Procedure	Procedure for Data Analysis	Qualitative Data Analysis Procedure
Assign numeric values to code data Prepare data for analysis with SPSS Clean data Recode or compute new variables for computer analysis	Prepare data for analysis with simple frequencies	Organize the transcripts, field notes, and memos Transcribe text Prepare the data for analysis by *NVIVO*
Inspect the data visually Conduct descriptive analyses Check for data trends and distributions	Examine the data	Read the data Record memos Develop a qualitative codebook to guide analysis
Choose statistical tests Using SPSS, analyze the data to answer proposed research questions Report inferential tests, effect sizes, confidence intervals	Analyze the data	Code data Assign labels to codes Group codes into themes Interrelate themes into categories Use qualitative data analysis software to analyze *(NVIVO)*
Present results Provide results in tables and or figures Examine quantitative data for trends, convergence and divergence	Provide a visual table for the representation of the data	Represent findings in discussions regarding the themes or categories Visually present themes in the form of models figures and/or tables Examine similarities and differences of themes
Validate and check reliability scores Establish validity and reliability from current data Assess the internal and external validity of results	Validate the data and results	Crosschecking by validation of 1/5 transcripts by an experienced qualitative expert
Discuss limitations of reliability and validity of instruments Explain how results address the research question Discuss the implications for research and practice	Interpret results	How research question was answered Discuss personal meaning of findings Explore and state new questions based upon findings

Expected Results, Interpretation, Possible Pitfalls. In addition to providing preliminary data for the updated version of the instrument, results from this study will form the foundation for an implementation model that will reflect the

perspectives of the IP NR team and will address the facilitators for, and barriers to, effective IP team functioning. Possible limitations for this aim include focusing on one data set over another data set (Creswell & Plano Clark, 2011). This limitation may be addressed by the quantifying of the qualitative data for side-by-side comparison to enhance transparency of the integration stage of the data analysis process.

Aim #3: Update and perform preliminary testing of an established NR instrument during NR simulations to incorporate recent Neonatal Resuscitation Program (NRP) of the American Academy of Pediatrics guideline changes and the perspectives of IP NR team members for the purpose of improving IP team processes in NR. ***Significance.*** Simulation based educational activities can have a translational impact on patient outcomes; however this impact can be determined only with measureable data (Griswold et al., 2012). Simulation-based educational programs can result in measurable outcomes at the three translational science levels, the laboratory level (T1), the patient care level (T2), and the patient/population outcome level (T3). The Performance Checklist to Assess Neonatal Resuscitation Megacode Skill was one of the only instruments identified that has well documented reliability and validity and measures for performance in IP NR teams. *The objective* of this aim is to incorporate recent NRP guidelines inclusive of pulse-oximetry, timeliness of interventions, and team cohesion. Dr. Jocelyn Lockyer, one of the instrument developers, was contacted to inquire about the existence of an updated version of the instrument. Dr. Lockyer referred the researcher to Dr. Singhal, the content expert for the instrument for further questions. Dr. Singhal recommended updating the original instrument and establishing face and content validity, with further psychometric testing to occur later in the development phases of the updated instrument. She recommended the consultation of an 12 person IP expert panel to review the proposed updates and the subsequent review by a NRP steering committee member. The Agree (Appraisal of Guidelines for Research and Evaluation) II framework provides a systematic process of appraising practice guidelines. Chosen for its rigor, transparency and clarity, the Agree II will be used to guide the instrument update. The updated instrument will undergo preliminary testing in this simulation-based pilot study to assess team performance by individual self-assessment and observer rater assessment. To establish preliminary validity and reliability support, the following procedures will be completed. *To obtain the objective of this aim* the following procedures will occur:

1. Update the existing instrument, using the current NRP standards, algorithm, and the AGREE II framework (Appendix 6) as a guide.

2. Using a panel of 12 interprofessional content experts, establish face and content validity of the updated instrument.

3. Under the guidance of Dr. Nalini Singhal, one of the instrument original content expert developers, finalize the preliminary version of the updated instrument for testing.

4. Use the instrument for preliminary testing in the proposed study.

The *rationale for this aim* is the need for an appropriate, standardized, current, measure of IP team performance in NR that is reflective of current NR practices and addresses important aspects of NR such as timeliness, correct sequencing, and team cohesion.

Content validity. Content validity represents the extent to which the instrument adequately measures the intended content and the relevance of the interpreted scores to the content under exploration (Waltz, Strickland, & Lenz, 2010). Measures of content validity are best established with content area experts. To support content validity of the updated instrument, a 12-person interprofessional panel will review individual items and provide feedback per item, including other aspects of the scale such as instructions, and the ability of the instrument to measure the construct of interest.

Internal reliability. The alpha coefficient will be used to measure internal consistency reliability. Using this approach each individual item will be correlated with every other item in the instrument and the alpha coefficient will be measured. The more correlated the instrument items, the greater the instrument reliability. An alpha of 1.00 represents complete agreement while a measure of 0.00 represents lack of agreement (De Vellis, 2012).

Criterion referenced Interrater reliability. To test criterion-referenced interrater reliability, two raters will be used to rate using the instrument, once the results are obtained, *Po* and *K* will be calculated to determine interrater agreement. *Po* is the percent of agreement and is represented by the number of exact agreements divided by the

number of possible agreements (Waltz, Strickland & Lenz, 2010). The value of *Po* can range from 0 to 1.00 with a value of 0 representing total disagreement, and a value of 1.00 representing complete agreement. *K* is always less than or equal to *Po* (Waltz, Strickland, & Lenz, 2010). The drawback of using criterion referenced interrater agreement is that a small sample size can lead to rater bias, and inaccurate results. Another drawback is that as the number of response categories increases, the more the extent of agreement usually decreases. These limitations will be considered when interpreting the results.

Expected Results, Interpretation, Possible Pitfalls. While these procedures may provide preliminary support for use of the updated instrument, it is necessary to conduct further psychometric testing for additional data. Other types of validity testing include predictive validity, construct validity (known-groups approach), Multirait-Multi-method matrix (using discriminate and convergent validity) and are beyond the scope of this preliminary study. Moreover, researchers who employ the use of this and similar instruments should also conduct validity and reliability testing to determine the appropriateness of the instrument in their particular research settings.

Study Time line

AIMS/TASKS	MONTH 1-2	MONTH 2-3	MONTH 3-9
IRB APPROVAL	----------		
PARTICIPANT RECRUITMENT		----------	
AIMs 1,2,3 & 4			----------

Recruitment. The researcher will provide eligible interprofessional neonatal resuscitation team members with an information sheet describing the research. The PI is requesting waiver of signed consent for this study. Participation in the study is voluntary and participants can withdraw at any time. The informational sheets will describe participant rights, the purpose of the study, the tasks or procedures, duration of participation, confidentiality, and principal investigator contact information for questions. The participant will be provided an opportunity to ask questions in a private area in person, and the email and phone number of the PI to ask questions. The researcher will recruit participants using stratified purposive sampling, The researcher will make an effort to obtain a representative IP sample with a total of approximately up to 25 IP team members for quantitative assessment. The study population will consist of IP team members who are responsible for responding to neonatal resuscitative emergencies within the delivery room in this community hospital setting in Southern New Jersey. Eligible clinicians include labor room nurses, NICU nurses, neonatal nurse practitioners, respiratory therapists, and neonatologists. The total number of eligible candidates is approximately 200.. Potential participants will be told this study is separate from hospital training and that all data will be de-identified, and no access will be given to hospital staff and supervisors.

Sample Size Determination. Guest, Bunce, and Johnson (2006) recommend a sample size of 12-14 participants for a point of qualitative data saturation in small groups. While saturation determines sample size, the researcher must also ensure that the data answers the research question and addresses the study aims (Charmaz, 2006). To account for attrition and address the aims of this study, the sample size will be proposed for up to 25 participants. Purposive sampling is a method of sampling that allows the researcher to select information rich cases from diverse IP team members for the purpose of obtaining useful information to answer the research question (Devers & Frankel, 2000). The PI will use purposive sampling to gain a sample that is representative of the diverse members of the IP team to obtain a comprehensive understanding of the perspectives of the various points of view (Higginbottom, 2004).

E. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

- Describe the proposed involvement of human subjects.

- Describe the characteristics of the subject population, including their anticipated number, age range and health status.

There are minimal risks of embarrassment and fear of disclosure of information. While these risks exist, the PI will attempt to minimize these risks by protecting the study data by the de-identification of records, the maintenance of confidentiality and storage of the data on a password-protected, fire-wall secured, MUSC server at the College of Nursing that is used for research purposes.

Human participants who are IP team members who respond to neonatal resuscitations in the delivery room comprise the population for this study. Upon IRB review and approval by the MUSC IRB and the Virtua Health IRB, approximately 200 IP team members will be invited to participate in the study, with the goal of obtaining up to 25 IP team members. Participants will be given an information sheet describing the voluntary nature of the study, the study purpose and procedures. All data collected will be confidential and used strictly for research purposes. Additionally, study participants will be informed that the video data will be used for research purposes only.

Sample Population Characteristics. Participants will consist of interprofessional neonatal resuscitation team members course at Virtua Health Systems. English speaking aged 21-70 adults who perform NR in a delivery room or delivery setting as a part of their job responsibilities, including physicians, labor and delivery nurses, NICU nurses, nurse practitioners, and respiratory therapists with neonatal resuscitative responsibilities.

Inclusion Criteria

Participants will be eligible if they meet the following criteria:

Adult participants (male or female) over the age of 21

Labor and delivery nurses

Certified nurse midwives

Neonatologists

Neonatal Nurse Practitioners

NICU nurses

Respiratory therapists

Obstetricians

Exclusion Criteria

Clinicians in training

Clinicians with less than one year of clinical experience with LD/NICU population

Non-licensed personnel

Management personnel

Nurse anesthetists

Anesthesiologists

Refusal to participate

Women and minorities will be included in the study population. The researchers will use purposive sampling to ensure adequate enrollment of women and minorities, and that the enrollment reflects that of the study overall population.

INCLUSION OF CHILDREN

No children will be included in the study, as the eligibility criteria states that participants will be health care providers/clinicians over the age of 21.

Both the male and female genders will be included in the study, in addition to a variety of racial groups (provided the sample is diverse). Children will not be included in this study since the research study only addresses health care providers who perform neonatal resuscitation.

The study setting will be a suburban community hospital system in Southern New Jersey in which approximately 7200 deliveries occur annually. The simulations will occur within the labor and delivery at Virtua Health, Voorhees Campus.

Estimated/Targeted/Planned Enrollment Report

Study Title: Using Simulation to Assess Interprofessional Teamwork and Performance in Neonatal Resuscitation: An Exploratory Mixed Methods Study

Domestic/Foreign: Domestic

Comments

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	1	0	1
Not Hispanic or Latino	19	5	24
Ethnic Category: Total of All Subjects*	25		
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	3	2	5
Native Hawaiian or Other Pacific Islander	1	1	2
Black or African	4	0	4
White	11	2	13
More Than One Race	1	0	1
Racial Categories: Total of All Subjects*		5	25

**The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects".*

- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then you must present an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.

- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

Children will not be included in the study. The study population is comprised of licensed professionals who perform neonatal resuscitation.

b. Sources of Materials

- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

Video recorded simulation and debriefing data will be obtained during neonatal resuscitation simulations that will occur in situ in labor in delivery for this study. Interview qualitative data from a prior study and simulation session data will be compared for similarities and themes. Quantitative data will be collected on paper forms and kept in a locked cabinet in the office of the PI with key access only. No names will be used to identify study information including participant identity; each participant will be assigned a code. Only the PI and the supervisor/mentor (Susan Newman), and necessary IRB personnel, will have access to the coding information and the data.

c. Potential Risks

- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

Potential ***minimal risks*** to study participants include fear of disclosing information with employers and embarrassment and fear of loss of employment due to disclosing of information. While these risks are unlikely, the PI will take measures to minimize these risks by maintaining confidentiality and privacy by de-identifying records, and allowing participants to withdraw from study at any time.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

Recruitment and retention procedures: An information sheet will be given in person to potential participants for review, with PI contact information including PI phone number and email address, and Virtua IRB contact information. Participants will be encouraged to contact the PI with any questions regarding the study and the study procedures.

Information sheets will contain study information including the length of time to complete study activities, and the voluntary nature of the study. The researcher will emphasize that participation is voluntary and participants can withdraw at any point from the study.

b. Protection against Risk

- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

- Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects in Section 4 below.

The PI will obtain Institutional Review Board approval from both locations, Virtua Health and MUSC prior to the conduction of any research. Study informational sheets will provide information describing the nature of the study, procedures, any potential risks or benefits, video recording of simulations, confidentiality rights, and rights to withdraw without penalty or prejudice. The study information document will assure confidentiality of all information obtained in the study. Moreover, measures will be taken throughout the research process to ensure confidentiality and privacy. Video data will be captured on a password protected recording device. Video data will be confidential and reviewed for study purposes only. Records will be organized by codes and no participant names will be placed on data and records used for analysis. Although this research presents minimal risks to participants, each will have the opportunity to withdraw from study participation at any point. The PI will emphasize to potential participants that the study is voluntary and that withdrawal is possible at any time so that potential participants do not feel coerced into the study, however, the PI will retain the data collected up until that point as indicated in the informational sheet. All data will be de-identified to maintain confidentiality.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

While this study does not have any direct benefit for participants, the information gained from this study will provide useful information that may improve the process of neonatal resuscitation in the study setting, thereby contributing to the state of science for NR in the study setting. Upon conclusion of the study, the findings will be shared with study participants.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
Information gained in this study can facilitate development of an intervention to improve NR in the study setting. Addressing the facilitators and barriers of NR from the perspectives of the participants is essential to improving the process for better outcomes. Moreover, the identification of such facilitators and barriers will be instrumental in the development of a simulation-based, hypothesis-driven interventional study with the goal of improving team processes in NR.
- NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the research plan.

5. SUBJECT SAFETY AND MINIMIZING RISKS (Data and Safety Monitoring Plan)

*Studies that involve *clinical trials (see description below) must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints.*
The PI will compile records for each study participant that includes demographic records, PI field notes and video data. All video data will be recorded on a password protected-encrypted digital recorder and uploaded into the MUSC password protected, firewalled CON server reserved for research purposes. Paper surveys will be kept in

a locked cabinet in the office of the PI with key access. Participant will be given a code number and the PI will not place names of participants on records for data analysis. The PI and the faculty advisor (Dr. Susan Newman) will have the only access to the coded data. The PI will keep the codes and the associated codes in a codebook file with all research files stored in a password-protected, firewalled server at the MUSC College of Nursing. Data will be collected until the enrollment goal of participants is reached.

REGULATORY BINDER

A regulatory binder will be maintained that will include all pertinent study information. The binder will be stored in a secure locked location. Documents will be organized in the under the following tabs, and information will be stored in reverse chronological order, with the most recent information filed in the beginning of the appropriate section. Information will be categorized in the following labeled sections:

Contact information

Names and contact information of study PI, supervisor, emergency contact information, and off campus personnel will be kept in this section.

Protocol

The study protocol, and any amendments or changes to the protocol will be filed here. Protocols replaced with a newer version protocol version will be filed behind the current protocol and clearly labeled as obsolete.

Source documents

Any source documents will be stored here such as questionnaires, flyers, information and information brochures. Details of electronically stored data will be noted here to indicate the details of storage.

Laboratory

Information about the simulation laboratory and equipment used in the study will be described here.

Study logs

Enrollment of all consented participants and their study status will be maintained in the study log which will be stored in a secure location on a password protected computer and downloaded to the MUSC CON website and stored in the section of the regulatory binder upon completion of the study.

CVs and Qualifications

A current CV of persons conducting the study will be maintained in this section of the binder, and applicable certifications such as the CITI course certification and applicable licenses and certifications.

Staff signature log

Personnel involved in the study such as assistants and persons who will participate in the collection of data will be filed in this section.

Consents

All documents relating to study consent will be maintained in this section.

IRB approval

All IRB approvals, amendments, correspondence, and documents for auditing purposes will be stored in this section.

Correspondence

All related study correspondence will be maintained in this section in reverse chronological order.

*Clinical Trials
A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

F. REFERENCES/LITERATURE CITATIONS

List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.

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G. CONSULTANTS

Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.

H. FACILITES AVAILABLE

Describe the facilities available for this project including laboratories, clinical resources, etc.

The proposed facility is a community hospital in Southern New Jersey, Virtua Health. Virtua is a comprehensive South Jersey healthcare system with three hospitals in the New Jersey area. The study site for this research is the Voorhees Campus located in Voorhees, New Jersey. The Voorhees site houses a simulation learning lab with 5 human patient simulators, including a full-term neonatal simulator and a preemie simulator. The simulator to be used in this study is the Guamard Newborn HAL S3010 Tetherless Newborn Simulator, and advanced full-term infant simulator for use with a wireless tablet PC or standard simulation operators.

I. INVESTIGATOR BROCHURE

If applicable, attach the electronic version of the investigator brochure. Go to the application under "additional uploads" to attach this information.

J. APPENDIX

Attach any additional information pertinent to the application, such as surveys or questionnaires, diaries or logs, etc. Go to the application under "additional uploads" to attach this information.

Medical University of South Carolina
Protocol

PI Name: Valerie Clary Muronda, MSN-Ed

Study Title: **Bag-Mask Ventilation of the Neonate in Labor and Delivery: The Perspective of the Labor and Delivery Nurse: A Qualitative Descriptive Study**

Once protocol is complete, save it as a Word document. Go back to the IRB application and upload the protocol.

TABLE OF CONTENTS – *Prepare a table of contents based on the following outline, including page numbers, and insert here.*

A. SPECIFIC AIMS

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Need: When neonatal resuscitation is warranted at birth, timely and well-executed actions are necessary for optimal outcomes. The Neonatal Resuscitation Program provides an opportunity for inter-professional neonatal resuscitation team members to practice essential skills and review the latest recommendations established by the American Academy of Pediatrics and the American Heart Association. Despite this biyearly training, skills of neonatal resuscitation team members decay after three to six months, necessitating review of skills on a more frequent basis (Surcouf et al., 2013). To explore this issue, a qualitative study was conducted by this investigator, of interprofessional team member perceptions of facilitators and barriers to effective delivery room neonatal resuscitations. Team members interviewed were labor and delivery nurses, neonatal nurses, neonatal nurse practitioners, and nurse midwives. Although all the labor and delivery nurses interviewed maintain current NRP certification, a recurrent theme identified by participants was a need to improve positive pressure ventilation skills for labor and delivery nurses, a skill frequently used in neonatal resuscitation by these first responders. While the initial goal of this research was to create an interprofessional simulation-based intervention to improve team performance, the findings of this qualitative study revealed a target area for improvement that may be a key area for intervention that may improve neonatal outcomes. Ventilation of the lungs remains the most crucial step of neonatal resuscitation. However, if effective ventilation is not established within crucial seconds, the neonate may require a prolonged resuscitation that can result in long-term neurological injury. Of the participants interviewed, labor and delivery nurses overwhelmingly expressed a need for improvement of this specific skill. Neonatal

resuscitation guidelines have been updated several times to address the likelihood that providers may prematurely progress to circulatory support (chest compressions) without providing adequate ventilation (Sharma, Lakshminrusimha, Carrion, & Mathew, 2015).

Various challenges complicate the effectiveness of bag-mask ventilation (BMV), the most important step in initial neonatal resuscitation. Leakage of air, difficulty holding the mask, applying excessive pressure on the mask, and delivering a dangerously large tidal volume are some common mistakes that can impede an effective neonatal resuscitation (Wood & Morley, 2013). Although NRP provides an opportunity for practice, this training is offered biannually, and little time is spent on the specific skill of bag-mask ventilation. Neonatal resuscitations occurring in the delivery room are often unanticipated, usually with labor and delivery nurses as first responders to the emergency.

Targeting the skill of positive pressure ventilation, for the specific population of labor and delivery nurses, provides an opportunity to strengthen technical bag-mask skills. Refining this crucial skill for labor and delivery nurses, who are often first responders to delivery room resuscitations, may be key to enhancing the initial management of the apneic neonate. Improvement of the management of apneic neonates at birth can decrease the length and the extent of resuscitations since very few newborns will require chest compressions once adequate ventilation is established (AAP/AHA, 2016). In a systematic review by McIntyre et al. (2013) birth asphyxia was identified as the strongest risk factor for cerebral palsy in full term neonates. Adequate ventilation may be key in avoiding prolonged hypoxia and thereby preventing birth asphyxia (Pas, Sobotka, & Hooper, 2016). The goal of this research is to identify areas for improvement in implementation of bag-mask ventilation to the neonate by labor and delivery nurses. The Theoretical Domains Framework (TDF), an integrative behavior change framework frequently used in implementation research (Cane, O'Connor, & Michie, 2012), guides investigation of factors influencing health care provider clinical behavior and behavior change (French et al., 2012). Guided by the TDF, this qualitative descriptive study will explore the barriers to effective bag-mask ventilation from the perspectives of labor and delivery nurses, who are often initial responders to neonatal resuscitations, to determine specific areas for skill improvement. This information will guide future development of a simulation-based intervention addressing this specific, and crucial, skill.

Specific Aims:

Aim 1. Using the Theoretical Domains Framework, identify areas for improvement in delivery room neonatal resuscitations (Aim 1 achieved in previous qualitative study).

Aim 2. Assess the barriers and enablers to effective bag/mask ventilation in unexpected neonatal resuscitations in the delivery room from the perspectives of labor and delivery nurses in focus group interviews using a qualitative descriptive design.

Aim 3. Using the data from this qualitative study, identify specific intervention components for targeted practice by changing modifiable barriers and enhancing skill enablers of bag/mask ventilation techniques in a simulated environment for labor and delivery nurses.

B. BACKGROUND AND SIGNIFICANCE

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this protocol by relating the specific aims to the broad, long-term objectives. If the aims of the study are achieved, state how scientific knowledge or clinical practice will be advanced.

Most neonates will make the transition to extra-uterine life with little assistance other than the clearing of the airway and brief tactile stimulation. However, approximately 4-10% will not breathe spontaneously, requiring positive pressure ventilation to stimulate spontaneous respirations (American Heart Association/American Academy of Pediatrics [AHA/AAP], 2016). Some degree of neonatal resuscitation at the time of delivery may be expected secondary to the existence of risk factors such as prematurity, a non-reassuring fetal heart rate tracing, and other factors. However, some neonates may be born requiring ventilation assistance in the absence of such risk factors (AHA/AAP, 2016). Prompt intervention is crucial for the best neonatal outcomes. Labor and delivery nurses, trained in neonatal resuscitation, are often first responders to neonatal resuscitations in the delivery room.

Moreover, effective bag-mask ventilation skills are imperative for labor and delivery nurses for prompt recovery and establishment of spontaneous respirations in the neonate.

A prospective observation study by Trevisanuto et al. (2016) examined the perceived time of intervention in simulated delivery room neonatal resuscitations. The researchers showed that the timing of key resuscitation interventions was underestimated. Bag-mask ventilation is compellingly supported by the evidence as an essential skill in managing the apneic infant at birth (AHA/AAP, 2016). Experts in neonatal resuscitation stress the importance of ventilation in neonatal resuscitation; yet, little attention is given to this crucial skill in neonatal resuscitation training. Wood et al. (2008), in a small study evaluating the effectiveness of improving technique with face mask neonatal ventilation, suggested that additional training in bag-mask ventilation will likely reduce the incidence of failed bag-mask resuscitation, simplifying some neonatal resuscitations. Since the Wood et al.(2008) study, there have been few studies that focus on the simple task of bag-mask ventilation, the most crucial step in neonatal resuscitation. In an observational study by Binder et al. (2014), the researchers found that additional training using a respiratory function monitor or verbal feedback can improve the quality of bag mask ventilation by minimizing air leaks, thereby improving technique. Although the evidence supports ventilation as the single most important step in neonatal resuscitation, bag-mask ventilation skills can deteriorate as early as three to six months following NRP certification, further supporting the need for practice of this essential skill (AAP/AHA, 2016; Rubio-Gurung et al., 2013). While the establishment of effective ventilation of the lungs is an essential skill in neonatal resuscitation, the evidence suggests that bag/mask ventilation is a skill that both experienced and novice practitioners require frequent practice in outside of routine NRP training (Von Vonderen, Witlox, Kraaij & Pas, 2014; Wilson, O'Shea, Dawson, Boland, & Davis, 2014; Schilleman, et al., 2010). A randomized control trial was conducted by Binder et al. (2014) to determine if immediate feedback during mask ventilation of a simulator improves bag-mask technique. Practitioners in the Binder et al. (2014) study listened to feedback and made slight improvements in bag-mask ventilation, suggesting that practice with this single skill may improve bag-mask ventilation competency. Wilson et al. (2014) compared different mask holds for neonatal positive pressure ventilation and found no difference in leakage of air using different holds. However, the Wilson et al. (2014) study further supports existing evidence that practitioners may benefit from additional practice with positive pressure ventilation (Pearlman, 2016., Sharma et al., 2015). Deindl, Schwindt, Berger, and Schmolzer (2014) assessed the skills of 28 medical students using a bag and mask to ventilate a simulator. Some participants completed self-directed video training targeting the skill of bag-mask ventilation, with blinding of the raters (Deindl et al., 2014). Results of the study indicated that the self-instructional system significantly improved ventilation skills directly related to mask-holding techniques (Deindl et al., 2014).

While the importance of evidence-based practice and interventions has been emphasized in the literature, behavior change is a challenging and complex process, affected by numerous variables and factors (Cane, O'Connor, & Michie, 2012). Many Individual and organizational change theories exist and have been applied in healthcare research however, no one theory has been identified as most suitable for behavior change intervention implementation (French et al., 2012). Moreover, many of the existing behavior theories have not undergone rigorous testing, particularly in the area of implementation science. Developed by an expert team in behavioral and psychological change theories, the Theoretical Domains Framework (TDF) was created to guide health care intervention implementation using a systematic approach. Specifically created for use by interdisciplinary researchers, the TDF creates a means to bridge the knowledge-practice gap by using theory to guide intervention implementation (Michie et al., 2005). Designed to answer a need for an explicit, systematic theory informed guide for intervention implementation, the TDF was developed to address an extensive range of potential barriers and enablers that may impede or facilitate such interventions (French et al., 2012).

Foundational to the TDF is the use of theory to inform the development of intervention implementation (French et al., 2012). Michie et al. (2005) led the the development of the TDF by conducting a six-phase rigorous process of: identifying theoretical constructs, simplifying the constructs into construct domains, conducting an interdisciplinary evaluation of the domains, validating the domain list, and piloting interview questions. Developed from 33 existing theories and 128 related and often overlapping constructs, the TDF is an integrative intervention implementation theory that identifies potential intervention difficulties (Murphy et al., 2014). An expert panel established through consensus 12 domains to cover the main factors affecting behavior change in practitioners and individuals: knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; motivation and goals; memory, attention and decision processes; environmental context and resources; social influences; emotions; behavioral regulation; and nature of behavior (French et al., 2012). The TDF broad range of domains provides a wide base for the identification of potential barriers for consideration during the development of interventions (French et al., 2012). This extensive theoretical base brings clarity to the

change process by providing an understanding of multiple factors that may either enhance or impede change. Such an understanding can improve the chances that sustainable changes in behavior can occur.

The development phase of the TDF included application of the theory to a health care professional group in which change was desired in certain targeted behaviors. The study population was comprised of 42 general practitioners in Australia who manage patients with acute non-specific back pain. In the study, two specific behaviors were targeted for change. One behavior targeted was the restriction of ordering x-rays for these patients, and the second behavior targeted for change was the advisement to patients with acute non-specific low back pain to remain active. These behaviors were selected because of the strong evidence supporting the minimal use of x-rays in managing lower back pain due to their lack of diagnostic information and potential harm, and strong evidence supporting the benefits of exercise and activity in the minimization of pain and disability. Focus groups were used to identify the enablers and facilitators to the proposed changes, determining that the intervention should be delivered at the individual, clinician level. The implementation of the TDF to achieve the desired clinician behavior changes was systematic and transparent, involving a four step process of identification of the following: (a) targeted behaviors for change, (b) barriers and enablers to the proposed change, (c) change techniques or models of behavior to use, and (d) measurement and implementation of the change (French et al., 2012).

To refine and further support the validity of the TDF, Cane, O'Connor, and Michie, conducted additional research using behavioral experts to sort theoretical constructs of the TDF resulting in a refined framework with a strong empirical base. Fuzzy cluster analysis and discriminant content validity testing provided good support of the content and construct validity of the TDF for the basic structure of the framework, with the addition of two additional domains, "Optimism", and "Intention". The validity testing also resulted in a refinement of unique theoretical constructs from 112 in total to 78. A literature review by Francis, O'Connor and Curran (2012) identified 17 studies that used the TDF in an empirical study to guide health care clinician behavior changes, further supporting its use. The refined TDF will be used in this study.

Lipworth, Taylor and Braithwaite (2013) conducted a qualitative synthesis of successful evidence-based and/or clinical quality intervention research using thematic analysis to determine the *a priori* usefulness of the TDF. The authors employed the TDF to interpret the literature, using a comprehensive combination of Morse's outline of the cognitive base of qualitative research, and Charmaz's grounded theory approach to coding of data using an open coding, followed by a focused coding phase (Charmaz, 2006; Morse, 1994; Lipworth, Taylor and Braithwaite, 2013). Findings from the qualitative synthesis indicated a significant relevance of the TDF domain constructs to the barriers to and facilitators of clinical behavioral change. Moreover, Lipworth, Taylor and Braithwaite (2013) found no emerging themes that could not be mapped to the framework, further supporting the use of the TDF to guide evidence-based implementation interventions.

The transparency of the TDF process and the demonstrated reliability of the TDF in behavior change implementation in multiple studies are identifiable strengths of the framework. The TDF provides an evidence-based theoretical approach to improve the clinical behaviors of labor and delivery nurses, and ultimately, neonatal outcomes. Ventilation of the lungs is the single, most important step in neonatal resuscitation (AAP/AHA, 2016). Improving the bag-mask skills of labor and delivery nurses can potentially reduce the number of complex resuscitations by focusing on the establishment of spontaneous respirations.

C. PRELIMINARY STUDIES

Provide an account of the principal investigator's preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

A qualitative study was conducted by this investigator to examine facilitators of barriers to effective delivery room resuscitations as identified by individual interprofessional delivery room neonatal resuscitation team members. Team members included labor and delivery nurses, midwives, neonatal nurses, neonatal nurse practitioners and neonatologists. A central recurrent theme identified from the analysis of the interviews was the need for simulated practice in the area of positive pressure ventilation for delivery room nurses, who are usually first responders to unanticipated neonatal resuscitations. This low-level evidence supports the need for a better understanding of the perceived barriers and facilitators to implementing effective bag-mask ventilation from the standpoints of labor and delivery nurses. This study will explore the perceptions of the nurses who are first responders to delivery room resuscitations to determine specific factors affecting implementation of positive pressure ventilation. Data

from this study will be foundational in developing a skills practice program for review of positive pressure ventilation for labor and delivery nurses in addition to the biyearly NRP training.

D. RESEARCH DESIGN AND METHODS (including data analysis)

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Explain sequentially the study procedure, including all the visits, contacts, and interactions if the study will be designed in phases and each phase will require separate IRB approval, please specifically indicate this in the description. Include how the data will be collected, analyzed, and interpreted and specify what statistical methods will be used. Discuss the particulars of the research instruments, questionnaires and other evaluation instruments in detail. For well-known, established valid and reliable test instruments the detail here can be brief. If interviews or groups settings are to be audio taped or video taped describe in detail the conditions under which it will take place. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

A well-established modality for eliciting rich data from a homogeneous group, focus group methodology will be used to capture information for this study (Redmond & Curtis, 2009). Although not ideal for all research topics, homogenous focus groups can provide valuable information as they provide an opportunity to view the same phenomenon through many different lenses, while providing a commonality that may enhance the sharing of insights (Krueger, 2006). Use of social interaction to trigger conversation about a topic while providing a wide range of experiences is the aim of focus group methodology (Traynor, 2015). The researcher will serve as the moderator in interviewing consenting participants in 3 focus groups comprised of 6-8 participants each, using semi-structured questions from a standardized interview guide. Interviews will be audio recorded with verbatim transcription for data analysis.

A qualitative descriptive approach will guide data collection and analysis for this research. Qualitative description offers the researcher an opportunity to obtain a clear description of the research phenomenon (Magilvy & Thomas, 2009). Selected for its naturalistic underpinnings, qualitative description is a valuable method that presents the facts by remaining close to the surface of the words rather than delving into the more interpretive realms of other methodologies such as grounded theory, phenomenology, and ethnography (Sandelowski, 2000). Qualitative content analysis, a method of visual representation of the data for the purpose of summarization of the data, is typically the data analysis strategy of choice in qualitative description (Sandelowski, 2000). Directed content analysis uses an approach that provides structure to the data analysis process by using existing theory or prior research to organize and categorize the data (Hsieh & Shannon, 2005).

Using a systematic approach, the Theoretical Domains Framework will guide the formation of the interview questions, data analysis, and intervention development. Developed to address complex health care provider practice needs, the Theoretical Domains Framework provides an organizing guide to bridging the knowledge-practice gap (Cane, O'Connor, & Michie, 2012). Implementation of interventions to improve health care practitioner practice behaviors is well-documented in the literature however, the impact on behaviors has been varied (French et al., 2012). The use of evidence to guide interventions to improve skill execution is an approach that is optimal in theory. The Theoretical Domains Framework provides a systematic, methodological approach to designing interventions strongly supported by evidence-based rationale (French et al., 2012).

The 4 overarching TDF questions listed below will guide the categorization of the data. Interview guide questions based upon the refined TDF (Cane, O'Connor, & Michie, 2012) will be mapped to the 14 domains to ensure that the questions align with the framework domains. The 14 domains of the refined TDF will be used as a framework to map data for the purposes of organization and analysis: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism, beliefs about consequences; reinforcement; intentions; goals; memory, attention and decision processes; environmental context and resources; social influences; emotions; behavioral regulation. These domains will guide the formation of the interview guide questions, and the coding of the data.

The following questions from the Theoretical Domains Framework will guide the initial categorization of the data from this study:

1. Who needs to do what differently? (addressed in the previous study)

2. Which barriers and enablers need to be addressed?

3. Which intervention components (behavior change techniques and model(s) of delivery could overcome the modifiable barriers and enhance the enablers?

4. 4. How can behavior change be measured and understood?

Question 1 was addressed in a previous study in which interprofessional neonatal resuscitation team members were interviewed to determine facilitators and barriers to effective delivery room resuscitations; the data supported the need to target bag-mask ventilation training for labor and delivery nurses. A recurrent theme in the qualitative data analysis was the need to develop bag-mask skills for labor and delivery nurses, who are usually first responders to deliveries requiring neonatal resuscitation. The data from the interprofessional study identified a specific target group with potentially modifiable barriers, labor and delivery nurses, answering question one from the Theoretical Domains Framework methodology, also creating the basis for this study.

Sample and Setting

Sample Size Determination

Sample size in focus group research should depend upon the research topic and the ability of the moderator to maintain control of the group (Redmond & Curtis, 2009). Krueger (2006) suggests focus group sizes ranging from 4 or 5 for for topics that may evoke strong emotional response, and up to a dozen people for topics that may be of a less sensitive nature. Approximately 6-8 people will comprise each focus group with a total of 3 groups.

Recruitment and Enrollment

After attaining IRB approval from Virtua Health and MUSC, the researcher will provide potential participants with an informational sheet describing the study. The investigator is requesting waiver of signed consent for this study. The informational sheets will describe participant rights, the purpose of the study, the tasks or procedures, duration of participation, potential risks, confidentiality, and principal investigator contact information for questions. The participants will be provided an opportunity to ask questions in a private area in person, and the email and phone number of the investigator to ask questions. All potential study participants will be informed that participation in the study is voluntary and that participants can withdraw at any time. The researcher will make an effort to obtain a representative labor and delivery nurse sample with a total of approximately up to 24-25 labor and delivery nurses who are responsible for responding to neonatal resuscitative emergencies within the delivery room in the study setting. Approximately 6-8 people will comprise each focus group with a total of 3 groups. There are approximately 100 nurses who are eligible for recruitment. Potential participants will be informed that the data collected from this study is for research purposes only and no access to interview data will be given to hospital staff and supervisors.

Focus group interviews will be conducted outside of the work area in a private location easily accessible to participants. Ground rules will be presented to participants prior to the interview session stressing the confidentiality of the focus group, and instructing participants to refrain from discussing all information discussed in the group outside of the focus group session. All participants will be assigned a number for confidentiality and organization purposes. The investigator will serve as the moderator of the focus group interviews, which will be guided by the interview guide. The semi-structured questions from the interview guide will include appropriate probes will be used to ask labor and delivery nurse participants to describe perceived enablers and barriers to bag-mask ventilation. Data from the interviews will be recorded on an encrypted digital voice recorder. All interview data collected will be uploaded stored on a password-protected, firewall secured, MUSC server reserved for research purposes at the College of Nursing. Only the investigator and Dr. Susan Newman, the faculty advisor, and IRB officials at Virtua Health and MUSC will have access to the study's data and research files. Voice data will be transcribed word for word, and reviewed for accuracy. The digital recorder and the interview transcriptions will be kept in a secure location, in a locked file cabinet in the locked office of the investigator for later analysis by the investigator.

Interview guide:

Who are the first responders when you have to provide bag-mask ventilation for a neonate?

How often would you say you have to provide bag-mask ventilation for a neonate?

Can you describe the process and what typically happens?

What do you perceive as barriers to providing effective bag-mask ventilation for a neonate?

(Any environmental factors?)

What do you perceive as enablers to providing effective bag-mask ventilation for a neonate?

If you had to improve your resuscitation skills, what area would you like to work on?

The interviewer will use prompting word and phrases such as "Go on," "Tell me more," "Interesting," and "How did you feel about that?"

Data analysis

Qualitative data will be coded line-by-line, analyzed and summarized using a qualitative descriptive design with a direct content analysis approach. Directed content analysis uses an approach that provides structure to the data analysis process by using existing theory or prior research to organize, categorize, and code the data (Hsieh & Shannon, 2005). Selected for its application of theory to the data organization and analysis process, direct content analysis can be used to validate existing theory (Hsieh & Shannon, 2005). The TDF will guide the categorization of the data in this study. Key concepts and/or variables will be identified and used as initial coding categories, followed by the determination of operational definitions for each category (Hsieh & Shannon, 2005). Data from a previous study provides the answer for the first TDF question: Who needs to do what differently? The remaining TDF questions will form the initial coding framework for the data with the following categories: Barriers and enablers, behavior change technique, and modifiable barriers/methods to enhance the enablers (French et al., 2012). Text will be highlighted using the predetermined codes. Interview text that cannot be categorized with the TDF guided coded scheme will be assigned a new code for later coding in a separate category or subcategory of an existing code (Hsieh & Shannon, 2005). Findings from the data analysis will provide evidence either supporting or not supporting the TDF (Hsieh & Shannon, 2005).

Limitations

One limitation of the proposed study is the use of the labor and delivery nurse as the targeted population for the study. While not representative of the entire interprofessional group, establishment of adequate ventilation is a skill that labor and delivery nurses perform often, perhaps more than most interprofessional neonatal resuscitation team members, necessitating a targeted approach to this population. Moreover, establishment of effective ventilation in the initial resuscitation stages is key in preventing a more complex resuscitation. Simulation provides an excellent opportunity for review of skills that will be performed clinically. While the benefits of simulation-based training are well documented in the literature, the evidence supporting simulation as a means of improving patient outcomes has been inconsistent (Finan et al., 2012).

E. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

- Describe the proposed involvement of human subjects.

- Describe the characteristics of the subject population, including their anticipated number, age range and health status.

This research involves interviewing labor and delivery nurses who resuscitate newborns in the delivery room about their perceptions of the enablers and barriers to effective bag-mask ventilation of the newborn. The participants are healthy adult women and the age range is from 21 – 67.The risk to the participant is minimal, with the minimal risk being disclosure of information to employers. The investigator will protect the confidentiality of the participants and not share the data with employers, using it strictly for research purposes. Furthermore, the information sheet will contain information directing the participants to refrain from discussing the focus group information outside of the focus group setting. These instructions will be provided again, prior to, and following the

focus group sessions. In addition, the ground rules for the focus group sessions, which will be reviewed at the start of each focus group session, will also contain a statement about the importance of maintaining the confidentiality of the focus group session information. The interviews will be held in a comfortable private location, easily accessible to participants. Refreshments will be served. Prior to the start of the focus group interviews, each participant will be assigned an identifier. Each participant will be asked to say their assigned identifier prior to answering questions for organization purposes. Before each session, ground rules will be presented and reviewed with participants.

Participants ground rules are as follows:

All information discussed here is confidential and will not be discussed outside of this session.

If any participants becomes distressed during the meeting, she can leave the room and reenter the group or withdraw, whichever is preferred by the participants

Participation in focus groups is strictly voluntary and in no way related to conditions of employment.

Participants will say their identifier prior to speaking.

Participants can withdraw participation at any time and for any reason.

One person will talk at a time.

The focus groups will not exceed 90 minutes.

If the conversation becomes heated, we will take a 30 second break from speaking.

There are minimal risks of embarrassment and fear of disclosure of information. While these risks exist, the PI will attempt to minimize these risks by protecting the study data through the maintenance of confidentiality and storage of the data on a password-protected, firewall-secured, MUSC server at the College of Nursing that is used for research purposes. Transcriptions and the encrypted voice recorder will be kept in a locked file cabinet in the office of the investigator.

The study participants are employees of a community hospital in Southern New Jersey in which approximately 7200 deliveries occur annually. However, the interviews will occur off-campus at a location convenient to participants. Interviews will be recorded on an encrypted digital recorder for uploading to the MUSC password-protected firewall College of Nursing Research Server. Prior to each focus group session, participants will be informed of the privacy of the information gained from the group interviews. Also, since focus group discussions include personal opinions, extra measures will be taken to protect each participant's privacy. The researcher will begin the focus group by requesting that participants agree to the importance of keeping information discussed in the focus group confidential. She will then ask each participant to verbally agree to keep everything discussed in the room confidential and will remind them at the end of the group not to discuss the material outside of the focus group. Prior to the interviews, the investigator will inform participants that participation is voluntary, and withdrawal is possible at any point during the focus group session. Participants can withdraw without penalty. To minimize risks of disclosure to participant's employers, the participants will be assigned a number prior to interviews. Only the researcher and the research advisor will have access to the data collected. Any tapes and transcripts of the focus group will be destroyed after one year or at the end of the study.

Prior to the start of the focus group interviews, each participant will be assigned an identifier that will provide anonymity for participants and assist with the organization of the data. Each participant will be asked to say their assigned identifier prior to answering questions.

INCLUSION OF CHILDREN

No children will be included in the study, as the eligibility criteria states that participants will be health care providers/clinicians over the age of 21.

Since the study population is comprised only of females, males will not participate in this study. The researcher will seek to obtain a diverse sample. Children will not be included in this study since the research study only addresses labor and delivery nurses who perform neonatal resuscitation.

Estimated/Targeted/Planned Enrollment Report

Study Title: **Bag-Mask Ventilation of the Neonate in Labor and Delivery: The Perspective of the Labor and Delivery Nurse: A Qualitative Descriptive Study**

Domestic/Foreign: Domestic

Comments

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	0	0	0
Not Hispanic or Latino	25	0	25
Ethnic Category: Total of All Subjects*	25		
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African	5	0	5
White	20	0	20
More Than One Race	0	0	0
Racial Categories: Total of All Subjects*		5	25

**The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects".*

- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then you must present an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.

- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

Children will not be included in the study. The study population is comprised of licensed professionals who perform neonatal resuscitation.

b. Sources of Materials

- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. Potential Risks

- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

Potential risks in this study include risk of embarrassment, and risk of disclosure of information to employers. Study participants will be asked to keep the interviews confidential, and information gained from the interviews will not be disclosed to employers and supervisors. Furthermore, interviews will take place in a neutral private area outside of the work area. Interviews will be taped on a password-encrypted device, only accessible by the researcher. The data will be uploaded as soon as possible to the Medical University of South Carolina College of Nursing server, which exists for research purposes only. Data will be accessible only to the PI and the PI supervisor, Dr. Susan Newman.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

Participants will be recruited by flyer during non-work hours. All information pertinent to the study such as time of participation, study procedures, risk and benefits will be included in the flyer, in addition to study PI contact information for additional questions. Information gained from the study will be confidential and used for research purposes only. Data will be recorded on an encrypted digital recorder, and erased upon uploading to the Medical University of South Carolina College of Nursing research server. Information will not be shared with employers or supervisors. Willing participants will be asked to contact the PI by phone, and focus group interview sessions will occur at times when participants are available at a private location accessible to the participant.

Recruitment and retention procedures

b. Protection against Risk

- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects in Section 4 below.

Information will be confidential and not shared with employers or supervisors. The interview audio data will be uploaded to the Medical University of South Carolina College of Nursing Research Server as soon as possible.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

While this study does not have any direct benefit for participants, the information gained from this study will provide useful information that may improve the process of neonatal resuscitation in the study setting, thereby contributing to the state of science for NR in the study setting. Upon conclusion of the study, the findings will be shared with study participants.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
Information gained in this study can facilitate development of an intervention to improve NR in the study setting. Addressing the facilitators and barriers of effective ventilation of the neonate from the perspectives of first responders is an essential first step in developing a training program that can directly address existing skill deficits. Establishment of effective ventilations is the most important intervention that can improve outcomes for neonates who are unable to breathe at birth. Information from this study will be instrumental in guiding targeted training geared towards the maintenance of competency in bag-mask ventilation.
- NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the research plan.

5. SUBJECT SAFETY AND MINIMIZING RISKS (Data and Safety Monitoring Plan)

*Studies that involve *clinical trials (see description below) must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints.*
REGULATORY BINDER

A regulatory binder will be maintained that will include all pertinent study information. The binder will be stored in a secure locked location. Documents will be organized in the under the following tabs, and information will be stored in reverse chronological order, with the most recent information filed in the beginning of the appropriate section. Information will be categorized in the following labeled sections:

Contact information

Names and contact information of study PI, supervisor, emergency contact information, and off campus personnel will be kept in this section.

Protocol

The study protocol, and any amendments or changes to the protocol will be filed here. Protocols replaced with a newer version protocol version will be filed behind the current protocol and clearly labeled as obsolete.

Source documents

Any source documents will be stored here such as questionnaires, flyers, information and information brochures. Details of electronically stored data will be noted here to indicate the details of storage.

Study logs

Enrollment of all consented participants and their study status will be maintained in the study log which will be stored in a secure location on a password protected computer and downloaded to the MUSC CON website and stored in the appropriate section of the regulatory binder upon completion of the study.

CVs and Qualifications

A current CV of persons conducting the study will be maintained in this section of the binder, applicable certifications such as the CITI course certification and applicable licenses and certifications.

Staff signature log

Personnel involved in the study such as assistants and persons who will participate in the collection of data will be filed in this section.

Consents

All documents relating to study consent will be maintained in this section.

IRB approval

All IRB approvals, amendments, correspondence, and documents for auditing purposes will be stored in this section.

Correspondence

All related study correspondence will be maintained in this section in reverse chronological order.

*Clinical Trials
A clinical trial *is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).*
Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

F. REFERENCES/LITERATURE CITATIONS

List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.

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G. CONSULTANTS

Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.

H. FACILITES AVAILABLE

Describe the facilities available for this project including laboratories, clinical resources, etc.

Although the participants work at a local community hospital, the data collection for this qualitative study will take place outside of the work area in a private location convenient to participants.

I. INVESTIGATOR BROCHURE

If applicable, attach the electronic version of the investigator brochure. Go to the application under "additional uploads" to attach this information.

J. APPENDIX

Attach any additional information pertinent to the application, such as surveys or questionnaires, diaries or logs, etc. Go to the application under "additional uploads" to attach this information.