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MIDLINE CATHETER USE
IN THE
NEWBORN INTENSIVE CARE UNIT

by

Tricia L. Romesberg

A project submitted to the School of Nursing
in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

UNIVERSITY OF NORTH FLORIDA

BROOKS COLLEGE OF HEALTH

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Unpublished work by Tricia L. Romesberg

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Abstract

Ongoing evaluation of current practice and incorporation of evidence based research into guidelines and protocols is a requirement for the provision of high quality, cost efficient care. Despite some literature describing observational data, midline catheters (MCs) are not an appropriate vascular access device for Newborn Intensive Care Unit (NICU) patients due to insufficient high level evidence demonstrating safety and efficacy. In addition, national guidelines for MC use in neonatal and infant patients lacks sufficient information for safe and effective use of MCs.

The results of this small, online survey indicate that while some neonatal nurses and Nurse Practitioners report the use of MC use in the NICU, there is a wide range of practice pertaining to MC unit-specific protocols, competencies, success with placement, and clinician agreement of appropriate use for this vascular access device (VAD). Multicenter, randomized control trials are needed to evaluate current MC practice in the NICU, and institutions must incorporate current, evidence based practice into policies, procedures, and guidelines.

Keywords: catheters, infant, midline, neonatal, and premature

Introduction

Prolonged intravenous (IV) access is frequently required for critically ill and premature infants in the Newborn Intensive Care Unit (NICU) to provide nutritional and pharmacologic support. High level evidence must guide clinical decision making and management of all vascular access devices (VADs), including peripheral intravenous (PIV) catheters, peripherally inserted central catheters (PICCs), and midline catheters (MCs). Institutional and national PICC guidelines include basic MC information, but VAD decision making may be based on clinician preference rather than clinical evidence due to a lack of evidence based research in the form of high quality studies (National Association of Neonatal Nurses PICC Guidelines, 2007). When deciding upon which VADs are appropriate for individual patients, the NICU team may have difficulty reaching consensus based on professional experience and/or lack of knowledge regarding evidence based recommendations.

Prospective observational studies have demonstrated that when compared to peripheral IVs, MCs result in fewer cannulations, longer dwell times, less extravasation, and improved cost efficiency (Alexandrou et al., 2011; Anderson, 2004; Dawson, 2002; Frey & Pettit, 2010; Goetz, Miller, Wagener, & Muder 1998.; Griffiths, 2007; Leick-Rude and Haney, 2006; Lesser, Chhabra, Brion, & Suresh, 1996; National Association of Neonatal Nurses, 2007; Rosenthal, 2008; Victor, 1997; and Wyckoff, 1999). When compared to PICCs, prospective observational studies found MCs to have increased rates of chemical and mechanical phlebitis and lower rates of infection (Alexandrou et al., 2011; Colacchio, Deng, Northrup, & Bizzarro, 2012; Goetz, et al., 1998; Leick-Rude and Haney, 2006; Lesser et al., 1996; NANN, 2007; Victor, 1997). Several authors have reported that MCs may also improve cost efficiency by minimizing the time and equipment spent on repeated PIV cannulations (Alexandrou, et al., 2011; Anderson, 2004;

Griffiths, 2007; and Rosenthal, 2008). Dawson (2002) found that the potential for cost savings may result from fewer central line infections and shorter length of hospital stay, less nursing time required, and lower pharmacological costs. Unfortunately, there is a lack of evidence in the form of randomized control trials or systematic reviews, to support the observational findings suggesting that MCs may be a safe and reliable VAD for NICU patients.

Problem

As clinicians strive to improve health care in the information age of the 21st century, it is crucial that clinicians not only recognize, but accept and integrate evidence-based practice (EBP) into patient care on a daily basis. Rapidly advancing technology, an aging population, and increasingly complex medical diagnoses, challenge health care professionals to maintain a current knowledge base and to provide care that is proven to be effective, safe, and cost efficient. Integration of EBP is a steadfast requirement for clinical decision-making and for providing standardized care for patients across all settings. According to Grol and Grimshaw (2005), approximately 10,000 new randomized trials are added to MEDLINE every year. It is difficult for clinicians to synthesize the continual high volume of published evidence, and even more challenging to incorporate changes in clinical practice into daily patient management. As a result, there is a known gap between clinical evidence and clinical practice across disciplines. Prasad et al. (2013) found that of 35 studies testing standard of care, 46% contradicted current practice. In fact, studies suggest that 30-40% of patients do not receive care according to current scientific evidence (Grol & Grimshaw, 2005).

Another barrier to implementing current clinical evidence into daily clinical practice may reside in the dependence on clinical practice guidelines which are lacking in evidence based recommendations. Clinical practice guidelines are typically developed by professional

organizations and provide a foundation for state and institutional protocols. Unfortunately, guidelines and protocols may not be based on the most current evidence, and there is increasing concern about the quality of guidelines produced by national organizations (Cosgrove, Bursztajn, Erlich, Wheeler, & Shaughnessy, 2012; Singleton & Levin, 2008). As such, the quality of clinical practice guidelines may be variable and may not incorporate evidence based research into recommendations for standard of care. (Brouwers et al., 2010).

Silverman (2004) adeptly described the history and evolution of oxygen use in premature infants, beginning in the 1940s. The lack of evidence for the use of oxygen necessitated multiple attempts to guide the use of this unfamiliar “drug” and address the subsequent epidemic of blindness that followed. Guidelines for the use of oxygen in premature infants continues to evolve and elicit ongoing research today. Makic, Martin, Burns, Philbrick, & Rauen (2013) discuss the recognized problem of care being guided by tradition rather than current evidence. Implementation of a change in clinical practice guidelines may be another obstacle in the effort to improve patient care based on current high level evidence. In order to successfully implement a change in guidelines and protocols, it is important to acknowledge the potential for doubt about the need for innovation (van Achterberg, Schoonhoven, & Grol, 2008).

Solution

According to Raines (2013), EBP is “the conscientious, explicit, and judicious use of current research findings.” It is the “integration of individual clinical expertise with the best available external clinical evidence from systematic research” (p. 203). The importance of EBP is recognized by health care companies, government agencies, and national professional organizations (Makic, et al., 2013). When the highest quality of clinical research is completed, it then becomes the responsibility of multidisciplinary teams to synthesize the evidence and

incorporate the findings into clinical practice guidelines and protocols. The AGREE II tool was developed to “assess the quality of guidelines; provide a methodological strategy for the development of guidelines; and to inform what information and how information ought to be reported in guidelines” (Brouwers et al., 2010, p. 1).

The solution, then, lies in scrutinizing national, state, and institutional guidelines and protocols for inclusion of the most current and evidence based research. According to the Institute of Medicine (2011), clinical practice guidelines should provide an evaluation of current evidence based research in such a way as to enable clinicians to provide the highest quality of standardized care. If a change in clinical practice is indicated, the process for change must be implemented in such a way that allows for an understanding of the importance and necessity of EBP, and provides an opportunity for clinicians to embrace the need for innovation.

Project Purpose

According to the National Association of Neonatal Nurses (NANN) PICC Guidelines, establishing uninterrupted therapy, preserving the peripheral vasculature, cost efficiency, and patient comfort should be taken into consideration when deciding which VAD is most appropriate (2007). Limited data is available on MCs in the NICU and all available research is strictly observational (Anderson, 2004; BeVier & Rice, 1994; Goetz, et al., 1998; and Griffiths, 2007; Leick-Rude & Haney, 2006; Lesser et al., 1996; Mermel, Parenteau, & Tow, 1995; Wyckoff, 1999).

Ongoing evaluation of current practice and incorporation of current, evidence based research into guidelines and protocols is a requirement for the provision of high quality, cost efficient care. The use of MCs in the NICU is not supported by high level evidence. The project purpose is to provide for a diffusion of knowledge, via scholarly review and clinician education,

in such a way as to encourage understanding and support for the discontinuation of MC use in NICU patients, and subsequent change in an institutional protocol.

Rogers' theory for diffusion (2003) is applicable in the effort to implement change as the four main elements for changing MC use will involve diffusion, innovation, communication, and the social system of the NICU. Furthermore, as described by van Achterberg et al. (2008), activities to guide change may be involuntary, such as official changes to guidelines and protocols; or voluntary, such as when educational efforts and clinical support result in extrinsic and intrinsic motivation. The project will incorporate Rogers' theory for diffusion while encouraging multidisciplinary motivation for what will ultimately be a change in clinical practice as MCs become discontinued as a viable VAD for use in NICU patients.

In accordance with the American Association of Colleges of Nursing Essentials of Doctoral Education for Advanced Practice (2006), several objectives for graduate learning outcomes are realized by a thorough review of the literature, evaluation of current policies and procedures, and analysis of current trends in clinical decision making regarding the use of MCs in the NICU. Competent leadership skills are required to successfully institute a feasible and sustainable change in practice as a result of diffusion of knowledge based on a lack of high level evidence for the use of MCs in the NICU.

Definition of Terms

Midline catheter (MC). The MC is a peripheral vascular access device with the tip terminating in the basilic, cephalic, or brachial vein (Infusion Nursing Society, 2011).

According to Frey and Pettit (2010):

The midline catheter, composed of polyurethane or silicone, is longer than a peripheral IV catheter and is intended for use in neonates and children who require therapy of

intermediate duration. The catheter is inserted into a peripheral vein in the antecubital area and is advanced into the upper arm veins, but not past the axilla. Other sites for midline insertion include the leg (with the tip away from areas of flexion and below the groin) and the scalp (with the tip located in the neck and above the thorax).

Neonate. A newborn infant, in the first 28 days of life (Dictionary.com).

Peripherally inserted central catheter (PICC). The NANN PICC Guidelines define a PICC as a “device inserted into a peripheral vein and threaded into the central venous circulation” (p. 6).

Peripherally inserted non-central catheter (PINCC). According to Colacchio, et al. (2012), PINCCs are intended to be centrally located as a PICC, but do not reach a central position during the procedure. MCs are different from PINCCs as the catheters are shorter and they are not intended to be placed centrally.

Peripheral intravenous catheter (PIV). The tip of a PIV terminates in a peripheral vein.

Premature infant. An infant born at any date during pregnancy prior to the completion of 37 weeks gestation (Merenstein & Gardner, 1993).

Summary

To date, there are no randomized control trials or systematic reviews examining the use of MCs in the neonatal population. However, observational studies support the use of MCs for the infusion of IV fluids and medications in infants who meet criteria based on expected dwell time, infusate composition, and certain physiologic requirements. Professional experience and/or lack of knowledge may result in disagreement among clinical providers in regard to VAD decision making in the neonatal population.

Review of Literature

A PICO (i.e. Population, Intervention, Comparison, and Outcome) question was used to guide the literature review (Melnyk, Fineout-Overholt, Stillwell, & Williamson, 2010). The PICO question is: In the NICU, how is the incidence of infection and extravasation associated with VADs affected by the implementation of a MC Protocol? The population in this review is sick and premature neonates and infants in the NICU; the intervention is the development and implementation of an NICU MC Protocol; the comparison group is the group of infants who receive MCs based on protocol criteria; and the outcomes are the rates of PICC and MC related infection and extravasation after the MC Protocol is incorporated into the IV access algorithm.

Data Sources and Search Process

The keywords utilized in the search included *catheters, infant, midline, neonatal, and premature*. The databases utilized in the search were CINAHL, Cochrane Library, Joanna Briggs Institute, Ovid Medline, and Pubmed. Twenty-six publications were identified by database and hand searches. Eleven publications remained after duplicates were removed. Four publications were eliminated because they contained content about central lines (PICCs or umbilical lines) exclusively, and/or the VADs being reviewed were not clearly defined as central or midline. In addition to journal articles, the hand search included the Infusion Nurses (INS) Society Position Paper on (1997), the INS Standards of Practice publication and textbook (2011), and the NANN PICC Guidelines (2007). A total of 18 publications were included for the literature review (Figure 1). See Appendix A for Tables 1, 2, and 3 which provide a synopsis of the literature review.

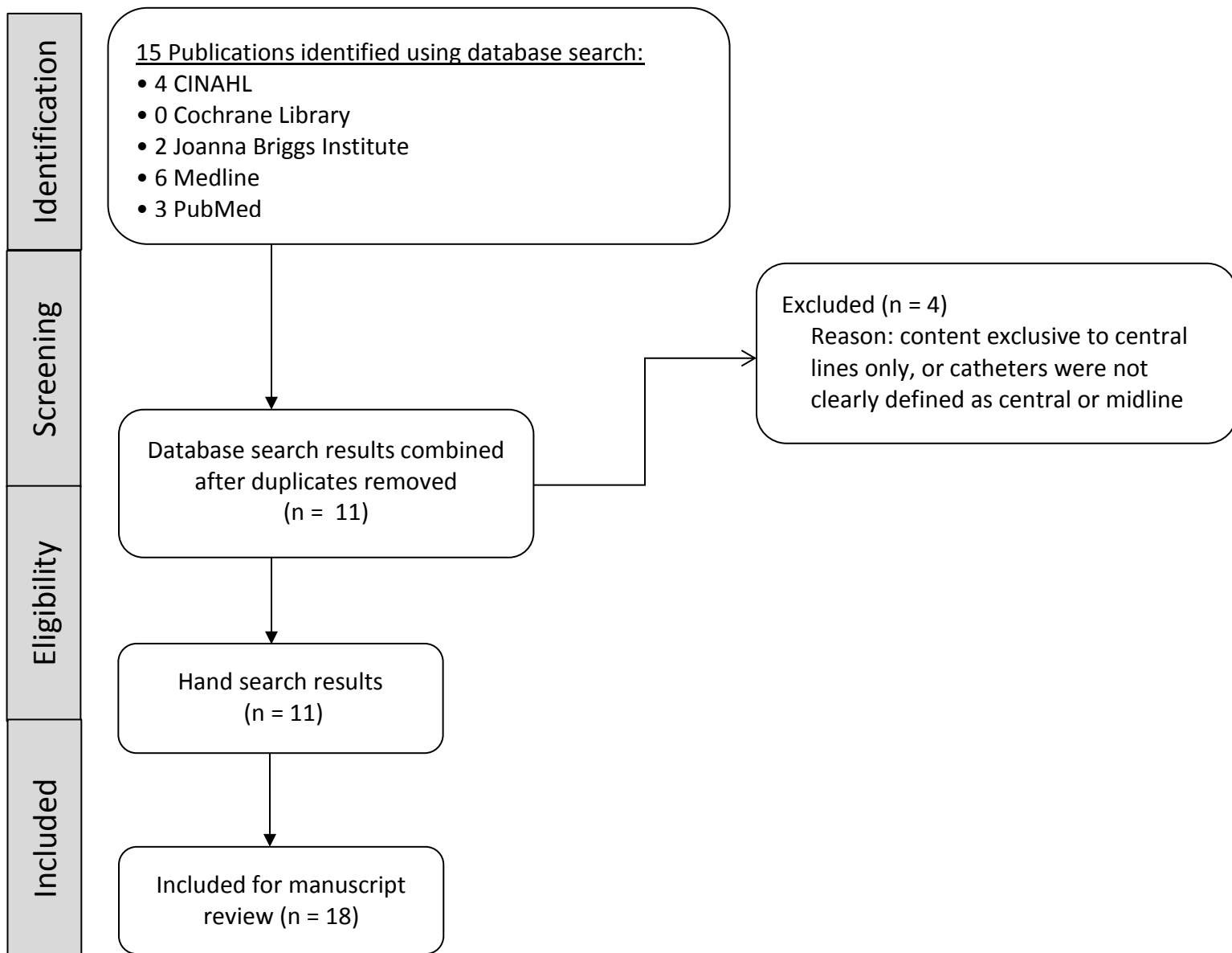


Figure 1. Flow diagram of publication selection process. Adapted from “Reprint - Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement,” by D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, and The PRISMA Group, 2009, *Physical Therapy*, 89(9).

Evaluation of Clinical Practice Guidelines

The original Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument was published in 2003 to assess the quality of clinical practice guidelines. The AGREE II Instrument replaced the original AGREE Instrument in 2010. In addition to the quality of guidelines, the AGREE II also assesses the “methodological rigor and transparency” of clinical guidelines development (Brouwers et al., 2010). The AGREE II Instrument includes 23 items which are organized into six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence. The NANN PICC Guideline for Practice, 2nd Edition (2007) was evaluated by the AGREEII Instrument (see Appendix B).

Scope and practice. The intent of the guidelines, as stated in the preface, is to support nursing practice and promote infant safety in regard to insertion and maintenance of PICCs in neonatal patients. The content of the guidelines includes a section on Potential Insertion-Related Difficulties and a troubleshooting guide to address clinical issues. Although the guideline is intended for infants, there is no mention of specific recommendations for gestational age, post-conceptual age, or weight.

Stakeholder involvement. The acknowledgments, state that BD Medical Systems provided an educational grant for the publication of the guideline. The authors and reviewers are also acknowledged. The target population perspective is addressed by the inclusion of a parent information guide in the appendix. Target users of the guideline are nurses trained in neonatal PICC insertion and maintenance.

Rigor of development. The guideline is most negligent in this domain as there is no mention of a systematic review of the literature or how evidence was selected for development of

the recommendations. A thorough reference section is included. The risks associated with PICC placement in the neonatal population are included in a section on Post-insertion Complications. The translation of evidence into practice recommendations is available in an appendix as Clinical Competencies. A list of external nursing reviewers is included in the acknowledgment section.

Clarity of presentation. Procedural guidelines for PICC placement are clear and specific. Midline catheter procedure guidelines are not included. VAD comparisons and infusate considerations are reviewed. Due to limited data on recommended dwell times for midline catheters, and variations in diagnosis, vascular assessment, and therapeutic and nutritional needs among NICU patients, an algorithm of recommended VAD decision making is not included.

Applicability. Other than a brief discussion of Food and Drug Administration reporting requirements for device malfunctions, there is no discussion of barriers, guideline utilizations, or quality indicators. Educational competencies, vein anatomy figures, a trouble-shooting guide, and documentation tools are included in the guidelines. Applicable cost-related issues are not included. Measurements of guideline recommendation outcomes are not included.

Editorial independence. The Acknowledgment section includes a statement declaring that although BD Medical provided a grant for the guideline development, they had no input into the content of the guideline. The developing group does not appear to have competing interests.

Overall Guideline Assessment. An evaluation of NANN's PICC Guidelines for Practice with the AGREE II tool, resulted in a score of 39%, with the highest possible score being 100% (Appendix A). The Rigor of Development and Applicability domains were scored the lowest. This clinical guideline for practice is recommended for use with modifications.

Analysis

Historical perspective. Midline catheters were first introduced in the adult population in the 1950s by Deseret Medical Corporation. The device was inserted by an introducer needle and was used for surgical patients requiring at least seven days of IV therapy (Anderson, 2004; Griffiths, 2007). The design of the midline catheter continued to evolve and a peel-away plastic introducer was developed in the 1980s. In 1992, Moran described a new midline catheter being used in the neonatal population. The Aquavene Catheter, manufactured by Landmark, did not entail an introducer or a guidewire, and was inserted by an over-the-needle design. At that time the Landmark catheter was felt to be advantageous, particularly for neonatal patients because the biocompatible polymer, Aquavene, reportedly softened to become flexible and expand in the vessel. This feature demonstrated dwell times comparable to silicone catheters, but with less risk for infection. The catheters were also felt to be less thrombogenic due to the hydrogel component (Alexandrou, et al., 2011; Goetz, et al.; Mermel, et al., 1995; Moran, 1992) .

Although more than 500,000 Landmark catheters had been sold by 1995, there was no published data available in which the catheters were cultured at the time of removal (Mermel et al., 1995). This lack of data was the basis for a prospective study by Mermel et al. in 1995, which evaluated the risk for infection associated with the use of the Landmark catheter in hospitalized patients. The findings confirmed a low risk for infections related to midline catheters, but it also became evident that the Landmark catheters had been associated with several life threatening adverse reactions. The authors described the adverse reactions associated with catheter placement in three patients and also found several similar unpublished cases which had been reported to the FDA. Based on concerns that the coating on the Landmark catheter was the cause of the adverse reactions, it was taken off the market in in 1997 (Anderson, 2004).

Device. MCs currently available for use in infants are composed of polyurethane or silicone as single or double lumen, and are available in 1.9-3.0 Fr., and in gauge sizes of 22-24 (Frey & Pettit, 2010; Infusion Nurses Society, 2011).

Placement. Alexandrou, et al. (2011) reported that MCs are not appropriate for adult patients with a history of thrombosis, hypercoagulopathy, medical conditions which impede venous flow from an extremity, or those with an arteriovenous fistula for dialysis. Variables to consider when evaluating which VADs are appropriate for infants including gestational age, weight, presence of congenital anomalies, cardiorespiratory monitoring requirements, sepsis, current clinical condition and ability to tolerate the procedure, anticipated type and duration of IV solutions and medications, previous history with VADs, and the expected duration of IV therapy (Moran, 1992; NANN, 2007).

Midline catheters are inserted into a peripheral vein in the antecubital fossa and advanced with the tip terminating in the basilic, cephalic, or brachial vein distal to the shoulder (Figure 2). According to the Infusion Nurses Society (1997, 2011) additional sites for consideration in infants include the external jugular, axillary, long and short saphenous, temporal, and posterior auricular veins (Frey and Petit, 2010; Wyckoff, 1999). In comparison to PICCs, the tip purposefully does not extend past the axillary vein or the inguinal fold (Colacchio et al., 2012).

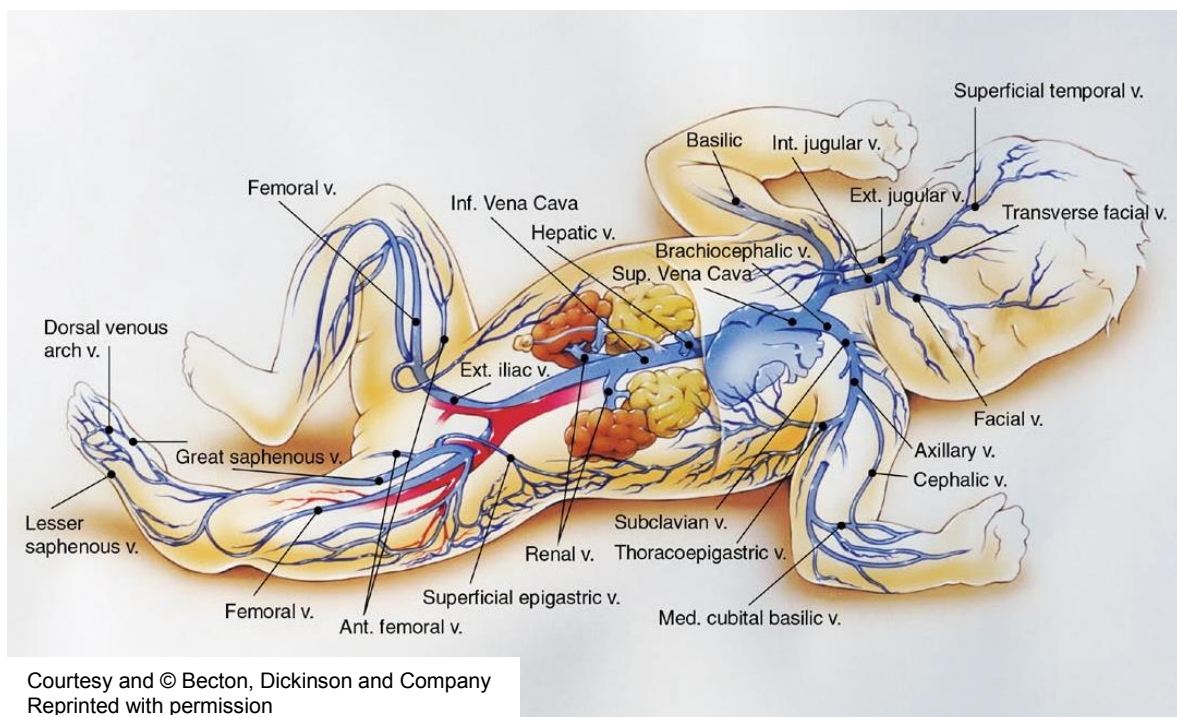


Figure 2. The major veins that may be used for PICC placement in young infants. From National Association of Neonatal Nurses. (2007). *Peripherally inserted central catheters: Guideline for practice* (2nd ed.) (p. 13). Glenview, IL: National Association of Neonatal Nurses. Reprinted with permission.

MC placement does not require radiologic confirmation as the tip lies in a large, peripheral vessel (Alexandrou, et al., 2011; Goetz et al., 1998; Griffiths, 2007). As a result of fewer X-rays with MC placement, Mermel et al. (1995) and Wyckoff (1999) reported reduced hospital costs. The Intravenous Nurses Society 1997 Position Paper on Midline and Midclavicular Catheters recommended X-ray confirmation only in the following clinical situations:

difficulty with catheter advancement; pain or discomfort after catheter advancement; inability to obtain free flowing blood return; inability to flush the catheter easily; the guidewire is difficult to remove or is bent after removal; pain, discomfort, feelings of fullness or coldness, or hearing gurgling sounds during flushing. (p. 177)

Dwell time. There is a recognized lack of consistent recommendations in the literature regarding acceptable MC dwell times. Lesser et al. (1996) enrolled nine infants less than 34 weeks' gestation and greater than five days of age if they were expected to require IV therapy for at least 10 days. The average dwell time for nine MCs was 9.0 ± 1.4 days and for 23 PIVs, the average dwell time was 3.1 ± 0.5 days.

In 1999, Wyckoff reported on dwell times for 135 MCs placed in infants less than 30 days old, ranging from 25 weeks to 46 weeks gestation, and ranging in weight from 540 grams to 4010 grams. The mean dwell time for these catheters was 10 days, with a range of one to 80 days. This data was compared to average PIV dwell times of approximately 27.5 to 49.5 hours.

In 2002, Dawson completed a retrospective chart review of 32 infants who received MCs. A unit protocol for this review included a requirement for MCs to be placed at the time of admission for all neonates expected to require a minimum of three days of IV therapy. The gestational age of the infants who received MCs ranged from 24 to 42 weeks. This data was compared to other infants of similar gestational age who received PIVs instead of MCs. The findings revealed that the infants with PIVs experienced an average dwell time of eight days, with approximately nine venipuncture attempts per day. The MC group of infants experienced an average dwell time of 6.3 days, with approximately 2.0 venipuncture attempts per day.

Leick-Rude and Haney (2006) conducted a prospective quality assurance monitoring review of 1,130 MCs placed in 858 infants of gestational ages 23 to 42 weeks, weighing 360-8,000 grams. The MCs were inserted when the infants were 23-61 days of age. The scalp was the most frequently used site, with an average dwell time of 9.2-10 days. MCs placed in the scalp were discontinued electively more than any other site, had the least number of infiltrations (17%), and 19% were removed for occlusion. Upper extremity MCs were removed due to

infiltration 21% of the time and occlusion 12% of the time. Average dwell time for upper extremity MCs was 8.1 days. Lower extremity MCs were the least common site used. Average dwell time for knee insertion was 12.9 days and for ankle insertion was 7 days.

Leick-Rude and Haney (2006) reported that 22% of the MCs were removed for infiltration, 17% for occlusion, 11% for leaking, 4% for dislodgement, 2% for phlebitis, and two MCs were removed for malposition based on clinical presentation. There were 39 blood cultures obtained from the infants while a MC was in place and 8 MCs were removed because of a positive blood culture. Sixty-one percent of the infants with positive blood cultures also had a central line in place when the culture was drawn. Of the infants with positive blood cultures, 1.3% had only a MC.

Some authors suggest the feasibility of choosing a MC for a patient is based on an expected need for IV therapy greater than seven days (Goetz et al., 1998). Griffiths (2007) reports that Vygon, a company which makes MCs, recommends that dwell times be based on the expected duration of treatment, rather than on a specified time scale. The INS recommends consideration for MC placement in neonates when IV therapy is expected to last 1-4 weeks. The NANN recognize that mean MC dwell times are typically reported to be between six to 10 days, but acknowledges the fact that current data does not exist to support a limit to the dwell time of properly functioning MCs.

Cost. MC use in the NICU may result in cost savings associated with lower infection rates, less nursing time required due to fewer venipunctures, less pharmacy costs for antibiotics, and ultimately a shorter length of stay (Alexandrou et al., 2011; Dawson, 2002; Joanna Briggs Institute, 1998; Lesser et al., 1996; Rosenthal, 2008). When compared to PIVs, MCs are typically more cost efficient in patients who meet criteria for placement (Anderson, 2004).

According to the NANN PICC Guidelines, the cost of a MC is equivalent to that of a PIV after 3-4 days of therapy. In patients who are clinically appropriate for home IV therapy, MCs are more cost effective than PICCs as a result of the ability to allow for an earlier discharge home (Griffiths, 2007). In comparison to PICCs, MC placement may also result in cost savings as they do not require an X-ray to confirm the location of the catheter's tip (Mermel et al., 1995; Wychoff, 1999).

Practice criteria. MCs are recommended for solutions with a maximum dextrose concentration of 10% and isotonic solutions with a pH range of 5 to 9 (Alexandrou et al., 2011; Griffiths, 2007; Leick-Rude and Haney, 2006; NANN, 2007; Rosenthal, 2008). The INS (2011) and NANN (2007) recommend infusion of fluid and medications with osmolalities <600 mOsm/kg for MCs. Examples of vesicants and hyperosmolar medications and IV fluids which are not considered safe for infusion through MCs include Total Parenteral Nutrition with dextrose concentration of D12.5% or greater, Amphotericin B, Calcium, chemotherapy medications, Dilantin, vasopressors, and Vancomycin (NANN, 2007; Rosenthal, 2008).

Summary

There are few studies evaluating MC outcomes, particularly in the pediatric and neonatal population (Anderson, 2004). In comparison to the multitude of high level research available on PICCs, there is an absence of randomized control trials and systematic reviews evaluating MCs . Larger, prospective studies are needed to evaluate current MC practice in the NICU, and the rates of infection and extravasation associated with their use (Mermel et al., 1995; Victor, 1997). The INS (1997, 2011) recommends that institutions establish outcome data on specific patient populations for each VAD, and incorporate evidence based practice into current policies, procedures, and guidelines. Despite some literature describing observational data, midline

catheters are not an appropriate vascular access device for NICU patients due to insufficient high level evidence demonstrating safety and efficacy.

Project Methodology

University of North Florida Institutional Review Board Attachment B for Protocol # 558281-2 is included as Appendix B. This document describes the Participant Population, Study Procedures and Materials, Risk/Benefit Analysis, and Data and Safety Monitoring, for the project entitled “Midline Catheter Use in the Newborn Intensive Care Unit: Current Practice Inquiry”.

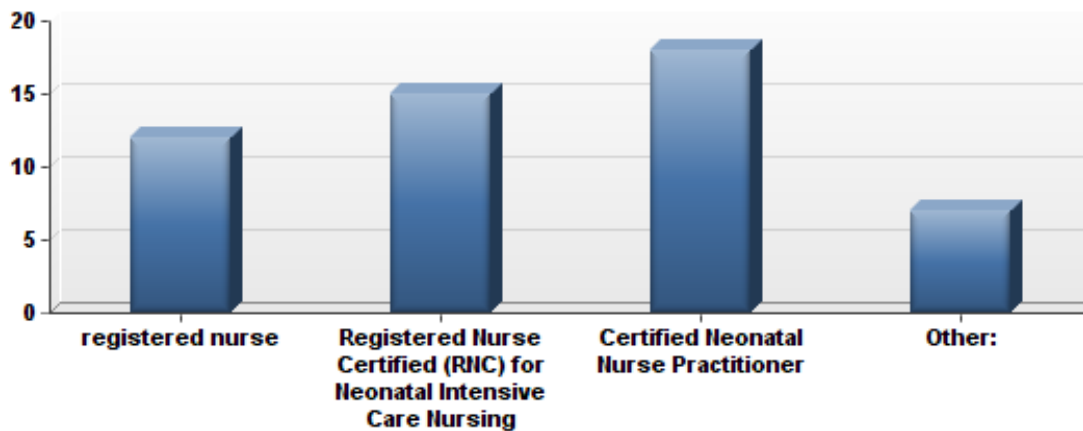
Results

A 22 question survey was available for 30 days (as allowed by NANN) on the NANN website for members to voluntarily complete. The Survey Objectives are included as Appendix E. NANN reports a membership of 7500 which includes neonatal nurses and Neonatal Nurse Practitioners. The survey was created and the data was compiled via Qualtrics software. Thirty six surveys were completed.

Demographics

NICUs are designated as Level 1, 2, 3, or 4 depending on the level of care they are able to provide for neonates and infants. Level 1 typically equates to a Newborn Nursery with healthy newborns, and Level 2 for clinically stable infants weighing greater than 1000 grams at birth. Level 3 NICUs provide most surgical and consultative services for critically ill infants. Level 4 NICUs additionally offer Extracorporeal Membrane Oxygenation, or ECMO, for the sickest of infants. Seventy-six percent (28) of respondents completing the survey reported working in a Level 3 NICU.

Eighty-six percent of participants reported that they work in a NICU and Figure 3 describes participant level of nursing education. The remaining 14% (5) reported their places of employment as the Newborn Nursery, the Pediatric Intensive Care Unit, and/or Newborn Transport Teams.



* Other = BSN, CNS, DNP

Figure 3. Education

Procedure Guidelines, Protocols, and Training (Figures 4-8)

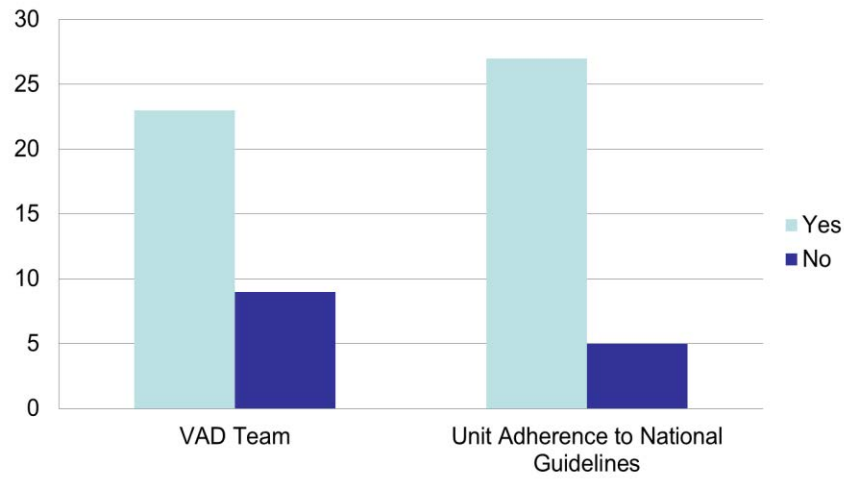


Figure 4. Procedure Guidelines

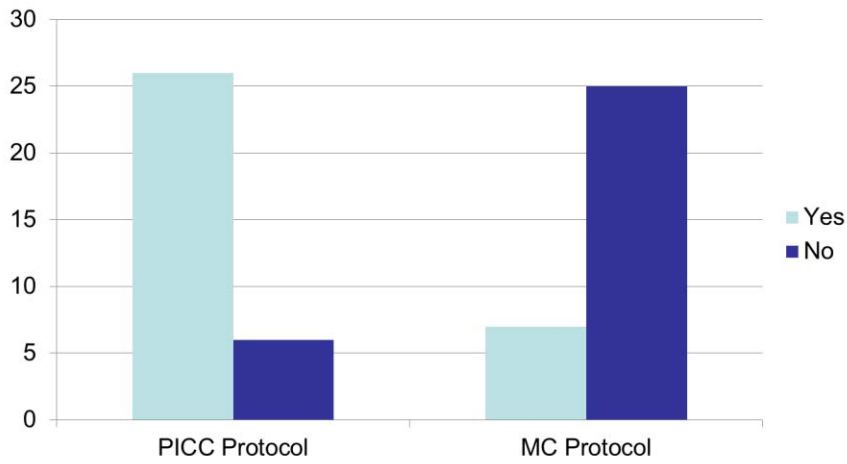


Figure 5. Procedure Protocols

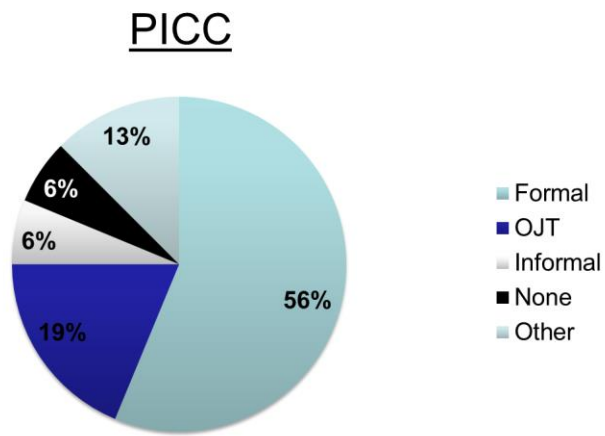


Figure 6. PICC Training

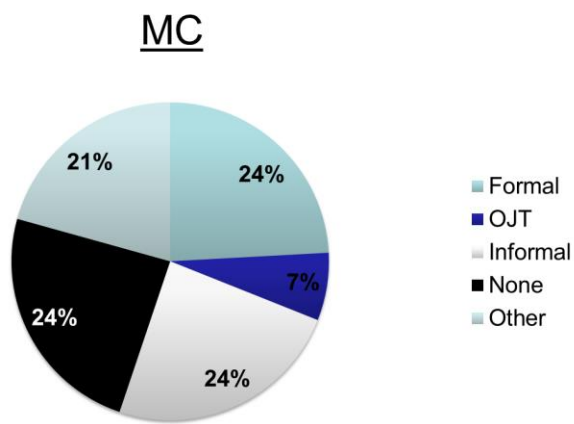


Figure 7. MC Training

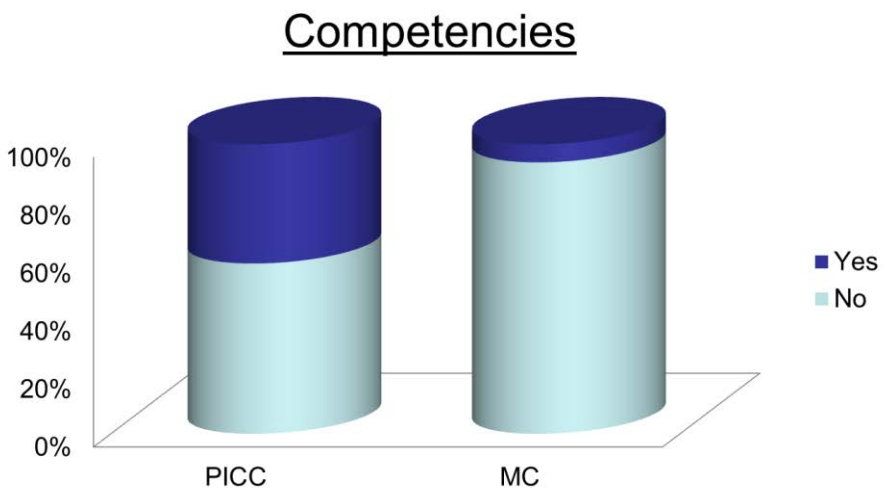


Figure 8. VAD Competencies

Participant Estimation of Successful VAD Placement and Usage (Figure 9)

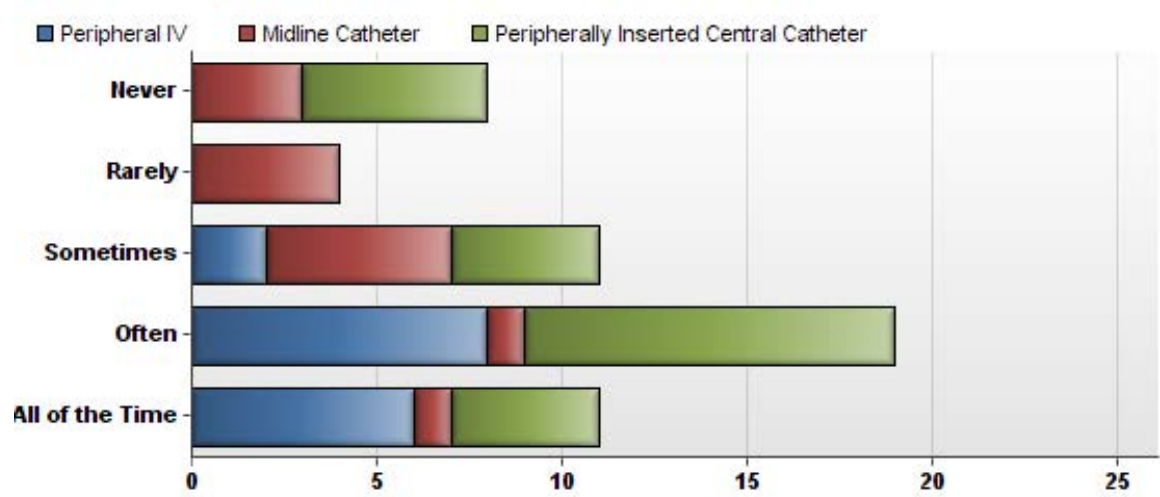


Figure 9. VAD Placement

Of nineteen responses, the number of PICCs placed annually ranged from 6 to 1000, with an average of 272. Of seventeen responses, the number of MCs placed annually ranged from 0 to 500, with an average of 82. Survey results from the questions asking about rates of infection and extravasation for VADs were tabulated incorrectly and are therefore not available for analysis.

Knowledge and Beliefs (Figures 10 and 11)

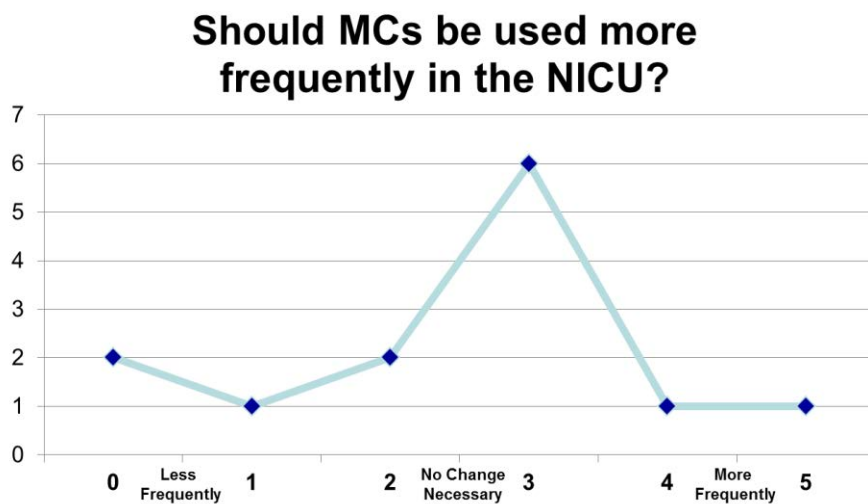


Figure 10. VAD Use

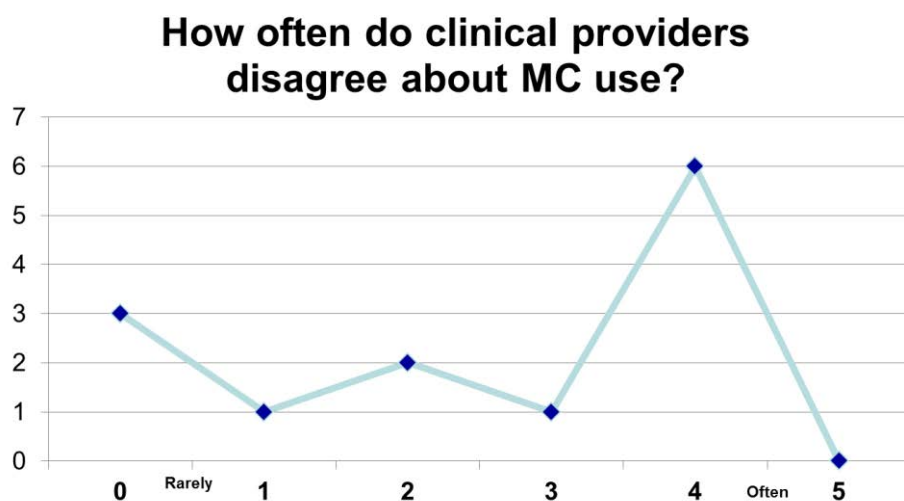


Figure 11. VAD Agreement

Comments

Several participants submitted comments in the section provided at the end of the survey. The majority of the comments referred to their experience of using PICC lines as MCs when they are not centrally placed. One respondent indicated that MCs are often considered a “default” when a centrally placed PICC is not obtained. Another commented that “if a PICC becomes dislodged, it may be salvaged as a MC”. Some mentioned that they do not use different MC devices and that these catheters are referred to as “peripheral PICCs”. And finally, one participant reported that their unit is having difficulty in obtaining agreement among providers to use MCs due to lack of research.

Discussion

Findings

Demographics. The majority of respondents are Certified Neonatal Nurse Practitioners or Registered Nurses certified in Neonatal Intensive Care Nursing and reported working in Level 3 NICUs located in urban areas.

Procedure Guidelines, Protocols, and Training. Survey responses indicate that most NICUs have a VAD Team and follow National Guidelines for VAD insertion and maintenance. Interestingly, while most reported having a unit-specific PICC Protocol, the majority of responses also indicated the absence of a MC protocol. More than half reported formal PICC training, but only one quarter of surveys indicated formal training as a requirement for placing MCs. In addition, while over half of the participants reported that they are required to complete competencies on a regular basis for PICCs, only 2 participants reported a requirement to complete MC competencies.

Participant Estimates of Successful VAD Placement and Usage. Participants estimated personal success with VAD placement to be highest with PIV and PICC attempts, and lowest with MC attempts. Although the answers varied greatly, all participants indicated more PICCs are placed annually in their units, than MCs.

Knowledge and Beliefs. Respondents were able to correctly identify the definitions for PICC and MC. Of the 13 participants that responded to the questions pertaining to their beliefs about MC use, most indicated that no change is necessary, which suggests that they feel current MC use in their unit is appropriate. However, the same participants also indicated that clinical providers often disagree about MC use. In addition, the comments by participants point to a lack of consistency in regard to MC use in the NICU.

Implications for Practice

In order to integrate high level clinical evidence into patient care, clinicians are challenged to synthesize mass quantities of published data, and incorporate these changes into daily practice. Furthermore, institutional and national guidelines currently in place may not be evidence based, and some clinicians may be reluctant to practice differently if the evidence does

not coincide with tradition or clinician experience. According to Black and Brennen (2011), successful implementation of practice change depends upon the ability to translate knowledge into practice, account for unit culture, manage change, encourage staff buy-in, incorporate a multidisciplinary approach, and utilize peer champions.

The only currently available national guideline for MC use in the neonatal population is NANN's PICC Guidelines for Practice which currently lacks sufficient information for safe and effective use of MCs. Neonatal nurses and Nurse Practitioners who rely on these guidelines for MC use may appreciate the need to improve upon them by individually evaluating this document using the AGREE II tool.

Multicenter, randomized control trials are needed to evaluate current MC practice in the NICU, and the rates of infection and extravasation associated with their use. This data must be disseminated in such a way that provides clinicians with the evidence necessary to incorporate these changes into patient care on a daily basis.

Conclusion

The results of this small, online survey indicate that while some neonatal nurses and Nurse Practitioners report the use of MC use in the NICU, few have MC-specific protocols in place. In addition, few receive formal MC training and MC competencies are rarely required, which may explain participant estimation of less success with MC placement. And finally, survey responses and comments indicate a lack of consistency in MC use and some disagreement among providers regarding appropriate use of this VAD.

Ongoing evaluation of current practice and incorporation of evidence based research into guidelines and protocols is a requirement for the provision of high quality, cost efficient care. MCs are not an appropriate VAD for NICU patients due to insufficient high level evidence

demonstrating safety and efficacy; thus, the continued use of this VAD may be called into question with regard to ethics, cost, and liability. In summary, institutions must establish outcome data for MC use which is specific for neonates and infants, and incorporates current, evidence based practice into policies, procedures, and guidelines.

Appendix A: Midline Catheter Literature Review

Table 1

Midline Catheter Literature Review: Background and Discussion

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations |
|--------------------------|---|--|---|---|--|
| Alexandrou et al. (2011) | Lit Review | Fewer PIVs, Cost-effective, Potential to avoid infection, no XR confirmation necessary | Risk of extravasation can be high, not recommended for dextrose solution >10%, pH >5 and <9, most common complication is mechanical phlebitis | Not suitable for patients with history of thrombosis, hypercoagulopathy, or compromised venous circulation | MC may be used in a variety of acute care setting where multiple peripheral cannulas traditionally have been used or as a replacement for a PICC or CVC. |
| Anderson et al. (2004) | Lit Review and program implementation process | In comparison to PIVs, fewer needle sticks, lower rates of infiltration and phlebitis, increased patient satisfaction, savings in nursing time and equipment costs | High rates of phlebitis and thrombosis with vesicant drugs | Few studies investigating MC outcomes | Use of a MC in place of a PIV comes at no extra operational costs to the hospital system, but offers a significant gain in positive outcomes. |
| Colacchio et al. (2012) | Retrospective Observational (PICC) | | MCs not evaluated | MCs are different from PINCCs as they are shorter IV catheters, typically placed in the extremities with the tip purposefully meant to extend no further than the axillary vein or the inguinal fold. | MCs can be used both safely and effectively to provide stable IV access and to avoid many of the complications typically associated with central lines. |

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations |
|------------------|--|---|---|--|--|
| Dawson (2002) | Retrospective chart review (PIV) and program implementation (MC) | Fewer venipunctures attempts; no mortality or morbidity factors associated with use; cost savings due to less nursing time, less pharmacy cost, and shorter length of stay; less handling and longer periods of uninterrupted sleep which could result in improved weight gain and shorter length of stay | Only acceptable for solutions safe for PIVs; average dwell time of 6.3 days | MCs placed on admission for all patients requiring 3+ days of IV therapy | Use of MCs to deliver fluids in neonatal patients is appropriate |
| Griffiths (2007) | Synopsis | Fewer PIVs, well tolerated by patients, may allow for earlier discharge, XR confirmation not typically required, ease of insertion, patient comfort, ideal for patients with limited venous access, cost effective, acceptable for analgesia infusion | Not appropriate for Dextrose >10% or vesicants (such as antibiotics), does not accommodate >70 mL/min, gravity infusion may not be possible, mechanical phlebitis, not applicable if venous anatomy is compromised, lack of trained personnel | Few studies available; institutional policy will dictate frequency of flushing; nursing procedure that requires medical order; dwell time may be for the duration of treatment rather than a specified time scale | MCs are a reliable VAD suitable for the safe delivery of IV drugs and fluids for patients who require medium to long-term therapy. |
| Moran (1992) | Synopsis | | FDA discontinued the use of Landmark Aquavene catheters in the 1990s for concerns for hypersensitivity reactions; mechanical phlebitis only reported in this study | Factors to consider when choosing a VAD – gestational age, weight, congenital anomalies, cardiorespiratory monitoring, sepsis, the number and frequency of caustic infusions, previous history of venous access devices, and the duration required | |

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations |
|--------------------------|-------------------------------------|---|---|---|---|
| Rosenthal (2008) | Synopsis | Better hemodilution than PIVs; doesn't require suturing; shorter hospital stay, improved patient satisfaction | Not appropriate for isotonic drugs/solutions, for infusion of continuous vesicants or irritants such as >10% Dextrose, parenteral nutrition, or for meds with high or low pH values like Vancomycin (2.4) or Dilantin (12); requires trained personnel; associated with insertion-related phlebitis | | MCs are an effective tool to preserve a patient's peripheral access and offer a cost-effective alternative to frequent IV site rotations. |
| Victor (1997) | Commentary Re: Lesser et al. (1996) | Provides developmentally appropriate and less stressful environment, may decrease the risk of iatrogenic complications from PIV | | This study should be replicated with a larger sample size to validate the results | MCs are a safe and effective method for delivering IV therapy for 1-2 weeks. |

Table 2

Midline Catheter Literature Review: Observational Studies

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations | N = |
|---------------------------|-------------------------------|---|--|--|--|---|
| Goetz et al. (1998) | Prospective Observational | Fewer PIV starts, XR not required, cost savings, potential to preserve veins in patients with limited access, minimizes patient transfer in some institutions | Potential for chemical and mechanical phlebitis, and obstruction | Recommended for dwell times > 7d | MCs can be used for prolonged IV therapy and are associated with infection rates comparable to PICC/CVL. MC is superior to PIV for patients with limited access who need extended IV therapy. | - 248 patients - ages 23-98 years - 334 MCs |
| Leick-Rude & Haney (2006) | Prospective Quality Assurance | Longer dwell times and fewer venipunctures than PIVs; fewer complications than PICCs; safe for antibiotics, Insulin, Prostaglandin, and blood transfusion products; may be used for antibiotics when sepsis is proven and PICC discontinued | Not appropriate for vesicant chemotherapy, parenteral nutrition, >10% dextrose or 5% protein, solutions or meds with pHs <5 or >9, or osmolality >500 mOsm/liter; 34%-49% removal rate due to infiltration, leaking, or edema; not suitable for Vasopressors; not suitable to draw blood samples | Catheter duration by patient weight/ insertion site and reasons for catheter removal described in detail; PICC and MCs placed at time of umbilical catheter removal; care practices aimed at extending catheter dwell time require further investigation | MCs can be effectively and safely used for preterm and other high-risk neonates to provide extended peripheral vascular access while avoiding many of the complications associated with central lines. | - N not described - 23-42 weeks gestation - 1,130 MCs |

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations | N = |
|----------------------|---------------------------|--|----------------------|--|--|---|
| Lesser et al. (1996) | Prospective Observational | PIVs lasted 3.1 +/-1.5 days compared to 9.0 +/- 1.4 for MCs; time and cost for CVCs and MCs are comparable but with fewer complications | | | MCs provide easy, safe, and prolonged intravenous access in low birth weight infants. | - N not described - 25-34 weeks gestation - 9 MCs |
| Mermel et al. (1995) | Prospective Observational | Low risk for infection, reduce hospital and patient cost, XR not indicated | | More prospective studies are needed to establish safety. | MCs fill an important niche in the care of acute and chronically ill patients. | -130 patients - age not described - 140 MCs |
| Wyckoff (1999) | Prospective Observational | External jugular, axillary, long and short saphenous, temporal, and posterior auricular veins are appropriate sites for consideration; MC dwell times have been reported to be almost 3x longer than PIVs; XR not typically required; may enable DC home for completion of IV therapy; decreased skin extravasation; decreased risk of infection, cost efficient | | | MCs appear to be a valuable alternative to PIVs in neonates requiring long-term IV access. | - N not described - 25-46 weeks gestation - 143 MCs |

Table 3

Midline Catheter Literature Review: Policies and Procedures

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations |
|----------------------|-----------------|---|---|---|--|
| Frey & Pettit (2010) | INS textbook | Potential sites in neonates include antecubital, leg, and scalp | Infusate comparable to recs for PIVs, average dwell time in neonates is 6-10 days, approximately 50% of neonates MCs are removed due to comps with migration/infiltration | More studies are needed | |
| INS (1997) | Position Paper | In neonates, antecubital, external jugular, axillary, long and short saphenous, temporal, and posterior auricular veins may be considered | XR recommended if difficulty with advancement, pain or discomfort, no blood return, or if guidewire is bent after removal | No medical device is without risk, VAD assessment should lead to choosing the least invasive device | Institutions must establish outcome data on their specific patient populations for each device and establish and revise policies and procedures based on the outcome data. |

| Author (Year) | Lit Type | Advantages | Disadvantages | Comments | Recommendations |
|-------------------------|-----------------------|---|--|--|--|
| INS (2011) | Standards of Practice | Appropriate for therapies anticipated to last 1-4 weeks; may be used for hydration, IV solutions, pain medications, and some antibiotics; catheter tip does not enter central vasculature; available as single or double lumen, polyurethane or silicone, and in gauge sizes of 22-24; additional insertion sites (leg, scalp) may be considered for neonates | Reported dwell times for neonates is 6-10 days; not appropriate for vesicant therapy, parenteral nutrition, infusates with pH<5 or > 9, and infused with osmolality >600 mOsm/L | Tip location at or below the axillary line | Indications and protocols for VADs shall be established in organizational policies, procedures, and/or practice guidelines and according to manufacturers' directions for use. |
| JBI Best Practice(2008) | EBP Info Sheet | | | | MCs appear to be associated with lower rates of phlebitis and infection than short peripheral catheters and cost less than central venous catheters. |
| NANN (2007) | Guidelines | Dwell times reported to be between 6-10 days and up to four times as long as PIVs; fewer PIV restarts and longer lifespan; cost of MC equivalent to 3-4 days of PIV | Not appropriate for dextrose >10%, parenteral nutrition, Ampicillin, Cefotaxime, Sodium Bicarbonate, and Phenobarbital, or osmolality >600mOsm/kg, not appropriate for vesicants such as Amphotericin B, Vasopressin, resuscitation meds, Dopamine, or Calcium | No data exist to support dwell time limits | MCs offer an alternative for those infants who do not require a PICC, but who need several days of IV therapy. |

Appendix B: AGREE II Author Score Sheet of NANN PICC Guidelines for Practice

| Domain | Item | AGREE II Rating | | | | | | |
|-------------------------|---|-------------------------------|---|---|---|---|---|----------------------------|
| | | 1 <i>Strongly Disagree</i> | 2 | 3 | 4 | 5 | 6 | 7 <i>Strongly Agree</i> |
| Scope and purpose | 1. The overall objective(s) of the guideline is (are) specifically described. | | | | | X | | |
| | 2. The health question(s) covered by the guideline is (are) specifically described. | | | X | | | | |
| | 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described. | | X | | | | | |
| Stakeholder involvement | 4. The guideline development group includes individuals from all the relevant professional groups. | | | | | | | X |
| | 5. The views and preferences of the target population (patients, public, etc.) have been sought. | | | | X | | | |
| | 6. The target users of the guideline are clearly defined. | | | | | | X | |
| Rigor of development | 7. Systematic methods were used to search for evidence. | X | | | | | | |
| | 8. The criteria for selecting the evidence are clearly described. | | X | | | | | |
| | 9. The strengths and limitations of the body of evidence are clearly described. | | X | | | | | |
| | 10. The methods for formulating the recommendations are clearly described. | X | | | | | | |
| | 11. The health benefits, side effects and risks have been considered in formulating the recommendations. | | | | | | | X |
| | 12. There is an explicit link between the recommendations and the supporting evidence. | | | X | | | | |
| | 13. The guideline has been externally reviewed by experts prior to its publication. | | X | | | | | |
| Clarity of | 14. A procedure for updating the guideline is provided. | X | | | | | | |
| | 15. The recommendations are specific and unambiguous. | | | | X | | | |

| Domain | Item | AGREE II Rating | | | | | | |
|------------------------------|---|-------------------------------|-------------------------|---|---|---|---|----------------------------|
| | | 1 <i>Strongly Disagree</i> | 2 | 3 | 4 | 5 | 6 | 7 <i>Strongly Agree</i> |
| presentation | | | | | | | | |
| | 16. The different options for management of the condition or health issue are clearly presented. | | X | | | | | |
| | 17. Key recommendations are easily identifiable. | | | | X | | | |
| Applicability | 18. The guideline describes facilitators and barriers to its application. | X | | | | | | |
| | 19. The guideline provides advice and/or tools on how the recommendations can be put into practice. | | | | X | | | |
| | 20. The potential resource implications of applying the recommendations have been considered. | X | | | | | | |
| | 21. The guideline presents monitoring and/ or auditing criteria. | X | | | | | | |
| Editorial independence | 22. The views of the funding body have not influenced the content of the guideline. | | | | | | | X |
| | 23. Competing interests of guideline development group members have been recorded and addressed. | | | | | | | X |
| Overall Guideline Assessment | 1. Rate the overall quality of this guideline. | | | | X | | | |
| Overall Guideline Assessment | 2. I would recommend this guideline for use. | Yes | Yes, with modifications | | | | | No |
| | | | X | | | | | |

Appendix C: Permission for Figure Reprint

We have considered your request submitted on 2/13/2014 12:24:07 PM. BD will grant your request and will release the material referenced in your submission provided that you, acting as or on behalf of Licensee, agree to the Terms and Conditions of Use attached to this message. Your affirmative response to this message will constitute full acceptance of, and agreement to, these Terms and Conditions of Use.

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Last Name: Romesberg

Organization: University of North Florida

Name of Individual Authorized to Sign Permission Form (Signatory): Tricia Romesberg

Relationship of Signatory to Licensee: same

Relationship with BD: requesting permission to use figure

Describe in detail the material(s) for which you request permission to reprint: (e.g., include a) the full title, author and copyright date of published article, as well as the document number, if known; or b) distinguishing characteristics of digital images and source description; or c) specific URLs for web page content; or d) full draft of the press release or other marketing material, etc.)

Figure 1 on page 13 of the National Association of Neonatal Nurses Peripherally Inserted Central Catheters Guideline for Practice, 2nd Edition (2007). The figure is entitled "The major veins that may be used for PICC placement in young infants".

Catalog Number (if known):

Describe in detail for what purpose the material(s) will be used: email sent

For what duration will the material(s) be used? for publication

Do you have samples of the material(s) requested? yes

Name of your contact at BD: none

Date permission required: 2/15/2014

Appendix D: UNF IRB # 558281-2 Attachment B



Attachment B - Request for Exempt Review

Please note: This attachment is required for all submission packages involving research with human participants for which an *exempt review* is requested. Please see the [Documents Checklist for Exempt Projects](#) to ensure all of the required documents are submitted. Please note that in addition to completing this document, the North Florida - IRB Protocol application within IRBNet will also need to be completed and submitted. For directions on how to find that document within IRBNet, please refer to the [UNF IRBNet FAQs](#).

Exemption from further IRB review may be granted for research that presents no more than minimal risk to human participants or others if that research fits into one or more of the exempt categories listed in the federal regulations ([45 CFR 46.101](#)). Please select the exempt category or categories that you believe apply to your project (select all that apply). If none of the below categories apply to your project, the project will not qualify for exempt review. The categories are described here using the language found in [45 CFR 46.101\(b\)](#). If you have questions about how your proposed study might fit one of these categories, please contact Research Integrity staff.

1. Research conducted in established or commonly accepted educational settings and involving *normal educational practices*, such as
 - i. research on regular and special education instructional strategies, or
 - ii. research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
2. *Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior *unless*:
 - i. information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly (e.g., through the use of identifiers) *and*
 - ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

***Exempt category 2 cannot be used for research involving children unless the only activities involve educational tests or observations of public behavior where the researchers do not participate in the activities being observed.**
3. Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if:
 - i. the subjects are elected or appointed public officials or candidates for public office; or
 - ii. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subject.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - i. Public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures; *or*
 - iv. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies if,
 - i. wholesome foods without additives are consumed or
 - ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Special Note: The exemptions stated on the previous page do not apply to research involving prisoners. However, the exemptions can apply to research involving pregnant women. As noted above, some elements of exempt category 2 (i.e., survey procedures, interviews, or observations of public behavior) can *not* apply to minors. Other research that includes vulnerable populations may not qualify for exempt review and may instead fall into one or more of the [expedited review categories](#) or require full IRB review, depending on level of risk.

1. Participants Population(s)

a. Describe the participant population(s) including gender, ethnicity, and age range. If any population will be specifically targeted (e.g., UNF students, minors, UNF employees) please state as such.

The online survey will be offered to neonatal nurses and neonatal nurse practitioners via the National Association for Neonatal Nurses (NANN) website. Those completing the survey will be primarily female, of varying ethnicities, and age range will likely be 24-65. The survey will be available to 7500 NANN and NANN Nurse Practitioner (NANNP) members.

b. Is your study likely to include non-English speaking individuals?

- Yes
 No

2. Potential for Undue Influence or Coercion

Indicate whether or not you intend to include study populations that may be vulnerable to undue influence or coercion. Common examples of populations vulnerable to undue influence or coercion include, but are not limited to, students for which researchers have responsibility, employees who report to the researcher or an affiliate of the researcher, and patients or individuals who receive services from the researcher, the researcher's organization, or an affiliate of the researcher.

There are no foreseeable instances of undue influence or coercion based on study population (skip to item 3).

Participants may be vulnerable to undue influence or coercion. (Explain the nature of the undue influence or coercion and how this will be minimized.)

3. Study Procedures

Describe the proposed study procedures, including the sequence and timing of all activities. In your response please also describe the data collection setting (e.g., in person, one-on-one, small groups, large groups, online). If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained.

Following IRB approval, the Qualtrics Survey link will be posted to the NANN website for NANN members entitled myNANN. The voluntary survey will be available for interested NANN and NANNP members during a one month period in 2014. All survey data will be collected and stored via the Qualtrics site through the University of North Florida (UNF). All survey data will be collected and analyzed via Qualtrics with the "Anonymize Response" and "Anonymous Link" options, and data will only be analyzed and published in aggregate form. No individually identifiable data will be collected. Review of data will be limited to Tricia Romesberg, UNF student and Dr. Carol Ledbetter, PhD, APRN-BC. No unauthorized personnel will have access to the data.

4. Study Materials

List the names of all study materials that will or may be used in your study (e.g., titles of survey instruments that will be used in study). It will also be necessary to submit copies of all study materials to the UNF IRB for review and approval. If you plan to utilize copyrighted information, permission from copyright owner may be necessary.

Survey entitled "Midline Catheter: Use in the Newborn Intensive Care Unit: Current Practice Inquiry"; NANN Survey Introduction Letter/Informed Consent

5. Risk/Benefits Analysis & Compensation

a. Risk/Benefit Analysis

Briefly describe the expected benefits and foreseeable risks of research participation and the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants, a scholarly discipline, or society.

Participation is voluntary. The risk of participation in this survey is considered minimal. The participant may find that the survey questions pertain to information that the participant does not know but feels he/she should know. The potential benefits of participation in this survey outweigh the minimal risk and include enjoyment of contributing to the research process; and, making a contribution that potentially could benefit a health care practice and possibly society.

b. Compensation/Incentive

- Participants will *not* be compensated or incentivised in any way.

Participants will be compensated/incentivised* Describe below (e.g., extra credit toward course grade, reimbursement for travel expenses). *Please note that monetary compensation may require collection of name, social security number, and address be reported to UNF controller's office if value of compensation is \$100 or more. Collection of aforementioned information may affect whether and how subjects are identified.

6. Data and Safety Monitoring**a. Confidentiality/Anonymity**

Data will be anonymous. In the space below, please explain *how* you will ensure that data will be anonymous. If you are collecting data through an online data collection program such as Qualtrics, please note that data may not automatically be collected anonymously so you will need to take steps to ensure identifiers are not associated with

- responses (i.e. select "Anonymize Response" in the Survey Options section of Qualtrics. If you will send the survey via email using Qualtrics, you will also need to use the "Anonymous Link" option under Advanced Options in the Distribute Survey tab in Qualtrics). For more information, please contact a research integrity administrator.

Survey will be anonymized through Qualtrics. Steps will be taken to ensure identifiers are not associated with respondents. The survey link will be located on the NANN member website, which is accessible to NANN and NANNP members only. NANN will not have access to survey responses.

- Data will be confidential. In the space below, please describe the procedures for protecting confidentiality of data collected and stored. Be sure to state whether any limits to confidentiality exist and identify any external agencies (e.g. study sponsor) that will have access to the data.

- Data will be identifiable (i.e., identifiers will be included in publications, presentations, or reports). If additional explanation is needed, please provide below.

b. Data Storage, Security, and Monitoring

Check all that apply. Please see [UNF IRB Guidance on Secure Data Storage](#) for information on best practices in data storage. *Any breach in data safety and all unexpected problems involving risk must be reported to UNF's IRB immediately (within 3 business days or as soon as practicable).

- Data will be stored electronically, on a secure server (UNF I-drive, dedicated secure server space etc.). *The UNF IRB recommends this as the most secure option.*
- Data will be stored in a locked cabinet in a secure UNF office/laboratory.

- Data will be stored on a personal computer.
- Data will be encrypted using [TrueCrypt](#) or another UNF approved encryption mechanism.
- Data will be protected by a [strong password](#)
- Other (describe below). Be sure to identify where data will be stored, who will have access to the data, the security of this location, and how data will be monitored.

Data will be stored electronically within Qualtrics survey tool, a secure server; De-identified aggregate data will be downloaded and stored on personal computer of PI.

c. Safety Monitoring

Describe your plan for monitoring your participants and identifying any adverse effects they may experience during and (if necessary) after data collection.

participants complete survey on personal computer at their leisure; no adverse events are expected, and adverse events will be reported to the UNF IRB within three business days

Appendix E: Survey Objectives

MC Use in the NICU: Current Practice Inquiry

1. Are MCs being used in NICUs across the US? And if so, where and how frequently?
2. Are the MCs being used, truly MCs by definition?
3. What level of nurses are placing MCs?
4. What type of training is required for nursing and NNPs to place MCs?
5. What are individual nurse and NNP success rates for MC and PICC insertions?
6. Do NICUs follow NANN and/or institutional protocols for PICCs and MCs?
7. What are the rates of infection, extravasation, and phlebitis associated with VADs in NICUs?
8. What are the individual and institutional preferences for the use of MCs in NICU patients?
9. Do nurses and NNPs have an understanding of the available literature and recommendations regarding evidence based practice for MC use in the NICU?

Appendix F: National Association of Neonatal Nurses Online Survey

Midline Catheter Use in the Newborn Intensive Care Unit: Current Practice Inquiry

Q1 Dear National Association of Neonatal Nurses (NANN) and National Association of Neonatal Nurse Practitioner (NANNP) Members: My name is Tricia Romesberg. I am a doctoral student conducting a survey for my Doctor of Nursing Practice (DNP) Project at the University of North Florida (UNF) in Jacksonville, Florida. I am requesting your assistance to help me understand midline catheter use in the Newborn Intensive Care Unit (NICU). Your participation is important because survey results could add to the body of knowledge regarding current vascular access device practices for NICU patients. To be included in the sample for the survey, you must be a NANN and/or NANNP member. This survey will take approximately 10 minutes to complete. Qualtrics, the survey software, is designed to insure that all data will be submitted anonymously. I will not have access to your identity at any time. To insure further data security, data submitted will be stored on a locked and secure computer. Your participation is voluntary. While there are no anticipated risks involved in completing and submitting the survey, if you start the survey and then decide not to complete it, you may simply log out of Qualtrics and no data will be submitted or saved. Participation and completion of the survey will acknowledge your consent. Participation is limited to those who are at least 18 years of age. The survey will be available for participation during a one month period between May 2014 and September 2014. Please print a copy of this document for your records. This study has received the approval of Institutional Review Board at the University of North Florida, IRB # 558281, which functions to insure the protection of the rights of human participants. If you have any questions about being a research participant, you may contact the UNF Institutional Review Board at _____ or via email at irb@unf.edu. Approval to post this survey on MyNANN was granted by the NANN Research Institute. You may contact me via email at _____ or by phone at _____. I would like to thank you in advance for your participation in this survey. Respectfully, Tricia Romesberg, MSN, ARNP
 University of North Florida DNP Student Dr. Carol Ledbetter, PhD, APRN-BC, FAAN
 University of North Florida DNP Project Chair _____ By
 clicking the “next” button, you agree to participate in this survey.

Q2 What type of geographic area do you work in?

- rural
- urban
- metropolitan

Q3 If you work in a Newborn Intensive Care Unit, what is the level of acuity?

- Level 1
- Level 2
- Level 3
- Other: _____

Q4 How many total months and years have you worked in the Newborn Intensive Care Unit as a nurse and/or Nurse Practitioner?

- months
- years

Q5 Do you care for infants in a setting other than the Newborn Intensive Care Unit?:

- No
- Yes - please describe: _____

Q6 What is your level of education specific to caring for neonates and infants? Check all that apply:

- registered nurse
- Registered Nurse Certified (RNC) for Neonatal Intensive Care Nursing
- Certified Neonatal Nurse Practitioner
- Other: _____

Q7 Have you been trained to place Peripherally Inserted Central Catheters? If yes, check all that apply:

- At a formal training seminar
- As a procedural requirement for your job
- Informally by another nurse or nurse practitioner
- Self taught or no training
- Other: _____

Q8 Are you required by your unit or institution to complete competencies on a regular basis to place Peripherally Inserted Central Catheters?

- Yes
- No

Answer If Are you required by your unit or institution to complete competencies on a regular basis to place Peripherally Inserted Central Catheters? Yes Is Selected

Q9 If yes, how often are Peripherally Inserted Central Catheter competencies required? Every:

_____ months
 _____ years

Q10 Have you been trained to place Midline Catheters? If yes, check all that apply:

- At a formal training seminar
- As a procedural requirement for you job
- Informally by another nurse or nurse practitioner
- Self taught or no training
- Other: _____

Q11 Are you required by your unit or institution to complete competencies on a regular basis to place Midline Catheters?

- Yes
 No

Answer If Are you required by your unit or institution to complete competencies on a regular basis to place Midline Catheters? Yes Is Selected

Q12 If yes, how often are Midline Catheter competencies required? Every:

_____ months

_____ years

Q13 Please answer yes or no:

| | Yes | No |
|---|-----------------------|-----------------------|
| Does your unit have a vascular access or Peripherally Inserted Central Catheter Team? | <input type="radio"/> | <input type="radio"/> |
| Does your unit adhere to NANN's 2007 Peripherally Inserted Central Catheter Guidelines for Practice? | <input type="radio"/> | <input type="radio"/> |
| Does your unit have a unit-specific Peripherally Inserted Central Catheter Protocol for neonates and infants? | <input type="radio"/> | <input type="radio"/> |
| Does your unit have a unit-specific Midline Catheter Protocol for neonates and infants? | <input type="radio"/> | <input type="radio"/> |

Q14 At your current place of employment, please estimate percentages of the following:

| | Click to write Column 1 | Click to write Column 2 | Click to write Column 3 |
|---|-------------------------|-------------------------|-------------------------|
| Peripheral IVs | Infection | Extravasation | Phlebitis |
| Midline Catheters | | | |
| Peripherally Inserted Central Catheters | | | |

Q15 In your best estimate, how many Peripherally Inserted Central Catheters are placed annually in your unit?

- _____
- How many are placed by you? _____

Q16 In your best estimate, how many Midline Catheters are placed annually in your unit?

- _____
- How many are placed by you? _____

Q17 Please rate your personal success in achieving insertion and proper placement of the following vascular access devices:

| | Peripheral IV | Midline Catheter | Peripherally Inserted Central Catheter |
|-----------------|-----------------------|-----------------------|--|
| Never | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Rarely | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Sometimes | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Often | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| All of the Time | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Q18 Based on your clinical experience with Midline Catheters in the unit you currently work in, it is your opinion that Midline Catheters should be used: _____

Q19 Disagreement about Midline Catheter use among the clinical providers in you unit occurs: _____

Q20 The definition of a Peripherally Inserted Central Catheter is: "a device inserted into a peripheral vein and threaded into the central venous circulation."

- True
- False

Q21 The definition of a Midline Catheter is: "a peripheral vascular access device with the tip terminating in the basilic, cephalic, or brachial vein."

- True
- False

Q22 Midline Catheter use in neonates and infants is supported by high level evidence such as systematic reviews and/or randomized clinical trials.

- True
- False

Q23 Comments on your experiences with Midline Catheter use in neonates and infants?

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Vita

Tricia Lynn Romesberg was born . After completing high school , she attended the University of New Mexico and graduated in 1993 with a Bachelor of Science Degree in Nursing. In 1997 she attended Beth-El College of Nursing in Colorado Springs, Colorado and completed National Certification Corporation requirements for the specialty of Neonatal Nurse Practitioner. She attended the University of New Mexico from 2002-2004 and graduated with a Master of Science degree in Nursing Administration.

Tricia worked as a Neonatal Nurse and then a Neonatal Nurse Practitioner in both of the Level 3 Newborn Intensive Care Units in Albuquerque, New Mexico from 1993-2011. Her nursing career in New Mexico included caring for critically ill infants and their families, and providing emergency newborn transport via ground, helicopter, and fixed wing. She later developed a Neonatal Palliative Care Service and became a nationally recognized expert in the field of grief and end-of-life care for infants. As a result of knowledge dissemination by both formal and informal teaching, manuscript publications, and program development, the Neonatal Palliative Care Service at the University of New Mexico Children's Hospital became recognized across the state as providing the highest level of care for dying infants and their families.

In 2011 Tricia and her family moved to Satellite Beach, Florida where she currently resides. She works at the Florida Hospital for Children in Orlando, Florida where she is involved many clinical projects and committees aimed at providing the highest level of care for infants in the Level 3 Newborn Intensive Care Unit. In the Fall of 2012, she entered the Graduate School at the University of North Florida, Brooks College of Health in Jacksonville, Florida to pursue a Doctor of Nursing Practice (DNP) degree. Following completion of her DNP, Tricia will begin

work at Nemours Children's Hospital in Orlando, Florida. There she plans to incorporate her doctoral education, research experience, and leadership skills into her extensive clinical experience as an ARNP in the NICU.