

WESTERN UNIVERSITY OF HEALTH SCIENCES

Pomona, California

**PERIPHERALLY INSERTED CENTRAL CATHETERS (PICC) AND THE
EFFICACY OF TIP PLACEMENT CONFIRMATION WITH ECG
ULTRASOUND-GUIDED TECHNOLOGY AND CHEST RADIOGRAPHY**

A dissertation submitted to the

College of Graduate Nursing

in partial fulfillment of the requirements for the degree

Doctor of Nursing Practice

Elizabeth Ann Morrell

College of Graduate Nursing

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DEDICATION

You are never too old to set another goal or dream a new dream. ~ C. S. Lewis

This DNP journey is dedicated to my family and to nurses. I am especially grateful to my parents, Donald and Barbara Maiwurm, for instilling the importance of education in my life. They believed that anything was possible at any age if you put your heart into the experience. My mother, Barbara, passed away during this journey but I know she is proud of the person I am today.

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To all the nurses in the world, you are all 'diamonds taking shape'. Keep changing health care through evidence-based nursing practice; we are making a difference one person at a time.

ABSTRACT

PERIPHERALLY INSERTED CENTRAL CATHETERS (PICC) AND THE EFFICACY OF TIP PLACEMENT CONFIRMATION WITH ECG ULTRASOUND-GUIDED TECHNOLOGY AND CHEST RADIOGRAPHY

by Elizabeth Ann Morrell, DNP

AIM: The aim of this study was to appraise the efficacy of peripherally inserted central catheters (PICC) tip placement confirmation using a fully-integrated magnetic tracking system and ECG ultrasound-guided insertion technology performed at the patients' bedside by venous access nurses and validated by the post-insertion chest radiography (CXR) report. Labor costs and time were compared with the interventional radiology (IR) team and the venous access nurses to determine if there was a noteworthy cost difference with PICC insertions.

BACKGROUND: PICCs have gained popularity due to improved ECG ultrasound-guided tip navigation technology. Real-time ECG ultrasound-guided technology is the safest, most accurate method of PICC insertion.

METHODS: A retrospective chart review of 125 adults between 18 to 90 years of age who met the indications for a PICC that were inserted at the bedside by competent venous access nurses. Post insertion CXR were compared for accurate tip placement.

RESULTS: A sample of 125 patients had bedside PICCs inserted by qualified venous access nurses from July 2016 to June 2017 in one southern California acute care hospital. Study findings revealed 97.6% of PICCs was properly placed as validated by post CXR. Demographics included age (Mean = 62 years, Range 25-86) and gender (70.4% male,

29.6% female). No complications occurred during PICC insertions. A separate cost comparison of average labor costs during PICC insertions was measured among bedside venous access nurses and interventional radiology. Labor costs for venous access nurses performing PICC insertions were \$67.47 (75 minutes) versus \$81.17 (110 minutes) in interventional radiology, a cost savings of \$13.70 per PICC insertion.

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CHAPTER I

INTRODUCTION

Annually, 2.5 million peripherally inserted central catheter (PICC) procedures are performed in acute care facilities and infusion centers in the United States (iData Research, 2016). Dependable venous access is the standard of care for safe and effective patient outcomes. Advances in technology have improved the insertion of venous access devices in the health care environment (Gorski et al., 2016). A PICC is an indwelling central catheter inserted through veins in the upper extremity of the arm. The catheter tip is placed in the superior or inferior vena cava, preferably at the cavoatrial junction (CAJ) just superior to the right atrium (Gorski et al., 2016). PICCs, a type of central venous access device, have gained popularity due to the ease of use at the patients' bedside, and advanced ultrasound tip navigation software to visualize proper PICC tip placement (Moureau, 2012).

Central Lines and PICCs

Central lines, like a PICC, can be an access point for germs to enter the body causing deadly blood infections; therefore, they need to be inserted correctly and kept clean. The implementation of appropriate PICC insertion techniques and utilizing evidence based practice guidelines for PICC maintenance can help reduce the risk of central line-associated blood stream infections [CLABSI] (The Joint Commission, 2012). Bloodstream infections are associated with significant morbidity and increased mortality resulting in billions of dollars in added health care costs (O'Grady et al., 2011). According to National Healthcare Safety Network, public use data from 2009-2013, CLABSIs decreased 46.0% in the United States, however an estimated 30,100 CLABSI

still occur in intensive care units and acute care hospitals (Centers for Disease Control and Prevention, 2016; Dudeck et al., 2015; Stevens et al., 2014). Public use data were compared in graduate medical teaching hospitals within the United States, bed size of 201-500, with the number of CLABSIs on the medical surgical inpatient floors from 2009-2013. There is an upward trend in CLABSIs in the medical and surgical areas (Figure 1).

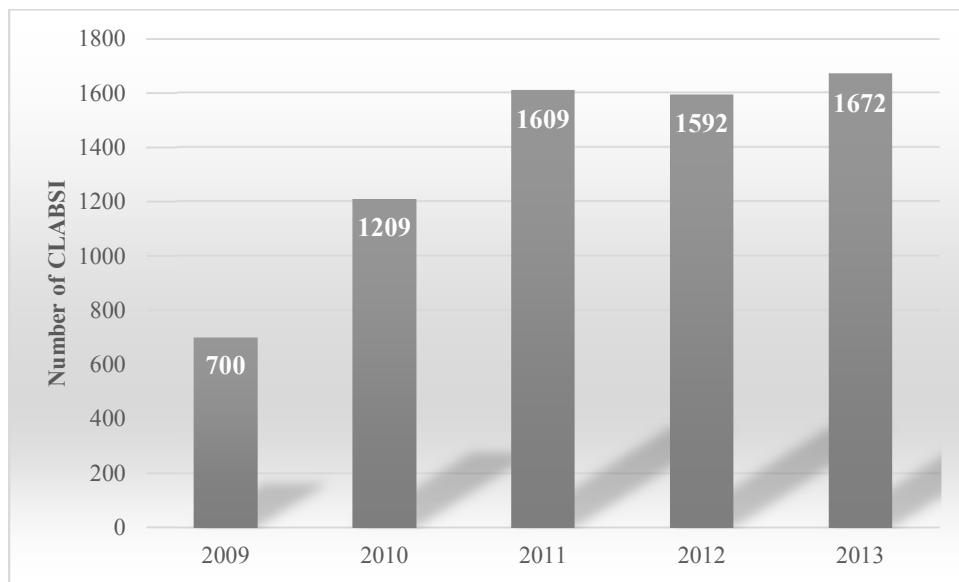


Figure 1. National central line-associated blood stream infections (CLABSI) Medical-Surgical Area – 2009-2013. Adapted from “National Healthcare Safety Network (NHSN) report, data summary for 2013, device-assisted module,” by M. A. Dudeck et al., 2015, American Journal of Infection Control, 43.

The Institute of Medicine (2001) identified six aims to improve health care in the United States. These aims focused on safe, effective, patient-centered, timely, efficient, and equitable care. The Institute of Healthcare Improvement (IHI) Triple Aim goals were to improvement in the patient experience for individuals and in the community, lower cost of care and improve patient safety (Institute for Healthcare Improvement, 2017).

Healthcare leaders need to change the delivery of care through the guiding principles identified by the IHI.

Specialized nurses, physicians, and physician assistants insert PICCs in the patients' upper arm for dependable venous access. PICCs are indicated for the administration of fluids, blood, medications, and frequent blood draws. The PICC tip is placed in the superior vena cava of the heart and risks during insertion can lead to complications, such as occlusions, malpositioning, thrombophlebitis, and blood infections (Pikwer, Akeson & Lindgren, 2012; Song & Li, 2013; The Joint Commission, 2012). PICCs are central catheters and, when inserted properly and maintained correctly, PICCs are safe and effective.

Technological advances of intracavitary electrocardiography (ECG) and ultrasound-guided tip placement devices are rapidly changing the health care landscape. Integrated imaging attached to mobile ultrasound systems provides immediate confirmation of catheter placement or malposition (Lelkes, Kumar, Shukla, Contractor, & Rutan, 2013; Oliver & Jones, 2013). The benefits of advanced PICC-tip placement include improved turn-around time to medication administration, reduced radiation exposure to the patient, and cost savings. Correct PICC tip position requires verification in order to begin infusion therapy and to prevent risks and delays in medication administration resulting from the need to reposition the catheter (Pittiruti, La Greca, & Scoppettuolo, 2011). The Infusion Nurses Society's (INS's) standard of practice for central vascular access device (CVAD) tip location with the greatest safety profile in adults is the CAJ and the distal superior vena cava (SVC), above the right atrium (Gorski et al., 2016).

An electrocardiogram is electrical activity of the heart generated by each depolarization during a heartbeat (Entman, Jacob, & Oliver, 2014). Ultrasound-guided technology uses high-frequency sound waves to view images, guide a needle inside the body, and used daily for image-guided therapies (Stoll, 2014). The ECG and ultrasound-guided technology assist clinicians during PICC insertions. The INS practice criteria (Gorski et al., 2016) recommended that the safest, most cost effective and accurate method of CVAD insertion placement was real-time ECG ultrasound-guided technology.

If the ECG is absent of the P wave, a post procedure chest radiography (CXR) is needed to determine appropriate tip catheter placement and is considered an acceptable method. Chest radiography should be used in the absence of ECG ultrasound-guided visualization (Gorski et al., 2016). The accuracy rate of PICC insertions with ECG ultrasound-guided technology is greater than 90% (Pittiruti et al., 2011). The ECG ultrasound-guided tip technology is a clinically safe and accurate device for PICC insertions (Liu et al., 2015).

Purpose

The purpose of this study was to evaluate the efficacy of PICC tip placement confirmation using a fully-integrated magnetic tracking system and ECG ultrasound-guided insertion technology performed at the patients' bedside by venous access nurses and validated by the post-insertion CXR report.

Problem Statement

The use of advanced ECG ultrasound-guided technology insertion for bedside PICC placement is increasing in hospitalized adults throughout the United States and internationally (Eriksson & Dörenberg, 2013; Zhao et al., 2016). There was a need to

analyze bedside PICC-tip-placement practices at one acute care facility in Southern California. The health care system has fully-integrated magnetic tracking with ECG ultrasound-guided insertion technology at all of the inpatient hospitals. The patient who receives a PICC ECG ultrasound-guided technology also receives a post insertion CXR to confirm proper placement. This study assessed whether the technology could confirm proper PICC placement as validated by the post procedure CXR and separately examined the average costs associated with PICC insertion in the interventional radiology (IR) department and bedside PICCs inserted by the venous access nurses using ECG ultrasound-guided technology. Data tracking from fiscal year 2014-2017 analyzed the trends in the number of inpatient PICC insertions by the venous access nurses compared to the IR department.

This study was a retrospective analysis of 125 adult patients who had a bedside PICC inserted utilizing the integrated Sherlock 3CG® TCS ultrasound-guided equipment. The study took place at one acute care hospital in Southern California. Data collection included a review of the medical record, the PICC insertion documentation record, and the post insertion CXR impression report.

Practice Question

In the adult hospital setting, is advanced ECG ultrasound-guided PICC tip location technology effective as validated by the post procedure chest radiography report?

Aim

The aim of the retrospective study was to appraise the practice of PICC insertion placement utilizing ECG ultrasound-guided technology to enhance clinical outcomes and improve quality patient care. This study took place at one acute care hospital in Southern

California. The sample population was 125 inpatients that had PICCs inserted at the bedside by a qualified venous access nurse from July 2016 to June 2017 and the tip location was compared with the post insertion CXR impression report. Results of the study will be shared with the hospital quality team, site physician leadership committee, and the health care system division of radiology. Following the initial presentation, the findings will be shared with the other four hospitals in the system; which may potentially be a significant cost savings for the system and the patient.

The following specific aims were addressed in this study.

Aim 1: Process change. Increase the number of inpatient PICC insertions by the venous access nurses.

Measure 1: Compare the number of PICCs inserted in IR and the number of PICCs inserted at bedside by venous access nurses (FY 2014-2017).

Aim 2: PICC Outcome. Confirm proper PICC tip location by venous access nurses to the post insertion chest radiography report.

Measure 2: Examine the accuracy of PICC ECG ultrasound-guided tip location using the post procedure chest radiography and matching of ECG ultrasound to chest radiography positions.

Aim 3: PICC Cost Analysis. Examine the costs associated with PICC insertion (a) in IR and (b) venous access nurses using ECG ultrasound-guided technology.

Measure 3: Compare the average cost of the number of PICCs inserted in IR and the cost of PICCs inserted at the bedside by the venous access nurses; determine if there is a significant cost difference.

CHAPTER II

THEORETICAL PERSPECTIVES

The theoretical framework selected for the project was Kurt Lewin's Three-Step Change Theory (1951). Lewin's change theory or theory of planned change has been used in many health care research studies and the theory remains relevant to the modern world (Burnes, 2004; Burnes & Cooke, 2013). Lewin's change theory is simplistic and best utilized with planned change. This framework worked well in the pre-work project to identify a new and innovative way of providing PICC insertions at the patients' bedside.

Motivation for change must be created in order for change to occur. The identification of forces and the ability to understand why groups or individuals act in certain ways will either strengthen or lessen the forces needed for change to occur (Burnes, 2004; Shirey, 2013).

Lewin's Change Theory

Complex adaptive systems require organizations to maintain balance and stability in order to survive in an ever-changing environment. The health care industry must change quickly; however, change varies depending on the impact of that change and the individuals involved. Lewin (1951) created a three-step change model: unfreeze, movement, and refreeze (as depicted in Figure 2), promoting change and managing progress toward the goal. Lewin perceived that human behaviors triggered the driving (i.e., helping forces) or restraining (i.e., hindering forces) movement towards a goal. The driving forces were aimed at the status quo and pushing the positive forces for change to cause that change to occur.

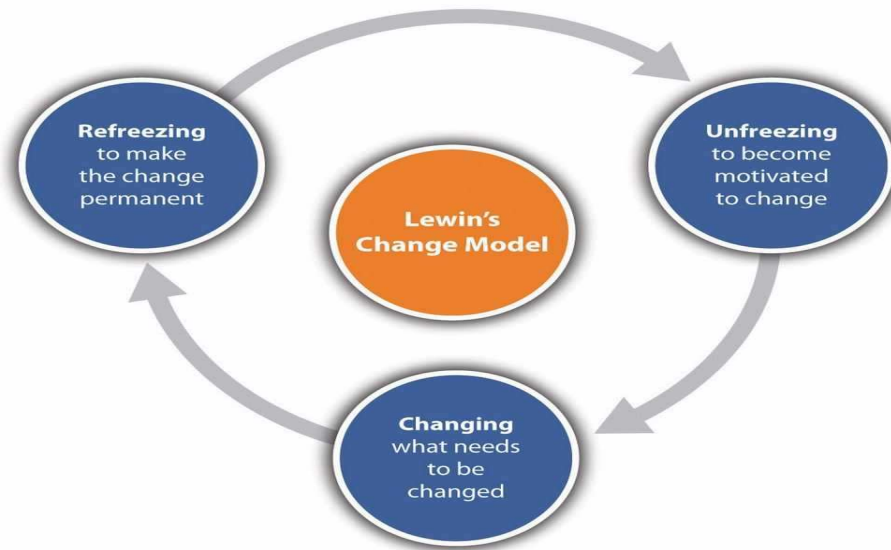


Figure 2. Lewin's change model. Adapted from "2.2 Goal setting" in L. Portolese *Human relations*, v. 1.0, 2015. Copyright 2015 by Flat World Knowledge. Used with permission (Appendix H).

The first stage, unfreezing, is a process of changing behaviors from existing situations. Unfreezing involves evaluating the forces and motivating individuals or groups to change. Preparing organizations to change successfully requires challenging groups or individuals their beliefs and attitudes about what must change. The unfreezing stage is the most difficult and stressful stage. There must be strong support from senior leadership with a clear message about the reason for change. Multiple stakeholders are part of this phase and leaders play a key role in creating a sense of urgency, including an openness to listen to individuals' concerns and address them relative to the change (MindTools, 2017a).

Movement, the second level of change, is where change is initiated, and individuals develop a perspective of the change. Clear communication should occur often during the planning and implementation phases. Also, sharing with the staff the benefits of the change, how change will affect the group, answering questions openly and

honestly, and empowering and engaging people in the change process. Short-term wins are then celebrated involving key informal leaders.

Refreezing is the third and final stage of the change theory. The refreezing stage is a critical time for constant attention to involve clinical nurses and leadership. The initiative starts from a top-down, stable environment and provides ample time to produce change (Manchester et al., 2014; Shirey, 2013), anchoring change into the culture and ensuring leadership support. The refreezing process also includes identifying feedback systems, providing ongoing support for people, reassessing training sessions and gaps in the new change, as well as celebrating successes. The new change must be part of the individual's daily routine. Change becomes the standard and the forces are back in alignment. The new process must be sustainable, measurable, and hardwired, otherwise individuals will revert to the old process (Stichler, 2011).

Lewin's Planned Change Applied to the PICC Project

Lewin's change model was applied to the PICC project to implement change from IR staff inserting PICCs in IR to the venous access nurses inserting PICCs at the patient's bedside. The dimensions were carefully assessed with a clear plan to unfreeze the system, provide movement, and then refreeze to a normative state. Tools used during the change project included: Strengths, Weaknesses, Opportunities, Threats (SWOT) analysis, timeline, process mapping, and an inter-professional collaborator tool.

Unfreezing

The announcement of advanced bedside PICC technology was shared with the director and the manager of the radiology department in 2015. Prior to 2015, the IR nurses and radiology technicians performed PICC insertions using ultrasound-guided

technology in the radiology department via fluoroscopy. A post insertion CXR was performed for tip location confirmation. At the time, the venous access nurses were intravenous (IV) nurses, supporting the inpatient units for all peripheral IV catheters insertions and dressing changes.

There was a need to provide an open discussion and to share creative ideas for the PICC change. The change was endorsed and approved by the site chief nurse executive and the system-wide radiology care line co-management division. The nursing director accountable for the IV nurses performed a SWOT analysis of the current workload and developed the transition plan from the IR team inserting PICCs in the IR department to the venous access nurses inserting bedside PICCs with advanced technology. The radiology nurses and venous access nurses had the opportunity to share their views and input about the vision of bedside PICC insertions. Each nurse presented concerns and ideas for the planned change to nursing leadership. A system wide IV Therapy algorithm was created and communicated to all health care providers on indications of use with each type of access line.

SWOT analysis. A SWOT analysis provided structured planning to analyze a group or project. The assessment identified the SWOT. The results of the SWOT analysis (Appendix B) were shared with the venous access nurses and IR team; it provided a framework for evaluation and included the challenges and opportunities towards the completion goal (MindTools, 2017b).

The SWOT analysis clearly outlined the benefits of the new roles, expectations of the venous access nurse, and the reason to expand new procedures for the IR teams. The nursing title changed from *IV nurse* to *venous access nurse*. The initial expectations of

the IV nurse were (a) to insert peripheral intravenous catheters, (b) assess peripheral lines viability, and (c) change all central lines dressings. Peripheral intravenous line insertions and dressing changes transitioned to the bedside nurse. The IV nurses transitioned to the new role as a venous access nurse and the expectations were to (a) insert bedside PICCs using ECG ultrasound-guided technology and (b) be an expert in access management. After the SWOT analysis was finalized, the next step was the establishment of a PICC transition timeline by the group members.

PICC transition timeline. A timeline provides a visual, easy-to-use tool to display events in chronological order. Individuals or groups were assigned to specific duties and tasks. Completion dates were established for each task. The two teams, the IR staff and venous access nurses, reviewed the PICC transition timeline weekly and tracked progress. The team clearly understood the transition steps and stayed within their scope of responsibility to achieve the goals outlined in the transition timeline (Appendix C).

During the unfreeze stage a communication plan for managers and clinical staff was created and shared with nursing leadership and support services. The communication guide was disseminated weekly throughout the hospital and key individuals were notified of venous access issues or concerns. Daily rounding by nursing leadership provided staff support for those involved in the change, including an open dialogue that provided clear ongoing communication.

Movement

The movement stage was initiated with a PICC transition timeline and communication plan along with venous access education, didactic, and hands-on PICC insertion training. By 2015, the hospital had a venous access nurse-led team comprised

of four full-time nurses. The nurses were trained with the Bard Site-Rite® 8 ultrasound system. Patients with a confirmed P wave on ECG were candidates for the integrated Sherlock 3CG® Tip Confirmation System. The system had a magnetic device that tracked the PICC-tip movement during insertion. ECG software technology confirmed the location in the superior vena cava or above the right atrium in the heart. Once the appropriate placement was confirmed, a printed copy of the tip location with the ECG tracing was placed in the patients' chart. A post insertion CXR was performed for tip location confirmation.

Prior to the venous access nurses performing PICC insertions, the nurses completed (a) a 3-hour online PICC course (Bard Access Systems, 2017), (b) one full 8-hour day of PICC didactic training with the new device, and (c) 6 hours of hands-on training with the company's clinical nurse specialist (CNS). The Bard CNS observed the venous access nurses insert five bedside PICCs with the Site-Rite® 8 ultrasound system and integrated Sherlock 3CG® Diamond TCS software. Prior to independently inserting bedside PICCs, each venous access nurse was critiqued by the CNS on PICC technical competency and clinical proficiency using the PICC competency checklist and clinical observation tool. By February 2015 and after 3 months of PICC training and insertion, each venous access nurse was competent to place bedside PICCs.

The PICC insertion note was used as the documentation record for all PICC insertions. During the movement and refreezing stages, monthly volume reports tracked the type of venous device inserted and the progression of technical competency by each venous access nurse. The monthly numbers of PICC insertions were shared with specific site-physician groups and the senior leadership team.

The venous access nurses had full back-up support from the IR team in case the nurses were backlogged with PICC insertions. The medical-surgical nurses were encouraged to assist the venous access nurses by making every effort to have the physician complete the preformatted physician order prior to the venous access nurse's arrival to the patient's bedside.

The new role of the venous access nurses expanded to (a) inserting bedside PICCs with advanced ECG ultrasound-guided technology, (b) inserting all inpatient midlines, and (c) becoming experts in assessing appropriate line access. The venous access nurses used the system wide IV Therapy algorithm for all line placements. A process map was created during the movement stage for the venous access nurse and the IR team (Appendix D).

Process Mapping. A process map aided the staff with redesigning the various workflows (Agency for Healthcare Research and Quality, 2013); a tool for time-and-motion study measurement for observers to understand the process. The current state outlined the standard work or steps of a process. Seven identified steps when the venous access nurses inserted at the bedside. Nine steps were identified when the IR team placed a PICC in the IR department. These two processes were needed as PICCs may be placed in either location. Patients who did not have a P wave on the ECG continued to have PICCs inserted in the IR department. Average times could be assigned to the steps for noncomplicated patients to understand cost comparisons for PICC insertions.

Prior to the end of the 6-month movement stage, the senior director made a baseline assessment of collaboration. The Interprofessional Collaborator Assessment Rubric (ICAR) tool measured the growth of the venous access nurses.

Interprofessional Collaborator Assessment Rubric. Individual accountability and assessing competencies as health care providers expand interprofessional collaboration. The utilization of valid tools such as the ICAR tool (Curran, et al., 2011) helped to address areas of opportunities for venous access nurses to reflect progress. Baseline ICAR assessment was completed in October 2015 with the venous access nurses and an ICAR reassessment was completed in August 2017. The dimensions assessed included collaboration, roles and responsibility, collaborative patient-/client-centered approach, communication, team functioning, and conflict management/resolution. The ICAR reassessment results increased from *developing* (Rating 2) to both *competent* (Rating 3) and *mastery* (Rating 4) in all six dimensions. The reassessment results provided affirmation to the group and to leadership that all venous access nurses had expanded their knowledge of their new role; the desired behavior was elevated in all six dimensions.

Refreezing

The refreezing stage incorporated the need to track monthly PICC and midlines insertions, including the location (department) and the inserter (nurse, physician, or physician assistant). Monthly data were shared with the executive team, the radiology department, and the venous access nurses. The volume in 2015 was 702 PICC insertions.

During the refreezing stage, a new peripheral venous device (i.e., midline) was released. Midline catheters, around 8 in. long and the distal tip dwelling in the basilica, cephalic, or brachial vein outside the heart, were introduced in October 2015 and the venous access nurses were trained on insertion of the midline catheter. The nurses

followed appropriate indication criteria, resulting in a decrease to 470 PICC insertions (33.0% decrease) and an increase in midline catheters insertions in 2016.

The PICC and midline process change was completed in 2016 and the venous access nurses recommended the appropriate line placement to clinicians using the system wide IV therapy tool, a patient assessment, and the patient's clinical condition. The venous access nurses gained more confidence in their role with line selection, built trust with physicians, and increased their collaboration among all clinicians caring for the PICC patient population. The IR staff and the venous access nurses gained trust and self-assurance between each other, becoming a stronger and more professional collective team.

The detailed PICC transition timeline and steps for the planned changes were successfully implemented. Identified interventions and progress were tracked through supporting data and, in turn, provided a positive change in individual behaviors.

Conclusion

The value of proposing a theory-based intervention for change provided a foundation for planned strategies and addressed barriers upfront for successful implementation. Lewin's change theory in health care was used to evaluate the outcomes of the planned change. The tools used for this project included a SWOT analysis (structure), PICC transition timeline (structure), communication plan (structure), ICAR (outcome), and process mapping (structure). Quality metrics were measured monthly (outcome). The planned change needed to be stable and sustainable in order to ask the practice question for this study. The benefits of the PICC change project positively impacted the venous access nurses and the IR team, created competent bedside PICC

insertion nurses, and provided a clear standard practice for PICC insertions. The various assessment tools incorporated into the planned change served as a reminder that planned change could be successful. If a project revealed an improvement in patient outcomes, then the clinical staff and physicians might be more apt to support the change.

CHAPTER III

REVIEW OF THE LITERATURE

The concept of proper PICC catheter-tip placement has been well established in the research. A structured review of the literature was conducted to analyze the evidence and appraise the practice of PICC-insertion placement with ECG ultrasound-guided technology. This chapter discusses the process and shares the findings about the evidence.

A structured review of the literature was undertaken searching CINAHL, Ovid Medline, PubMed, Pumerantz Library Discovery Service, and ScienceDirect. Studies were limited to full text articles published in English between 2006 and 2017. Search terms included central lines, central venous catheters, chest radiography (CXR), PICC, bedside PICC, and tip location.

The search yielded 42 articles that were reviewed and analyzed. Studies related to children and neonates with PICCs and any PICC outside of the hospital setting were eliminated, thus resulting in 34 articles. All 34 articles were applicable to the study and all were selected for review. Themes related to PICCs included evidence-based practice tools and guidelines for PICC practice throughout the nation, research studies of PICC technology, PICC ultrasound-guided imaging, catheter tip location, PICC tip placement technology, PICC insertion malpositions, PICC post-insertion outcomes, PICC training, and PICC cost analysis with bedside insertions. A separate PICC cost analysis literature review was completed and is discussed in the results section; therefore, those articles are not included in the level of evidence analysis.

Table 1

Literature Search Methodology

Database	Keywords	Results
CINAHL	Chest radiography, PICC technology, ultrasound-guided imaging, central venous catheters, PICC placement, PICC training, PICC malpositions	15
Ovid MEDLINE	PICC tip placement technology	7
PubMed	Catheter tip placement, central lines, malpositions, PICC insertion outcomes, PICC costs	5
Pumerantz Library		
Discovery Science	PICC insertion malpositions	3
ScienceDirect	PICC costs	4

The Johns Hopkins Nursing Evidence Rating Scales tool (Dang & Dearholt, 2017; Appendix I) was used to appraise the strength of the 34 studies. The strength of the evidence was rated from the highest (Level I) to the lowest (Level V). The quality of the evidence was rated of high, good, or low quality. The tool was completed on all 34 articles. The results of the evidence level and the quality of the evidence in Table 2 depicted an equal distribution of studies in Levels II, III and IV. Only one study was appraised as a Level IA. Eight articles were appraised as Level II. Seven studies were appraised as Level III and Level V. Eleven studies were appraised as Level IV. Most of the studies had a quality of the evidence rating of high or good and a majority of the PICC practice studies were published within the past 5 to 7 years.

Table 2

Articles for Literature Review: Evidence Level and Quality

Level	Quality	Total
I	A	1
II	A	2
	B	6
III	A	1
	B	6
IV	A	7
	B	4
V	A	1
	B	6

Evolving Evidence Based PICC Practices

By 2020, the Institute of Medicine Roundtable on Evidence-based Medicine's (2009) goal is to identify clinical decisions that are accurate, on time, safe, and cost effective 90% of the time. Melnyk and Fineout-Overholt (2011) and the Institute for Johns Hopkins Nursing (2015), acknowledged the importance of improving the nation's well being, and health care providers need to use the highest level of evidence to promote appropriate care and continue to expand evidence-based research.

Michigan Appropriateness Guide for Intravenous Catheters (MAGIC) is a guide that recommends types of appropriate vascular access devices based on patient condition (Chopra et al., 2015). Tested on a variety of patient populations and evidence-based

practice, the MAGIC assessment tool guides clinicians through appropriate indications for PICC insertion.

Swaminathan, Calleja, and Bercea (2016) utilized a standard PICC assessment tool using the MAGIC criteria to evaluate the appropriateness of a PICC prior to placement. In their study, significantly fewer PICCs were inserted after implementation of the PICC tool ($N_{\text{Pre}} = 348$ vs. $N_{\text{Post}} 281$, $p < 0.01$), suggesting that the MAGIC criteria could reduce the risk of PICC complications by suggesting more appropriate venous access methods. Of the PICC requests in the study, 40.0% were re-directed to other vascular devices because of the screening tool, as compared to 24.0% prior to implementation.

The INS released the *Infusion Nursing Standards of Practice* guidelines and addressed best practice for PICC insertion and maintenance in the field of infusion practice (Gorski et al., 2016). The INS Standards of Practice Committee created a rating scale for the strength of evidence for clinicians as a guide when implementing standards of practice. Ratings range from I to V. The highest rating (I) signified a meta-analysis or systematic literature review. Level II represented well-designed randomized controlled trials at two or more multicenters. A Level III rating indicated one well-designed randomized controlled trials or several well-designed clinical trials without randomization. The rating of Level IV represented a well-designed quasi-experimental study, case-control study, cohort study, correlational study, time series study, or a literature review of descriptive and qualitative studies. The lowest level, Level V, indicated a clinical article or case report (Gorski et al., 2016).

The American Board of Internal Medicine Foundation's *Choose Wisely*® initiative identified health care waste. This *Choose Wisely*® initiative recommended PICCs should not be placed solely for patient- or provider convenience and PICCs should be removed promptly when they are no longer indicated to decrease the risk of complications and infections (Choosingwisely.org, 2017). The *Making Health Care Safer I & II* report (Chopra et al., 2015; O'Grady et al., 2011), supported by the Healthcare Infection Control Advisory committee for the Centers for Disease Control and Prevention, identified levels of recommendation for proper placement of central lines in specific patient populations.

Ultrasound-Guided Imaging

According to Gorski et al. (2016), ultrasound-guided imaging is a safe and effective method of choice for all types of vascular cannulation in adults. Lamperti et al. (2012) acknowledged that ultrasound-guided imaging for vascular access has existed for more than 30 years. Recent advanced technology has improved vessel imaging, decreased complications, and increased success rates during vascular cannulation. The international multidisciplinary systematic approach of ultrasound-guided practice was developed in 2012, using validated scientific methodology to review the literature to further influence the clinical practice of guided, vascular imaging access. Ultrasound-guided cannulation experts in the field employ two methods of evaluation and provide evidence-based recommendations for vascular access ultrasound. One method entails a systematic literature search by multiple panel experts with the assistance of a professional librarian and based on the medical subject heading of ultrasound. The second method uses a systematic search of English-only articles from 1985-2010 by an epidemiologist

and the assistance of the librarian. The GRADE method was used to score the literature and classify the levels of evidence. A total of 229 articles were appraised with the methodological criteria, assigned levels of evidence, and grades recommended. The results were nine proposed definitions and 50 recommendations. Of the 59 proposals, only 47 recommendations achieved approval as final recommendations. The recommendations were then grouped by (a) technology and ultrasound cannulation technique; (b) ultrasound vascular access in adults and cost-effectiveness; and (c) education, training, and accreditation in vascular access ultrasound. The use of ultrasound guided central venous cannulation and standardization of terminology revealed *strong* evidence for safe and effective methods of choice for all types of vascular cannulation (Lamperti et al., 2012)

A recent study in the United Kingdom (UK) by the National Institute for Health and Care Excellence (NICE; 2015) reported nine of 16 facilities that used the Sherlock 3CG® TCS were no longer using CXR to confirm PICC tip location. Staff time and accuracy of the device were the key drivers for the change in practice. The improved vessel imaging technology resulted in decreased complications and improved success rates during vascular cannulation (Dale, Higgins, & Carolan-Rees, 2016).

Catheter Tip Location

The NICE (2015) Medical Technologies Guidance Program provides technical recommendations based on evidence and expert review for patients and for the U.K. National Health Service based on the current methods of management. Evidence supported the use of the Sherlock 3CG® TCS for placement of PICCs and suggested that the technology should be considered as an option for placement of PICCs in adults,

usually avoiding the need for a post-insertion CXR. Evidence supported the electrocardiogram method as a valid alternative to radiological verification of central venous catheter tip placement (Moureau, Dennis, Ames, & Severe, 2010; Pitturuti et al., 2011; Walker, Chan, Alexandrou, Webster, & Rickard, 2015). The INS guidelines (Gorski et al., 2016) endorsed the American standard for proper PICC tip placement in adults as the lower third or distal third of the superior vena cava (SVC) or cavo-atria junction (CAJ).

Hsu et al. (2006) analyzed 20 oncology adults with central venous catheters and verified tip positions of the SVC/RA junction with transesophageal echocardiography and radiologic landmark with thoracic vertebral levels. There was a significant difference between the carina to the radiographic SVC/RA junction and the carina to the echocardiographic SVC/RA junction. The vertebral body that correlated with the echocardiographic SVC/RA junction fluctuated from the sixth to the ninth level. Both radiographic SVC/RA junction and the thoracic vertebral bodies were not reliable landmarks for confirming proper venous catheter position.

IR quality improvement guidelines for central venous access have recommended the tip should be in the cavoatrial region or right atrium (Dariushnia, et al, 2010). According to Oliver and Jones (2014), CXR after a PICC insertion was not the recommended approach. Advanced technology, such as the Sherlock 3CG® TCS with ultrasound-guided technology, was considered the most reliable method for proper bedside PICC tip placement. Cotogni and Pittiruti's (2014) study supported this evidence and recommended accurate tip placement at the lower third of the SVC at the junction of the right atrium to minimize potential complications of PICC positioning.

PICC Tip Placement Technology

Health information technology has evolved over the past ten years and dramatically improved tip placement. Study results revealed greater efficiency, enhanced coordination, and improved patient care (Lavin, Harper, & Barr, 2015). The advancement of PICC tip location devices, such as the Sherlock 3CG® TCS technology resulted in an increase in accurate PICC tip placement insertions (Dale et al., 2011).

Hostetter, Nakasawa, Tompkins, and Hill (2010) conducted a systematic literature review spanning 1993-2009 of successful first time attempts of central venous catheter tip placement without the use of advanced tip placement technology. Nine studies were reviewed. Seven of the studies were prospective randomized single center studies and two were retrospective studies. Of the nine studies analyzed, the average proficiency rate for successful placement on the first attempt was 45.87% (range 39.0%-75.0%). Ultrasound and electromagnetic technology was recommended as the best practice to confirm tip location. The advanced technology can lead to the decrease in cost of supplies and time, a reduction in complications, and an increase in the degree of confidence of inserters to hit the targeted location on first attempt (Hostetter, Nakasawa, Tompkins, & Hill 2010).

A quantitative prospective nonrandomized study by Girgenti and Donnellan (2014) investigated the efficacy of dual vector technology utilizing a logical tip location algorithm with ECG and doppler scanning ($n = 25$). The target PICC tip location in the heart was the lower one-third of the superior vena cava. All 25 subjects had 100.0% correlation when compared to the post insertion CXR. The sample size was small,

however results confirmed dual vector technology with tip location algorithm software was cost effective and may result in the elimination of the post insertion CXR.

A retrospective study by Lelkes et al. (2013) researched the efficacy of the Sherlock® II tip location system and appropriate tip location. The optimal tip position in the heart was the SVC and right atrial junction (RAJ). The Sherlock® II tip location system was compared with a post-insertion CXR. Three hundred seventy five of 384 (97.65%) subjects had appropriate tip positions with the Sherlock II technology when compared to the post-insertion CXR.

Walker et al. (2015) conducted a systematic literature review on the effectiveness of electrocardiogram guided catheter tip positions during central venous access device insertions. Five prospective randomized control trials included 729 patients who had successful tip placement within the lower third of the subclavian vena cava. The results confirmed electrocardiogram guided insertion was more accurate than surface anatomy guided insertion (OR = 8.3; 95% CI 1.38, 50.07; $p = 0.02$). The electrocardiogram method was eight times more effective and every sixth patient on whom this method was used resulted in one more correct tip position.

Tomaszewski et al. (2016) performed a cross-sectional observational time and motion study at four U.S. hospitals. Two hospitals used the Sherlock 3CG® TCS real-time imaging to confirm PICC tip placement and the other two hospitals used only post-insertion CXR. In the group with real-time imaging, the release for intravenous therapy occurred in a mean time of 33.93 minutes with no malpositions noted. In the post-procedure CXR group, release for intravenous therapy was greater, with a mean time of 176.32 minutes with 20% malposition.

Malposition

Misplaced or malpositioned PICCs are a risk during insertion and can lead to repeat CXRs and procedures, delays in initiating treatment, and an increase in cost of labor and supplies (Pikwer et al., 2012). Johnston, Holder, Bishop, See, and Streater (2014) reported a case-series on the effect of malposition rates of PICCs using the Sherlock 3CG® Tip TCS in a U.K. National Health Service hospital. A previous study by the authors revealed the blind anthropometric technique for insertion with a confirmation post-insertion CXR resulted in 42.0% to 76.0% malposition rates in critically ill patients. A retrospective study compared malposition rates of adult ICU patients who had a PICC utilizing the Sherlock 3CG® TCS technology. In the study, the vascular access nurses inserted the PICCs with the device, and then confirmed the tip position with a portable CXR. Two authors independently reviewed the CXR. A total of 250 charts were reviewed where PICCs were inserted with the advanced technology. Of those charts, 11 were excluded for failed insertions ($n = 2$), no CXR post insertion ($n = 2$), unable to view tip position on CXR ($n = 2$), failure to interpret ECG criteria ($n = 4$), and catheter being too short ($n = 1$). The tip location was confirmed in 239 PICCs using Sherlock 3CG® TCS technology. Following the North American guidelines for adequate position, low SVC or CAJ, 134 catheters required repositioning (56.1%; 95% CI = 50.0% - 62.0%). According to the European guidelines, which defined adequate position as moderate-to-low SVC, CAJ, or high right atrium (≤ 2 cm from CAJ), 49 catheters need repositioning (20.5%; CI 16% - 26%). The malposition rate (21.0%) with the Sherlock 3CG® (21.0%) was consistent with other data reported.

Naylor (2007) conducted a single hospital facility evaluation over a 6-month trial evaluation of malpositions during PICC insertions. For 3-months, February through April 2006, the PICC team inserted 321 lines with a 13.4% malposition rate. Sherlock 3CG® TCS technology, used between September through November 2006, resulted in 317 catheters placed for a malposition rate of 2.50%. This evaluation revealed that the device enhanced the PICC teams' practice and improved the efficiency with a reduction in malpositions.

Song and Li (2013) studied the causes of misplaced PICCs in cancer patients. A total of 3,012 PICCs were placed and tips were tracked by CXR. Of those, 237 observed were repositioned (7.87%). The most common misplaced position was in the jugular vein ($n = 22$), then the axillary vein ($n = 20$). All were repositioned to the correct location prior to use. The authors recognized the need for established PICC protocols, strict placement guidelines, patient cooperation, and utilizing skilled health care professionals for insertions.

Tizard and Welters (2012) analyzed a retrospective review of central venous catheters placed in the internal jugular or subclavian route in intensive care patients ($n = 101$) with 137 new central venous catheters inserted; all were evaluated to confirm tip location. Twenty-five percent (34/137) of the catheter tips were placed 10 mm or greater below the carina; a potential risk of intracardiac placement. Thirty-eight percent (14/37) were left-sided catheters and did not cross the midline; 59.9% (22/37) were at an angle greater than 30 degrees to the vertical position with no immediate complications during insertion. The researchers noted wide variations of catheter tip placement locations with

no repositioning of the catheter and recommended the need of a clearer strategy for proper placement.

Bidgood (2016) tracked 88 PICC insertions using the Sherlock 3CG® TCS technology and observed 28 (32.0%) PICCs migrated into the incorrect position during the insertion procedure. Nonetheless, during the insertion all 28 were corrected successfully and placed in the acceptable position. All 88 (100.0%) confirmed the tips were in an acceptable position by CXR and no malpositions were experienced after PICC insertion with the new technology (Bidgood, 2016). Without the tip confirmation system, malpositioned PICCs would have required further repositioning, additional catheter cost, patient dissatisfaction, and increased nurse time.

Post Insertion Confirmation

The international standard of practice for accurate placement and confirmation of PICCs has traditionally been the post-insertion CXR. However, the correct location of the tip can be verified by three methods: fluoroscopy, trans-thoracic or trans-esophageal echocardiography, and intracavitary ECG. CXR and fluoroscopy are not always accurate in identifying the post insertion tip location because the traditional radiological landmarks of the cavo-atrial are not reliable (Wirshing et al., 2008).

Cotogni and Pittiruti (2014) recommended adopting the ECG method for monitoring the position of the tip for all CVAD insertions. Important features supporting the ECG method included prompt access, ease of use, a secure management system, cost effectiveness, and was as accurate as fluoroscopy.

Wirsing et al. (2008) presented a prospective randomized study in an intensive care unit with patients undergoing cardiothoracic surgery and compared 212 central

venous catheter tips using a TEE probe confirmation and a post insertion CXR confirmation read by a senior radiologist and two radiologists in training. Of the 212 central venous catheters inserted via TEE, five left sided tips settled in the upper right atrium. The specificity for the senior radiologist read was 94.0%; one radiologist in training was 44.0% and the second radiologist in training had a 60.0% accuracy rate. Results indicated that reading a bedside CXR alone did not provide accurate intraatrial central venous catheter tip location (Wirsing et al., 2008).

PICC Training

The PICC placement instructions for use for the Sherlock 3CG® TCS by C. R. Bard, Inc. (Bard Access Systems, n.d.) outlines the specific details on PICC training using Bard technology products. The proper and precise measurement for PICC placement and the presence of a P wave on ECG were emphasized as essential during competency training for all PICC insertions. Clinicians that use Bard technology are required to complete a 2 hr online clinical training course for the Sherlock 3CG® TCS (Bard Access Systems, n.d.).

A review of the literature by Moureau, Lamperti et al (2013) analyzed minimal requirements for training techniques of central venous access devices (CVAD). An international task force was formed and generated consensus with evidence-based recommendations for training of CVAD. Eighty-three papers were reviewed and graded based on the evidence. Sixteen recommendations focused on CVAD didactic or web-based education with insertion procedures, infection prevention techniques, ultrasound competency, complications, and care and maintenance of devices. Clinical observation and competency assessment based on a global rating scale was recommended instead of

reliance on the number of procedures performed in order to ensure safe and competent practice.

Economic Impact of Bedside PICCs

Four studies reviewed the economic impact of bedside PICC insertions. A cost-consequence model that utilized the Sherlock 3CG® TCS was submitted by Bard, Inc. for the NICE Medical Guidance technology group to analyze; however, the two cost evidence studies submitted contained insufficient data for critical analysis. The NICE External Assessment Centre analyzed the company's base model and recommended cost changes to reflect alternative scenarios (Dale et al., 2016). The External Assessment Centre recommended allocating nurse time of 64.49 minutes. Patients who did not meet the criteria for Sherlock 3CG® TCS technology needed to be treated with an alternative method that included fluoroscopy and a CXR. All costs in their report were based on 2014 values. The External Assessment Centre calculated the Sherlock 3CG® TCS without CXR incurred a cost of GBP 9.37 (\$14.61 USD) per patient, a cost savings of GBP 106.12 (\$165.54 USD) per patient compared with using the Sherlock Tip location system and fluoroscopy (Dale et al., 2016).

Royer (2001) evaluated the cost effectiveness and efficacy of a nurse-driven intervention that utilized advanced PICC technology. A single hospital facility calculated the cost for IR to place a PICC cost \$978.00 USD. Costs included the radiologist, radiology nurse, radiology technician time, depreciation on fluoroscopy and other equipment, IR maintenance, PICC insertion kit and other equipment, and PICC catheter. The cost of the bedside PICC nurse insertion was calculated at \$155.50 USD. Those costs included PICC insertion tray, gown, sterile towels, microintroducers, sterile probe

cover, and depreciation of two Bard SiteRite II machines; in addition of 1 hour of PICC nurse insertion time.

Naylor (2007) analyzed the cost of PICC insertions in the IR room by an IR team comprised of a nurse and a radiology technician. The total operational costs included: (a) one Sherlock catheter (\$30.00 USD), (b) one CXR (\$40.00 USD), (c) nurse time of 2 hr (\$100 USD), and (d) IR room with fluoroscopy (\$700 USD). The radiologist time was not included in the study. The IR nurse who placed the PICC with Sherlock technology averaged \$305 USD. This included an assumption that the insertions were not complicated. The study had only minimal cost information and did not include technician or physician time, thus making the actual costs of the study difficult to analyze.

Pswarayi et al., (2015) in a poster presentation examined the economic impact of adopting the Sherlock 3CG® TCS technology used in the United States as an alternative option to PICCs placed blindly at bedside in the United Kingdom; the incremental cost impact of 3CG® TCS technology compared to blind insertion was GBP 12.17 (\$18.73 USD). The 3CG® TCS compared to fluoroscopy had a predicted cost savings of GBP 106.12. (\$163.26 USD). Key benefits for adopting the Sherlock 3CG® TCS were reduced the need for confirmatory CXRs, reduced staff insertion time, and the potential to limit exposure to unnecessary radiation in patients and health care workers. Limitations acknowledged that the results were not based on head-to-head clinical comparisons and actual patient outcomes. The results were estimates and based on specific inputs; therefore, not generalized to all populations.

There were limited data surrounding the financial cost of PICC insertions. Further research is suggested to understand and appreciate the true economic impact of PICC placements using various methods related to cost.

Summary

Several aspects of PICC insertions have been addressed in this literature review. A structured review of the literature was conducted and appraised utilizing the Johns Hopkins Nursing Evidence-based Practice evidence rating scales tool. The findings and analysis of the evidence were presented about the practice of PICC-insertion placement with ECG ultrasound-guided technology. Previous research studies in this literature review guided the methodology of the current PICC project and discussed in Chapter IV.

CHAPTER IV

METHODS

The aim of the change project focused on the transition of venous access nurses to insert bedside PICCs in patients and the importance of proficient PICC insertions by the venous access nurse. Several tools utilized for the change process included SWOT analysis (Appendix E), a PICC transition timeline (Appendix F), a communication plan and ICAR tool, and a PICC process map of the current state for IR and venous access nurses (Appendix G). The tools used assisted the leadership team and provided staff with a detailed map of the plan and a timeline for implementation. The PICC training and education for the venous access team was comprehensive and allotted adequate time for staff to develop skills in inserting bedside PICCs. The extra cost of supplies and labor time might potentially impact the financial budget if PICCs were difficult to insert.

Over the six months, the venous access nurses continued to gain more confidence and proficiency in the role of line selection, built trust with physicians and clinicians, and increased their collaboration among all clinicians caring for the PICC patient population. An ICAR reassessment was completed again by three of five venous access nurses in August 2017. The results showed significant growth and moved from the developing stage to the competent and mastery stages in all six dimensions. The reassessment results provided affirmation to the group and to leadership that all venous access nurses had expanded their knowledge of their new role. The IR staff and the venous access nurses gained trust and self-assurance between each other becoming a stronger and more independent, professional collective team.

Identified interventions and progress were tracked and presented to the venous access nurse through supporting data and, in turn, provided a positive change in the individual behaviors. Quality metrics were measured monthly. The planned change needed to be stable and sustainable in order to ask the practice question for this study. The projected change resulted in a decrease in the number of PICCs inserted by the IR staff and an increase of PICC insertions by the venous access nurses. The measure of the change project tracked the number of PICCs inserted in IR by the IR team and the number of PICCs inserted at bedside by venous access nurses for fiscal years 2014 to 2017.

The project was a retrospective quality improvement study to evaluate the efficacy of the venous access nurse team PICC-tip location during insertion by venous access nurses in an adult population using the Site-Rite® 8 ultrasound system with integrated Sherlock 3CG® TCS technology manufactured by C. R. Bard, Inc. A post insertion CXR impression read by a radiologist validated tip location. This type of research has been conducted in other hospitals throughout the United States; however, in order to change practice within the study's health system, the protocol needed to be replicated, analyzed, and accepted as a prototype study in one of the system's hospitals.

The study reviewed health records of 125 adult patients who had bedside PICC placement using the Site-Rite® 8 ultrasound system with integrated Sherlock 3CG® TCS technology. The study took place at one acute hospital in Southern California within a larger health care system. Data collection included electronic medical chart review of the PICC insertion documentation record and the patient's finalized post insertion CXR report.

The inclusion criteria encompassed adults 18 to 90 years of age with a demonstrated need for PICC and the presence of a P wave on ECG. Exclusion criteria eliminated patients with atrial fibrillation, atrial flutter, lack of a distinct P wave on the ECG and patients under the age of 18 years.

A stratified, random selection of patients meeting inclusion and exclusion criteria was examined. All patients included in the study had PICCs inserted by the venous access nurses from July 2016 to June 2017 for a total of 125 PICC catheters. Data were abstracted from the electronic medical record, comprised of both scanned paper and computer documentation.

Quantitative data points included age, gender, primary diagnosis, nurse who placed the line (de-identified), verification of P wave present on ECG, indication for PICC, size and type of PICC catheter, vein inserted, PICC insertion date, and any problems encountered during the insertion. Additional data points included: time CXR completed post procedure, time final CXR read by the radiologist in the Centricity Enterprise system, radiologist who read the CXR (de-identified), the post CXR impression results, the number of CXR images post insertion, any malpositions or repositions needed post insertion, and, if repositioned, how many centimeters the catheter was pulled back. All data points were retrieved through McKesson Horizon Patient Folder data archival system.

An a priori power analysis was performed using G*Power (Version 3.1.9.2; Faul, Erdfelder, Lang, & Buchner, 2007) to determine adequate sample size. With a 0.3 (medium) effect size, 0.05 alpha level, 0.80 power (1 – beta error of 0.20), and 3 degrees of freedom, a total sample size of at least 122 was indicated. The researcher randomly

selected 125 patients to include in the study. Data were entered into Excel and subjects were de-identified. The Excel worksheet was then uploaded into SPSS (Version 24) for statistical analysis.

Data analysis included descriptive statistics with relative frequency distributions. The data included demographic information and elapsed time from PICC insertion to the time that the CXR was read.

The research approval process was initially endorsed through the study site's system-wide Radiology and Imaging Co-Management Care Line committee (Appendix A). The site Institutional Review Board (IRB) granted approval of the study (Appendix B) in conjunction with the waiver of authorization for research (Appendix C). A confidential data request form was completed and approved through the site's audit and compliance manager. The IRB authorization agreement was approved between the site institutions, then data collection commenced.

CHAPTER V

RESULTS

PICCS are effective central catheters that require skilled and competent clinicians to safely insert the devices. Indications, contraindications, and potential complications need to be considered prior to the insertion of a PICC. All health care providers need proper training in device use, site care, maintenance, and the recognition of PICC complications. The aims of the study focused on (a) a PICC change project, (b) advanced PICC technology outcomes, and (c) an evaluation of the costs for PICC insertion at one hospital. Prior to the venous access nurses' change project, there was no solid system in place to transition PICC insertions from the IR department to another group of clinicians. Data needed collection, assessment, and analysis with the teams in order to implement the process change. Lewin's change theory was used, and the venous access nurses were trained to insert bedside PICCs with ECG ultrasound-guided technology.

PICC Project Process: Change

The PICC transition project began in January 2015 and was tracked monthly through June 2017. The venous access nurses had a six month transition period (January 2015 – June 2015). Prior to implementing this PICC outcome study, the venous access nurses had to gain confidence as experts, clearly understand PICC indication criteria, and have the ability to perform bedside PICC insertions with ease using ultrasound-guided technology. PICCs inserted by the IR team decreased by two-thirds during the 6-month venous access nurse transition phase. Figure 3 depicts the transition of PICC insertions beginning January 2015 and the number of bedside PICC insertions compared to the number of PICCs inserted by the IR staff. The IR team continues to support the venous

access nurses for (a) difficult insertions, (b) patients not meeting PICC criteria for bedside insertion, and (c) excessive PICC insertion requests.

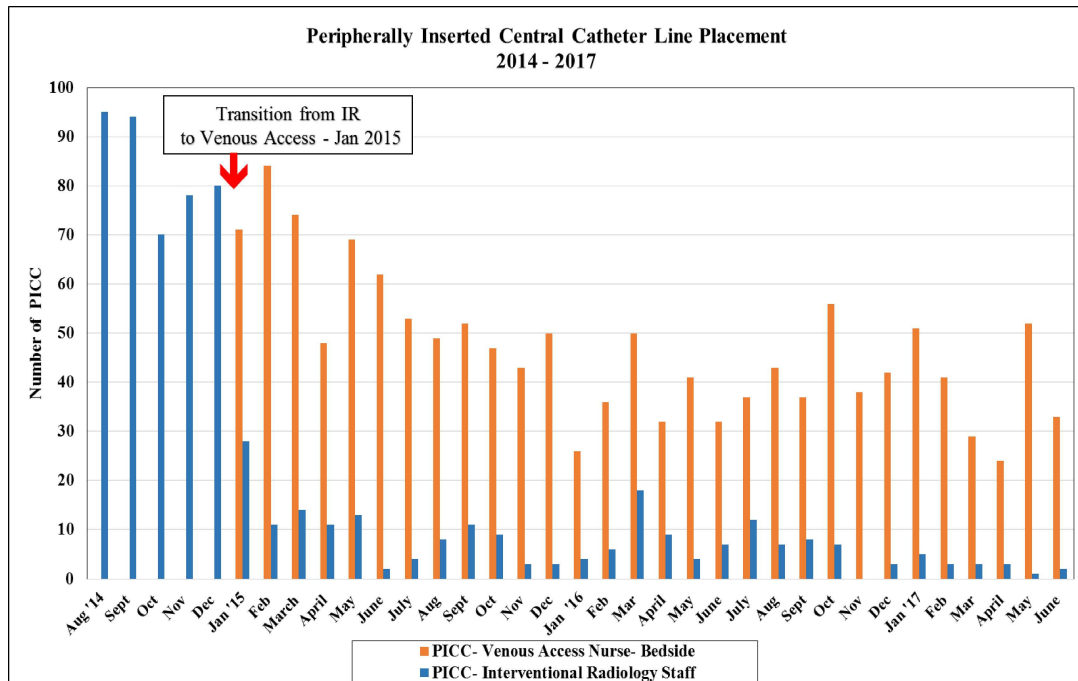


Figure 3. Peripherally inserted central catheter line placement (2014- 2017) by venous access nurses and interventional radiology staff.

The venous access nurses who inserted PICCs with ECG ultrasound-guided technology increased the number of insertions over time. The teams were collegial, cohesive and worked well together. The aim of the PICC change project was met and the project needed to be successful in order for the quality improvement project to be studied.

Advanced PICC Technology Outcomes

The aim of this study was to evaluate the efficacy of proper PICC tip location confirmation using ECG ultrasound-guided technology by the venous access nurses and matched by the post insertion CXR position. From July 5, 2016 to June 7, 2017, the researcher selected a stratified random selection of 125 patients in whom a PICC had been placed with Sherlock 3CG® ultrasound-guided technology. The inclusion criteria

were evaluated and met. Age as a variable was examined (Table 3). The mean age was 62 (range 25 to 86). The largest age group was 50 to 64 years of age.

Table 3

Age of Study Sample with PICC Insertions (N = 125)

Age Range (years)	N	Percent
25-34	7	6.0%
35-49	18	14.0%
50-64	46	37.0%
65-74	25	20.0%
75-86	29	23.0%
Total	125	100%

The genders of the subjects were not equal. Of the 125 patients selected, 88 (70.4%) males had PICCs inserted with ECG ultrasound-guided technology as compared to 37 (29.6%) females. The uneven distribution between males and females was concerning to the author. A more detailed review of the full PICC data set revealed similar results in gender distribution with 331 (65.8%) males and 172 (34.2%) females with PICCs inserted at the facility during the selected timeframe. The imbalance of more males than females was unpredicted for this study.

Primary indications for a PICC were antibiotics, total parenteral nutrition, chemotherapy and multiple medications. Table 4 provides a breakdown of subjects by primary indication and reason for the PICC. The primary indications aligned with the MAGIC guidelines.

Table 4

Primary Indications for PICC Necessity

Indication	<i>N</i>	Percent
Antibiotics	83	66.4%
Total Parenteral Nutrition	29	23.2%
Chemotherapy	9	7.2%
Multiple Medications	4	3.2%
Total	125	100%

Primary diagnosis of PICC patients was highest in the infection and cancer groups. The common groupings were in alignment with PICC insertions and the need to have central line access for these patients. Figure 4 depicts a pareto chart and the number of PICCs based on primary diagnosis.

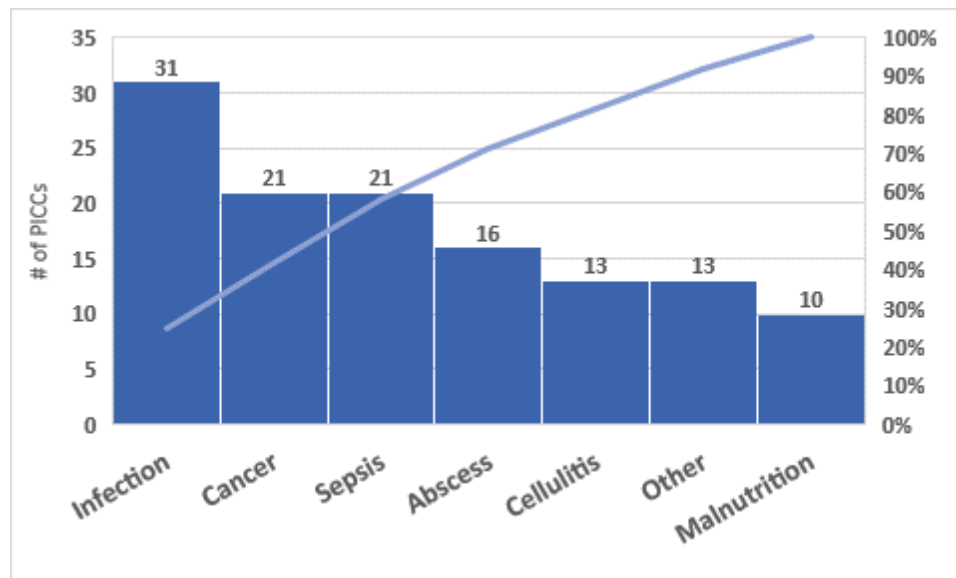


Figure 4. Pareto chart of number of PICCs by primary diagnosis.

Catheters, Veins, and Arm Selection

Catheter lumen size, type of catheter used, and veins selected during insertion were examined. There was an equal distribution of the lumen size between single lumen (49.6%; 62/125) and dual lumen (46.4%; 58/125) catheters, but not triple lumen catheters (4.0%; 5/125). Triple lumen catheters were used for patients on multiple medications. French (Fr) catheters were in either 4 Fr or 5 Fr size. Results indicated that 4 Fr catheters were used almost as often (49.6%; 62/125) as 5 Fr catheters (50.4%; 63/125).

Arm selection, right or left, was individualized for each patient. Left-sided PICCs required longer catheter lengths; therefore, more PICCs were placed in the right arm (80.2%; 101/125) than in the left arm (19.2%; 24/125). The three veins used for PICC insertion in the upper arms include the basilic, brachial, and cephalic veins. The basilic vein has the largest diameter with the greatest blood flow and the straightest route to the superior vena cava. The basilic vein was used most often (64.8%; 81/125), less often for the brachial vein (32.0%; 40/125) and the cephalic vein (3.20%; 4/125). A study by Jeon, Cho, Yoon, and Hwang (2016) noted brachial and basilic veins had more successful insertions when accessed through the right arm during non-fluoroscopic PICC insertion. Proper clinical assessment, patients' current history, selection of the appropriate vein for insertion, and adequate time to educate the patient about the procedure assisted the venous access nurses for a smooth PICC insertion.

Venous Access Nurse Insertions

This study tracked the venous access nurses who inserted the PICC with Sherlock 3CG® ultrasound-guided technology. Five nurses performed PICC insertions during this study. The nurses were de-identified and coded as Nurse A through E. Figure 5

illustrates the number of insertions by each venous access nurse. Three of the five nurses inserted more than 32 PICCs. One venous access nurse inserted only one PICC during the study; the remaining nurse worked part time and performed 18 PICC insertions. Nurse A had the most insertions and had no complications or repositions. Further analysis will be discussed in the PICC Reposition Section regarding the venous access nurse outcomes.

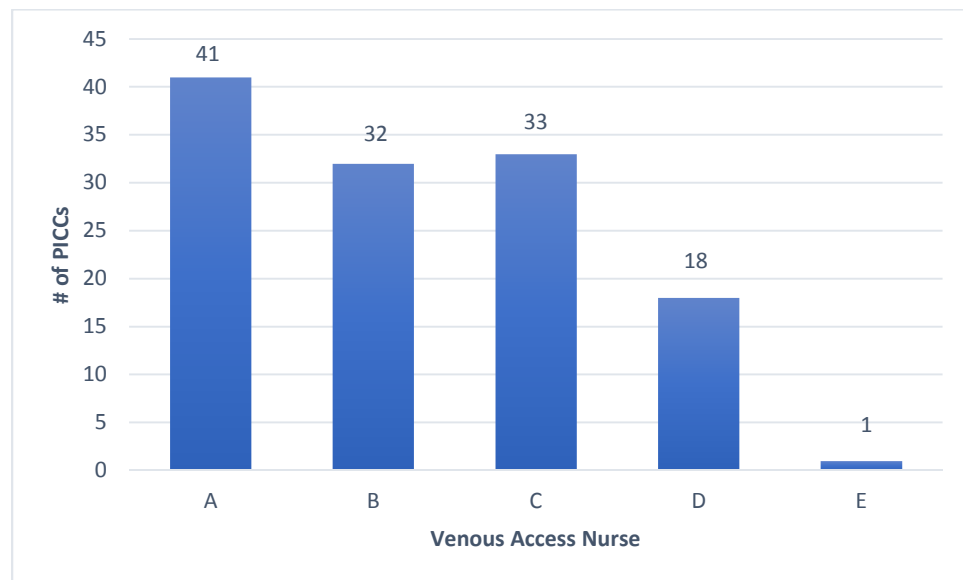


Figure 5. Number of PICCs inserted by venous access nurses.

Radiologists Chest Radiography and Turn Around Times

The author reviewed the notes of the radiologists who interpreted the post insertion CXR. All radiologists were de-identified for the study. In all, 14 radiologists read 128 CXRs; three patients needed their PICCs repositioned and the three patients had one additional CXR for tip confirmation. The three additional post insertion CXRs were not read by the initial radiologist who identified the malposition but by three different radiologists. This represents a consistent reading process with all 14 radiologists.

The turnaround read time was calculated in minutes (min) from the time the CXR was completed to the time the CXR results were in the computer system. This elapsed time ranged from 7 min to 183 min (*Mean* = 59.16, *Median* = 62.00, *Mode* = 13, *SD* = 36.23). The spread of values represented a fairly normal distribution as seen in Figure 6.

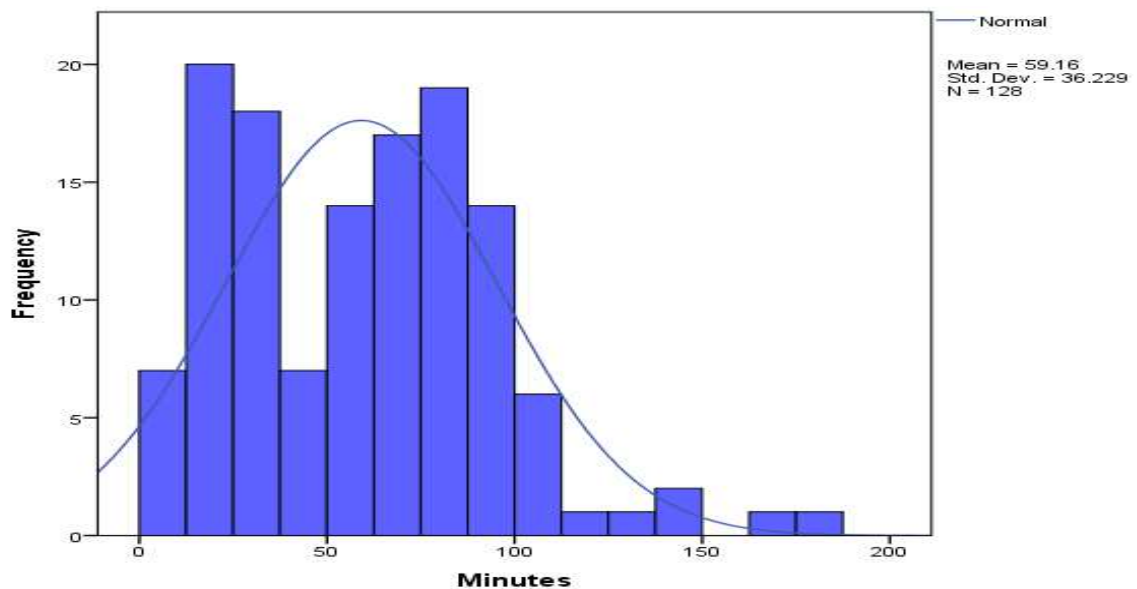


Figure 6. Histogram of elapsed time between CXR taken and CXR read into the electronic chart.

The current process for post PICC insertions is a stat CXR. If there is a significant finding, such as a malposition, the reading radiologist notifies the venous access nurse with an order to manipulate the PICC. The venous access nurse will follow out the order and document the change. A second CXR will be ordered stat after the PICC has been repositioned.

Repositions After PICC Insertion

Based on the post insertion CXR, few PICC insertions needed to be slightly pulled out and repositioned (2.40%; 3/125). There were zero complications during the insertion of 125 PICCs. Venous Access Nurse C inserted two of the three PICCs and Venous Access Nurse D inserted one of the PICCs that required repositioning. Venous

Access Nurse A inserted the most PICCs and did not have any complications or repositions during the PICC placement. The three repositions were all female patients and the tip was located in the right atrium of the heart via CXR. The height and weight of the three patients were analyzed. Table 5 shows the reposition results after the PICC insertion and prior to use. All subjects were 5'4" or less and weighed less than 66 kg (145.2 lbs). All three patients had one additional CXR, adding cost to the procedure. The CXR after repositioning in all three patients revealed the PICC tip was in proper position per the radiologist CXR report. There were no further documented complications in any of the 125 PICCs inserted at the bedside using ECG ultrasound-guided imaging.

Table 5

PICC Malpositions and Repositioning Data

ID	Position	Pulled Back (cm)	Lumen	Fr (size)	Arm	Vein	Height (in.)	Weight (kg)
43	Right Atrium	2 cm	Dual	5	Right	Brachial	62	66.0
63	Right Atrium	3 cm	Dual	5	Right	Basilic	60	64.2
76	Right Atrium	3 cm	Dual	5	Right	Basilic	64	52.0

Calculating the rate of success, 97.6% of patients had PICCs inserted by the venous access nurses using ECG ultrasound-guided technology on the first attempt. The a priori power analysis methodology recommended a total sample size of at least 122 PICCs and this study analyzed 125 PICC insertions. Based on this methodology, an ample sample size of the population for the study was achieved. The final part of the quality improvement study assessed the labor cost of PICCs inserted by two different groups.

PICC Cost Analysis

Health care costs continue to rise due to aging baby boomers, chronic diseases, and an increase in the use of the emergency department. Health care providers should be cognizant of all costs provided to the patient. The third aim of the PICC project was to examine the costs associated with PICC insertion (a) in IR and (b) venous access nurses using ECG ultrasound-guided technology.

This measure compared the cost of PICCs inserted in IR with the costs of a PICC inserted at the bedside by the venous access nurses to determine if there was a noteworthy cost difference. The author analyzed labor costs and time between the IR staff and the venous access nurses.

Labor cost. Labor costs and the time needed for staff to insert the PICC were examined utilizing each method. Table 6 depicts the average time the venous access nurse took to insert a bedside PICC with ECG ultrasound-guided technology (i.e., 60 min included consent, chart review, patient education, patient preparation, procedure, and documentation) and the radiology tech to perform a CXR (i.e., 15 min). The total labor cost for the venous access nurse and radiology tech was \$67.47 and the total procedure time was 75 min and seven process steps. Based on the results of this study, if the post CXR was eliminated, the labor costs and time would be limited to the venous access nurse time (\$57.53; 60 min) and could decrease the process steps to four steps and no fluoroscopy exposure during bedside PICC insertions.

The average time for IR staff to insert a PICC under fluoroscopy is detailed in Table 6 and included consent, chart review, patient education, patient preparation, procedure, and documentation. The total labor time for the IR RN, IR rad tech,

diagnostic x-ray tech and transporter time was 110 min with a total cost for labor of \$81.17. This includes nine process steps by the IR staff. The process would not change and no process steps would be eliminated since 3CG® tip placement is not performed in the IR department. Patients who do not have an existing P wave on ECG continue to have PICCs inserted in the IR department. There was no overtime accrued for either group as PICCs are not considered urgent or emergent and need careful assessment for appropriateness prior to insertion.

There was a labor costs savings of \$13.70 per PICC insertion if performed by the venous access nurses versus the IR team. If the post CXR were eliminated, there would be an additional savings of \$9.94; totaling a \$23.64 savings between the venous access nurses and the IR team. This is an opportunity of cost savings in labor time and should carefully be evaluated.

Table 6

Total Labor Costs: Estimated PICC Insertion (Noncomplicated)

	Minutes	Average Hourly Rate	Total Cost (US \$)
<u>At the Bedside</u>			
Venous Access RN	60	\$57.53	\$57.53
Diagnostic X-ray Tech for Portable Post CXR	15	\$39.74	\$9.94
Total Venous Access- min and cost	75		\$67.47
<u>In Interventional Radiology</u>			
IR RN (incl. transport to diagnostic room x-ray - 5 min)	40	\$62.09	\$41.36
IR Rad Tech to assist RN for fluoroscopy	30	\$49.38	\$24.69

Diagnostic X-ray Tech for Post CXR in IR	10	\$39.74	\$6.62
Transporter (Radiology to patient room)	30	\$17.00	\$8.50
Total IR- min and cost	110		\$81.17

Note. All costs are based on 2017 values.

Supply cost. The costs of supplies are important to evaluate for PICCs. The supplies used for PICC insertions are the same for both groups. For this study the actual supply costs were not itemized since the PICC kits are standardized throughout the system. A team who inserts PICCs should analyze annually each supply item in the standard PICC kit and remove or add necessary items for insertions. The system wide supply chain team can assist the nurses an itemized supply costs and revision of the PICC tray. There may be some leverage in negotiating kits to decrease the costs with different companies.

Labor costs and time to insert a PICC insertion was measured with the two groups. The venous access nurse total insertion time was 75 min and included a CXR. Labor costs for a PICC insertion at the bedside was \$67.47 USD. If the post CXR were eliminated, labor cost would be \$57.53 with a total of 60 min of venous access nurse time. There were seven total process steps to perform a PICC insertion by the venous access nurse. The average time the IR staff took to insert a PICC in IR under fluoroscopy was 40 min for the IR RN and 30 min for the radiology technician (included consent, chart review, patient education, patient preparation, procedure, and documentation), 10 min for the radiology tech to perform a CXR in the department and transporter 30 min from the patients' room to IR and then return to the patients' room from the department, a combined total a time of 80 min.

The current labor costs for a PICC insertion by IR team, transportation, and a post CXR costs \$81.17 USD, with a total time of 110 min. There were nine process steps to perform a PICC insertion by the IR staff. This process would not change and no process steps would be eliminated since 3CG® tip placement is not performed in the IR department. Patients who did not have an existing P wave on ECG would continue to have PICCs inserted in the IR department.

Summary of Findings

The PICC project used Lewin's change theory to transition the venous access nurses to insert bedside PICCs with ECG ultrasound-guided technology. The specific measures of the PICC project were to (a) compare the number of PICCs inserted in IR and the number of PICCs inserted at bedside by venous access nurses (FY 2014-2017), (b) examine the accuracy of PICC ECG ultrasound-guided tip location using the post procedure CXR and match of ECG ultrasound to CXR positions, and (c) compare the average cost of the number of PICCs inserted in IR and the cost of PICCs inserted at the bedside by the venous access nurses and determine if there was a significant cost difference.

Advanced PICC technology outcomes were analyzed. Findings revealed that, from July 5, 2016 to June 7, 2017, 125 patients selected who met the criteria had a PICC insertion with the Sherlock 3CG® ultrasound-guided technology. The mean age was 62 (range 25-86 years). The largest age group was 50 to 64 years. Gender confirmed 88 (70.4%) males compared to 37 (29.6%) females had a PICC insertion. Repositions after the initial PICC insertion necessitated the PICC tip to be pulled back 2.40% of the time (3/125) with zero complications. All subjects were 5'4" or less and weighed less than 66

kg (145.2 lbs). All three patients who had malpositions had one additional CXR, adding cost to the procedure. The CXR after repositioning in all three patients revealed the PICC tip was in proper position per the radiologist CXR read. There were no further documented complications in any of the 125 PICCs inserted at the bedside using ECG ultrasound-guided imaging.

The total average labor costs for the venous access nurses were \$67.47 compared to the IR team cost of \$81.17. The cost difference is \$13.70 per insertion. The aims of the PICC project were measured and achieved. There was a 97.6% success rate of proper placement using ECG ultrasound-guided technology on the first attempt by the venous access nurses in 122 patients.

CHAPTER VI

DISCUSSION AND IMPLICATIONS

The Institute for Healthcare Improvement's (2017) Triple Aim Initiative focuses on improving the patient's experience of care, improving the health of various populations, and reducing the per capita cost of health care. Many factors may contribute and impact proper PICC line positioning, necessitating an in-depth assessment of a patient's condition and plan of care. A clear understanding of the indications for PICCs is required to prevent complications related to PICC insertions and the potential risk of CLABSI. Research supports adhering to PICC best practice, proper maintenance of the access line, and a dedicated and competent nursing staff can improve patient safety and the patient experience, including a reduction of costs to the patient and the hospital.

Lewin's Planned Change for the PICC Project

Lewin's (1951) three-step change theory of unfreeze, movement, and refreeze promoted change and managed progress toward the goal. Lewin's model was simple to use and appropriate for the PICC project study.

Advanced ultrasound-guided tip-placement confirmation research supported proper tip placement location, decreased malpositions, and provided appropriate post-insertion confirmation of PICC tip location. Post insertion CXR studies confirmed the PICC tip locations were in proper position using 3CG technology.

PICC training focused on CVAD didactic or web-based education with insertion procedures, infection prevention techniques, ultrasound competency, complications, and care and maintenance of the devices. To ensure safe and competent practice, clinical observation and competency assessments were recommended instead of reliance on the

number of procedures performed. The literature review provided a solid foundation to initiate the study. The venous access nurses take full ownership of PICC line placement. The education provided empowerment and an increased value to each venous access nurse and commitment to the hospital. The venous access nurses found the use of the Sherlock 3CG® TCS ultrasound-guided technology was technically challenging at first was easy to use. The new magnetic tracking system views malpositions during insertion and the nurse can correct the error immediately. The use of this technology could potentially eliminate the post insertion CXR. The site leadership and system wide radiology physician group need to agree on this practice change in order to spread to the other four hospitals.

Future Research

Of the 125 patients selected, 88 (70.4%) males had PICCs inserted with ECG ultrasound-guided technology as compared to 37 (29.6%) females. A detailed review of all PICC insertions revealed similar results in gender distribution with 331 (65.8%) males and 172 (34.2%) females at the facility during the selected time. A study by Baiocco and da Silva (2010) analyzed PICC insertions males had a higher proportion 70.7% ($n = 162$) of PICC insertions compared to women of PICC insertions 29.3% ($n = 67$). The percentage of males versus females who received PICCs was similar for this study. Further research is warranted on PICCs insertions related to gender and whether females are less likely to receive a PICC than males. The number of malpositions for this study resulted in three female patients. Additional research is needed on malposition rates on females under 5'4 in. and less than 145 lbs. during PICC insertions. Mortality and morbidity outcomes with the various clinical diagnoses of PICCs should be studied.

Clinical practice must be cost effective and analyzed. Supplies are costly and with the burden of decreased insurance payments to hospitals all clinicians need to be cognizant of the cost and supply use. Not every patient will meet the criteria for placement with the Sherlock 3CG® TCS. New PICC technological advances will continue and nurses need to be aware of new evidence to support each type of device. Additional research on the cost of PICC insertions, supply usage per patient insertion and length of time to insert a bedside PICC need to be explored.

Communication with the venous access nurses and other health care providers was positive and the staff gained trust with the team on recommendations and input into the PICC assessment. A formalized and well-communicated educational plan is necessary when changing roles of staff. Nurse satisfaction in the new role was not evaluated for this study however further research on nurse satisfaction and new role expectations is warranted.

PICC placement using 3CG® TCS technology is predicted to be an economically favorable option. Further analysis and research of time and motion studies in diverse patient populations with actual PICC insertion times and patient outcomes would help further elucidate the findings. The benefits of the PICC change project positively impacted the venous access nurses and the IR team. There is a new clear standard practice for PICC insertions. Additional PICC research on patient satisfaction and hospital length of stay is recommended.

Implications for Practice

The steps to insert a PICC were varied between the venous access nurses and the IR staff. There were two less steps to insert the PICC by the venous access nurse than the

IR staff. If the CXRs were not necessary after insertion then the total steps for venous access nurse would be four total steps for insertion. The advantage of the bedside PICC is the patient does not need to leave the room. This can potentially decrease the stress of moving the patient for procedures and there is minimal radiation exposure. Process mapping for PICC insertions in other settings is warranted.

The results of the study will be shared with the site leadership and system wide radiology physician staff. To change practice within the study's health system, the results of the study serves as a prototype to adopt throughout the entire health system. The recommendation to the teams are those patients who have a P wave on ECG and are in stable condition that all bedside PICC insertions with Sherlock 3CG® TCS and consider eliminating the post insertion chest radiography.

Venous access teams that insert vascular devices at the bedside can be a cost-effective approach in the inpatient setting. The outcomes of this study pointed positively toward 125 PICC insertions that had an initial insertion success rate of 97.6% with zero complications. Utilizing PICC best practice protocols, advanced PICC technology with proper maintenance of lines, and a dedicated nursing team can improve patient safety and the patient experience, resulting in a reduction of costs to the patient and the hospital.

The American Association of Colleges of Nursing (AACN, 2006) detailed Essentials of Doctoral Education for Advanced Nursing Practice provides clear guidelines and detailed expectations of the Doctor of Nursing Practice (DNP) degree. The completion of the DNP degree takes on an expanded role in nursing through evidence-based practice and translating results at the bedside environment. The expectations of the DNP is to evaluate clinical practice in health care delivery systems, with an objective of

improving quality, patient safety and influencing health care outcomes. The value of DNP preparation for nurse administrators and all DNPs leaders is to provide supporting research to influence changes in health policy at the local, state and national level.

DNP nurses work collaboratively in a team approach to coach, guide and mentor students and staff. The goal is to expand interpersonal collaboration with administration and physician leadership groups to drive and evaluate effective use of supplies and propose cost savings initiatives. The DNP must utilize valid, reliable research tools and understand the critical techniques of facilitation to lead patient safety initiatives and quality improvement teams. DNPs need to strive to work harder to reduce patient errors and improve patient safety.

As a DNP scholar my responsibility is to make a concerted effort to work on interdisciplinary teams and focus on whole systems or populations rather than individuals. The utilization of advanced computer systems and data results will drive all healthcare providers to improve patient outcomes. The Institute of Medicine (2001) and Institute for Healthcare Improvement (IHI) (2017) mission provides safe, patient-centered, timely, and cost effective care for all individuals. This quality improvement PICC study achieved the IHI triple aims initiatives through the strength of the Essentials required for the DNP program.

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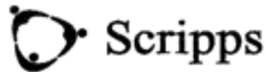
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APPENDIX A

CARE LINE REVIEW OF RESEARCH PROPOSAL



Research Proposal – Care Line or Co-Management Review

May attach comprehensive study information if desired, however please complete the summary sections below.

CARE LINE REVIEW REQUEST		
Study Title: Peripherally Inserted Central Catheters (PICC) and the Efficacy of Tip Placement Confirmation with ECG-ultrasound Guided Technology and Chest Radiography		Anticipated Start: August 2017
Care Line or Co-Management Committee: Imaging/Radiology		Meeting Date: July 2017
Study Item: Therapeutic / Drug: _____ Device: _____ Outcome: <input checked="" type="checkbox"/> Other: _____		
Study Coordinator / Research Primary Contact (Name & Phone Number): Elizabeth Morrell, 619-977-5058		
Principal / Co-Investigator(s) (Name & Phone Number): Elizabeth Morrell, 619-977-5058	Scripps Site(s) / Facility(ies): Scripps Mercy San Diego	Total Study Sites: One
Brief Description of Study: (Patient Population / Purpose /Intended Outcomes) Annually, 2.5 million peripherally inserted central catheter (PICC) procedures are performed in acute care facilities and infusion centers in the United States. PICCs, a type of central venous access device, have gained popularity with the ease of bedside insertions, improved ultrasound technology and tip navigation. The integrated imaging attached to mobile ultrasound systems provides immediate confirmation of catheter placement and potentially eliminates complications and further repositioning.		
Purpose: The purpose of this study is to evaluate the efficacy of PICC tip placement confirmation using fully integrated magnetic tracking and ECG ultrasound-guided insertion technology performed at the patients' bedside by venous access nurses and validated by the post-insertion chest radiography. This is a retrospective quality improvement project.		
Patient Population: Sample size: 125 Patients with bedside PICCs inserted by a venous access nurse between July 2016 - June 2017 and compare the tip location with the post insertion chest radiograph impression report.		
Intended outcome objectives and measurements:		
Aim: In the adult hospital setting, is advanced ECG ultrasound-guided PICC tip location technology effective as validated by the post-procedure chest radiography results?		
Aim #1: Confirm proper PICC tip location by venous access nurses to the chest radiography report.		
Measure: Examine the accuracy of ultrasound-guided tip location using the post procedure chest radiography and matching of ultrasound and chest radiography positions.		
Aim #2: Examine the costs associated with PICC insertion (a) in interventional radiology and (b) venous access nurses using ECG ultrasound-guided technology.		
Measure: Analyze the average cost of the number of PICCs inserted in interventional radiology and the venous access nurses; and determine if there is a significant cost difference.		
Anticipated Scripps Sample Size (w/ Control if applicable): 125;		Enrollment Period / Data Frequency Retrospective chart review- July 2016-June 2017
Study Sponsor: None	Funding: Commercial: _____ Grant: _____ Philanthropy: _____ Other: _____ <input checked="" type="checkbox"/> NONE	
Equipment / Devices FDA Approved Yes <input checked="" type="checkbox"/> No _____ If No List:	Equipment/Supplies Currently in the Scripps System Yes <input checked="" type="checkbox"/> No _____ If No List:	Procedures / Equipment Costs Not SOC: No change in cost of procedure

Reimbursement issues / Impacts to Hospital (Independent of Research Budget): None	
CARE LINE STEERING COMMITTEE ENDORSEMENT / COMMUNICATION (completed following review)	
Aligns with Strategic Goals (Define goal and alignment):	
Good Use of Scripps Resources (Per existing care line research portfolio, benefit outweighs cost, other cost mitigation/offsets): YES NO	
Likely to Adopt into Clinical Practice: YES NO In Practice Currently	
Financial impact to Scripps/Hospital site reviewed/accepted by Care Line/Site Finance	
ENDORSED by Clinical Care Line / Co-Management Steering Committee / Finance	
Signature (Care Line / Co-Management Administrative Lead)	<u>8/7/17</u> Date

APPENDIX B

IRB APPROVAL



Office for the Protection of Research Subjects

Scripps IRB

4275 Campus Point Court, CPB 200
San Diego, CA 92121

Approval Notice

Investigator: Elizabeth Morrell

Department: Scripps - Nursing Department

Approved
Research Sites: Scripps Mercy Hospital San Diego

Project Title: Peripherally Inserted Central Catheters (PICC) and the efficacy of tip placement confirmation with ECG-ultrasound guided technology and chest radiography

Protocol No: IRB-17-7024

Risk Category: Minimal

Type of Review: Expedited – NEW

Your research project indicated above was reviewed and approved by an IRB officer on the review date stamped below. Approval expires **12 months** from this date.

Approval carries with it the understanding that you will inform the Committee promptly should a serious adverse reaction occur, and that you will make no modification to the protocol or consent form (if applicable) without prior IRB approval.

The IRB may suspend or terminate the approval of research that is not conducted in accordance with the requirements set forth by the committee or that has been associated with unexpected serious harm to subjects.

Current, approved study documents can be downloaded from iMedRIS at <https://research.scripps.org>.

(Retrospective review of medical records for patients that had a bedside PICC inserted by a venous access nurse using the integrated Sherlock 3CG® TCS ultrasound-guided equipment between July 2016 – June 2017 at Scripps Mercy hospital San Diego. Requirement to obtain Informed Consent is waived under 45 CFR 46.116(d). Waiver of Privacy Authorization is granted under 45 CFR 164.512(i).

****NOTE:** Study cannot begin until a Confidential Data Request is approved by Audit/Compliance)


Signature applied by Jennifer Holmes on 08/30/2017 10:31:13 AM PDT

IRB Officer

APPENDIX C

WAIVER OF AUTHORIZATION



Office for the Protection of Research Subjects

Scripps IRB

4275 Campus Point Court, CPB 200
San Diego, CA 92121

WAIVER OF AUTHORIZATION FOR RESEARCH

Principal Investigator
or Project Manager: Elizabeth Morrell

Department: Scripps Mercy San Diego, Nursing Department

Title of Project: Peripherally Inserted Central Catheters (PICC) and the efficacy of tip
placement confirmation with ECG-ultrasound guided technology and
chest radiography

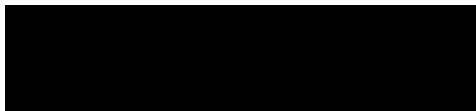
IRB Protocol Number: IRB-17-7024

The **IRB**, in its capacity as a **Privacy Board**, has determined that the project described above may use or disclose protected health information. The conditions for waiving the need to obtain individual authorization have been reviewed and determined to meet the regulations described in 45 CFR 164.512(i).

It is the responsibility of the Principal Investigator or Project Manager to keep records of how protected health information for an individual has been used and disclosed. You must limit your use of protected health information to the "minimum necessary" to achieve your research purpose.

Documentation of the Waiver will be maintained in the Scripps Office for the Protection of Research Subjects for at least six (6) years.

(Retrospective review medical records for patients that had a bedside PICC inserted by a venous access nurse using the integrated Sherlock 3CG® TCS ultrasound-guided equipment between July 2016 – June 2017 at Scripps Mercy hospital San Diego)



Signature applied by Jennifer Holmes on 08/30/2017 10:29:03 AM PDT

IRB Officer

APPENDIX D

IRB AUTHORIZATION AGREEMENT

Institutional Review Board (IRB) Authorization Agreement

Institution Providing IRB Review:

Name:	Scripps IRB
IRB Registration #:	IRB00004335
Federalwide Assurance (FWA) #:	FWA00007338

Institution Relying on the Designated IRB:

Name:	Western University of Health Sciences
FWA #	FWA00003774

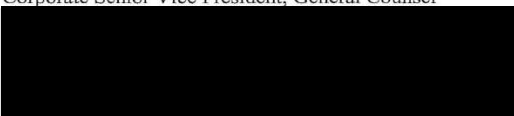
The officials signing below agree that **Western University of Health Sciences** may rely on the designated IRB for review and continuing oversight of its human subjects research described below:

This agreement is limited to the following specific protocol(s):

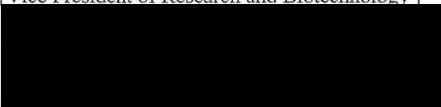
Name of Research Project:	Peripherally Inserted Central Catheters (PICC) and the efficacy of tip placement confirmation with ECG-ultrasound guided technology and chest radiography
Name of Principal Investigator:	Elizabeth A Morrell
Protocol Number:	IRB-17-7024

The review performed by Scripps IRB will meet the human subject protection requirements of **Western University of Health Science's** OHRP-approved FWA. The IRB at Scripps Health will follow standard procedures for reporting its findings and actions to appropriate officials at **Western University of Health Sciences**. Relevant minutes of IRB meetings will be made available to **Western University of Health Sciences** upon request. **Western University of Health Sciences** remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Richard Sheridan – Institutional Official):

Signatory Official: Richard R. Sheridan	
Title: Corporate Senior Vice President, General Counsel	
Phone:	
Email:	
 Signature	9-6-17 Date

Signature of Signatory Official (Western University of Health Science):

Signatory Official: [Steven Henriksen, PhD]	
Title: [Vice President of Research and Biotechnology]	
Phone:	
Email:	
 Signature	9-13-17 Date

APPENDIX E

SWOT ANALYSIS – APPLIED TO PICC PROJECT

<p>Strengths</p> <ul style="list-style-type: none"> • Practice change endorsed by Nursing leadership • Radiologists support the transition-allow for more difficult procedures in department • Interventional Radiology staff (RNs/Techs) support PICC transition to qualified bedside venous access team. □ • Open and positive dialogue between Radiology nursing and IV nurses. • Radiology and IV nurses report to same Nursing Director. • Highly skilled Clinical Nurse Specialist from company to support transition plan. • Small nursing staff to train (4) at one site. • One IV nurse technically competent on ultrasound-guided insertions. 	<p>Weaknesses</p> <ul style="list-style-type: none"> • Three seasoned IV nurses not familiar with ultrasound-guided imaging and lack confidence of insertion technique-may result in longer learning curve. • Nursing leadership overcommitted and needs to manage and support the plan every week till completion. • Radiology staff may want to keep volume of PICC procedures in Radiology. • Staffing shortages in the Radiology department and will need to fill Radiology nurse position prior to implementation.
<p>Opportunities</p> <ul style="list-style-type: none"> • Engage staff early in planning phase. • Involve and promote staff of the positive impact on patient satisfaction. • Annual education/training to intern/resident teams on PICC insertion and maintenance. • Work with corporate human resources on job description change from IV Nurse to Venous Access Nurse • Develop a budget workbook to purchase new equipment and advanced 3CG software technology. 	<p>Threats</p> <ul style="list-style-type: none"> • Staff not committed to the change project. • Corporate human resources and senior leadership may not support the job description change. • Venous access nurses may fear too difficult of a transition. • Determine funds are available for the new equipment.

Source: Manktelow, J. (2015). SWOT analysis. Discover new opportunities, manage and eliminate threats. Retrieved from

https://www.mindtools.com/pages/article/newTMC_05.htm

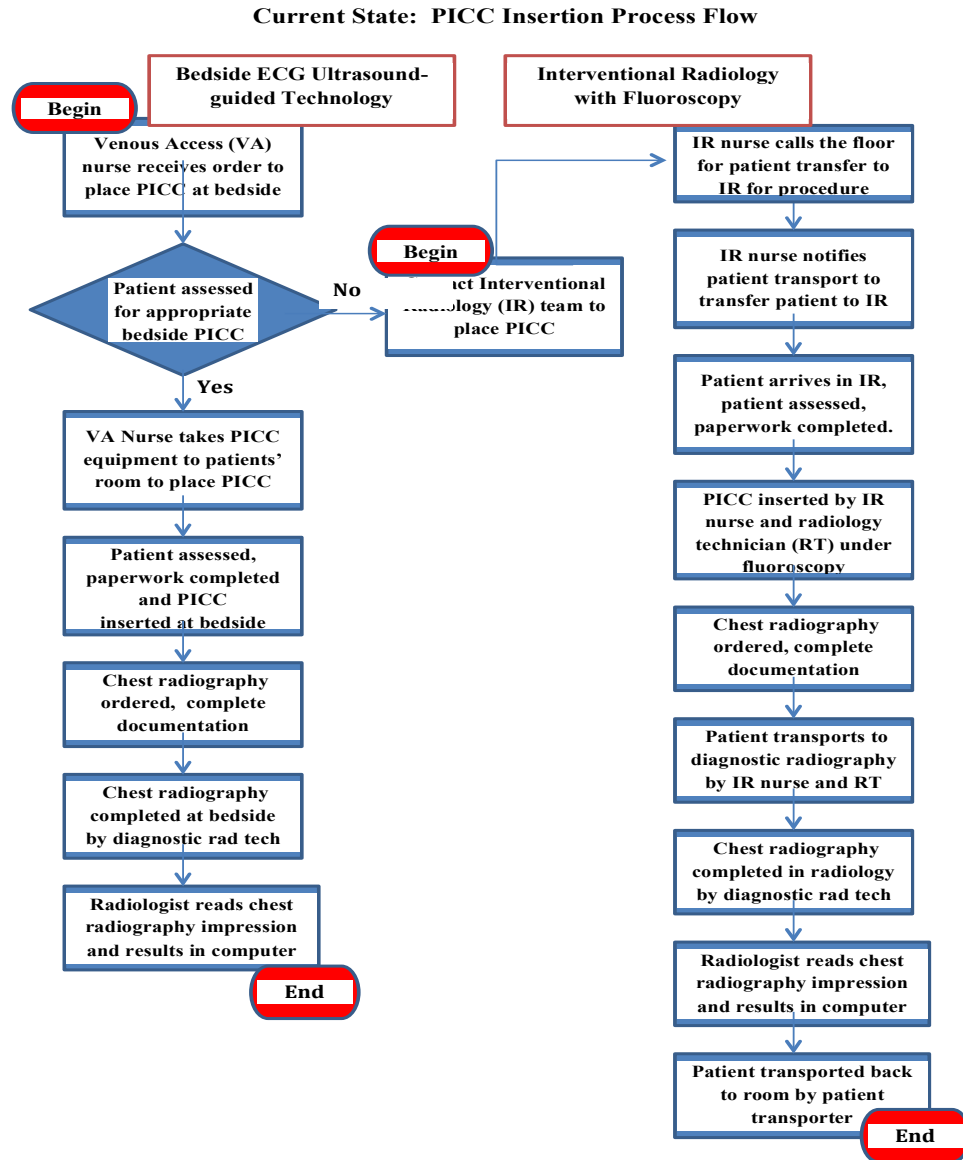
APPENDIX F

TIMELINE FOR PICC TRANSITION FROM RADIOLOGY STAFF TO VENOUS ACCESS NURSES BEDSIDE PICC INSERTION

Project Title: PICC Change Project- Bedside PICC Insertion with advanced technology		Project Sponsor: Schaffner- CNOE	
Project Lead: Morell			
Task WHAT	Responsible Party WHO	Start Date	End Date
1. Transition plan created- PICC change project proposal	Morell	1/15/14	1/30/14
1.a. Role definition of IR staff and IV staff	Morell	1/20/14	1/31/14
1.b. Work with IR on job descriptions- IV to V nurse	Morell/SM/HR Rep	2/4/14	3/3/14
1.c. Stakeholders consulted- IR & IV teams	IR and IV teams	1/20/14	4/30/14
1.d. Job description approve & title change to Venous Access Nurse	HR Rep/CNOE	6/2/14	6/13/14
1.e. Meet with each VA nurse and sign new job description	Morell	6/4/14	6/6/14
1.f. Receive approval from CNOE to move forward with project transition	CNOE/Morell	1/15/14	1/15/14
1.g. Logistics Meeting	IR staff/VN team/Morell	6/3/14	10/2/14
2. Develop & approve IV Decision Tree- systemside	MD Champion- System wide & workgroup	3/3/14	5/2/14
3. Financial- workbook request for new technology/equipment	Morell	4/1/14	8/15/14
3.a. Quote received from company	VA RN	4/7/14	4/11/14
3.b. Equipment approved/ordered	Finance/Bioxel	9/2/14	9/5/14
3.c. Biomed Equipment inspection, passed and ready for use	Biomed	10/2/14	10/6/14
4. Train educate PICC bedside insertions	CNS Staff/Morell	9/10/14	10/24/14
4.a. Online education- 3 CEUs	VA Nurses	9/10/14	9/30/14
4.b. Coordinates on-site CNS classes	Morell	9/15/14	9/16/14
4.c. Didactic 3 hours- 4 staff	VA Nurses	10/6/14	10/6/14
4.d. Hands-on training- 3 days	VA Nurses	10/7/14	10/9/14
4.e. CNS observe 5 PICC bedside inserts by VA RN, sign off's completed	CNS- Rep	10/7/14	10/24/14
4.f. V Nurses work together on PICC insertions	VA Nurses	10/25/14	2/1/15

APPENDIX G

PICC PROCESS CURRENT STATE



Knox, L., & Brach, C. (2013). *Practice Facilitation Handbook: Training modules for new facilitators and their trainers*. Module 5: Mapping and redesigning workflow. Rockville, MD. Agency for Healthcare Research and Quality. Retrieved from <https://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/mod5.html/>

APPENDIX H

PERMISSION TO REPRINT FIGURE OF LEWIN'S CHANGE THEORY

From: Vicki Brentnall [REDACTED]
Sent: Friday, October 13, 2017 6:05 AM
To: Dr. Laura Portolese : Vicki Brentnall; Elizabeth Morrell
Subject: Re: Fw: Permission to reprint Lewin's Change Theory Image

Hello Ms. Morrell,
Sorry for the delay in responding. Yes, you can use this image as long as you credit it properly, as it appears you have. Permission is granted.
Thanks for your interest in our titles.

Best,
VICKI BRENTNALL
Digital Content Manager [REDACTED]
[REDACTED] flatworld.com

On Thu, Oct 12, 2017 at 2:09 PM, Dr. Laura Portolese wrote:
Hi Ms. Morrell,
I have copied Vicki at Flat World to see if we own the rights to this image, as I am not sure. The content is obviously from Lewin's model, but I believe Flat World created the figure--so I'm not sure how this works in terms of our ability to grant permission to use it. Vicki, can you clarify and/or grant permission? Thank you, Laura

From: Elizabeth Morrell [REDACTED]
Sent: Thursday, October 12, 2017 9:37 AM
To: Laura Portolese [REDACTED]
Subject: Permission to reprint Lewin's Change Theory Image

Hello Dr. Portolese,
I am working on a DNP project regarding change theory at Western University of Health Sciences in Pomona, CA. I would like your permission to use your image in my project. I think it is simple and clearly describes the model. Please let me know if you grant permission and I will credit you in my study. Thank you. Elizabeth Morrell, RN, MSN
Laura, P., D. (2015) *Human Relations*, v. 1.0 [online] available from
<http://catalog.flatworldknowledge.com/bookhub/reader/6531?e=portolediasumrel_1.0-ch02_s02&qt; [20 July 2015]

APPENDIX I

EVIDENCE RATING SCALES

Johns Hopkins Nursing Evidence-Based Practice Appendix D: Evidence Level and Quality Guide

Evidence Levels	Quality Ratings
Level I Experimental study, randomized controlled trial (RCT) Explanatory mixed method design that includes only a level I quantitative study Systematic review of RCTs, with or without meta-analysis	Quantitative Studies A High quality: Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence. B Good quality: Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence. C Low quality or major flaws: Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn.
Level II Quasi-experimental study Explanatory mixed method design that includes only a level II quantitative study Systematic review of a combination of RCTs and quasi-experimental studies, or quasi-experimental studies only, with or without meta-analysis	Qualitative Studies No commonly agreed-on principles exist for judging the quality of qualitative studies. It is a subjective process based on the extent to which study data contributes to synthesis and how much information is known about the researchers' efforts to meet the appraisal criteria. <i>For meta-synthesis, there is preliminary agreement that quality assessments of individual studies should be made before synthesis to screen out poor-quality studies¹.</i> A/B High/Good quality is used for single studies and meta-syntheses ² . The report discusses efforts to enhance or evaluate the quality of the data and the overall inquiry in sufficient detail; and it describes the specific techniques used to enhance the quality of the inquiry. Evidence of some or all of the following is found in the report: <ul style="list-style-type: none"> – Transparency: Describes how information was documented to justify decisions; how data were reviewed by others, and how themes and categories were formulated. – Diligence: Reads and rereads data to check interpretations; seeks opportunity to find multiple sources to corroborate evidence. – Verification: The process of checking, confirming, and ensuring methodologic coherence. – Self-reflection and -scrutiny: Being continuously aware of how a researcher's experiences, background, or prejudices might shape and bias analysis and interpretations. – Participant-driven inquiry: Participants shape the scope and breadth of questions; analysis and interpretation give voice to those who participated. – Insightful interpretation: Data and knowledge are linked in meaningful ways to relevant literature. C Lower-quality studies contribute little to the overall review of findings and have few, if any, of the features listed for High/Good quality.
Level III Nonexperimental study Systematic review of a combination of RCTs, quasi-experimental and nonexperimental studies, or nonexperimental studies only, with or without meta-analysis Exploratory, convergent, or multiphasic mixed methods studies Explanatory mixed method design that includes only a level III quantitative study Qualitative study Meta-synthesis	

Evidence Levels	Quality Ratings
Level IV Opinion of respected authorities and/or nationally recognized expert committees or consensus panels based on scientific evidence Includes: <ul style="list-style-type: none"> – Clinical practice guidelines – Consensus panels/position statements 	A High quality: Material officially sponsored by a professional, public, or private organization or a government agency; documentation of a systematic literature search strategy; consistent results with sufficient numbers of well-designed studies; criteria-based evaluation of overall scientific strength and quality of included studies and definitive conclusions; national expertise clearly evident; developed or revised within the past five years B Good quality: Material officially sponsored by a professional, public, or private organization or a government agency; reasonably thorough and appropriate systematic literature search strategy; reasonably consistent results, sufficient numbers of well-designed studies; evaluation of strengths and limitations of included studies with fairly definitive conclusions; national expertise clearly evident; developed or revised within the past five years C Low quality or major flaws: Material not sponsored by an official organization or agency; undefined, poorly defined, or limited literature search strategy; no evaluation of strengths and limitations of included studies, insufficient evidence with inconsistent results, conclusions cannot be drawn; not revised within the past five years
Level V Based on experiential and nonresearch evidence Includes: <ul style="list-style-type: none"> – Integrative reviews – Literature reviews – Quality improvement, program, or financial evaluation – Case reports – Opinion of nationally recognized expert(s) based on experiential evidence 	Organizational Experience (quality improvement, program or financial evaluation) A High quality: Clear aims and objectives; consistent results across multiple settings; formal quality improvement, financial, or program evaluation methods used; definitive conclusions; consistent recommendations with thorough reference to scientific evidence B Good quality: Clear aims and objectives; consistent results in a single setting; formal quality improvement, financial, or program evaluation methods used; reasonably consistent recommendations with some reference to scientific evidence C Low quality or major flaws: Unclear or missing aims and objectives; inconsistent results; poorly defined quality improvement, financial, or program evaluation methods; recommendations cannot be made Integrative Review, Literature Review, Expert Opinion, Case Report, Community Standard, Clinician Experience, Consumer Preference A High quality: Expertise is clearly evident; draws definitive conclusions; provides scientific rationale; thought leader(s) in the field B Good quality: Expertise appears to be credible; draws fairly definitive conclusions; provides logical argument for opinions C Low quality or major flaws: Expertise is not discernable or is dubious; conclusions cannot be drawn

Dang, D., & Dearholt, S. L. (Eds.). (2017). *Johns Hopkins nursing evidence-based practice: Model and guidelines* (3rd ed.). Baltimore, MD: Sigma Theta Tau.