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The Impact of High-Fidelity Simulation Practice on the Perceived Confidence of Experienced ICU Nurses

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Executive Summary

Problem: High-acuity and shorter lengths of stay (LOS) are creating high-risk low-volume situations for patient care and increased risk for poor patient outcomes.

PICO **Population**: Experienced ICU nurses

Intervention: Simulation scenario practice utilizing a high-fidelity manikin

Comparison: Level of self-perceived confidence before and after simulation practice

Outcome: Improved performance of high-risk low volume IABP patient care skills

Question: Will repeat simulation practice improve the experienced ICU nurses' perceived self-confidence in performing high risk low-volume IABP patient care skills?

Purpose: The purpose of this study was to investigate the relationship between simulated skill practice and self-perception of confidence, comfort with role, and competence in performing high-risk, low-volume patient care skills.

Objectives:

1. Participants perceived confidence level will be increased as evidenced by improved scores in the post simulation evaluation.
2. Participants perceived comfort level in knowing their nursing role will be increased as evidenced by improved scores in the post simulation evaluation.
3. Participants perceived level of competence will be increased as evidenced by improved scores in the post simulation evaluation

Goal(s): To identify a safe alternative to actual patient experiences to provide the hand-on practice time to gain mastery and maintain competency of high-risk low-volume patient care skills.

Plan: This project utilized a pre-post evaluation process to measure the participant's self -perceptions.

Outcomes and Results: Although limited by participant size the data showed a positive correlation between simulation practice and improved self-perceptions of comfort with role and competence. The data did not find a positive correlation between skill practice and perceived level of confidence.

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The Doctor of Nursing Practice (DNP) program "culminates with a scholarly project, one that utilizes evidence to improve practice, processes or outcomes" (Zaccagnini & White, 2014, p.64). This project studied the relationship between repeated simulation practice of high-risk low-volume patient care skills and the confidence level perceived by the intensive care unit (ICU) staff nurse.

High-risk low volume patient care skills are defined as "therapies that are practiced infrequently and yet carry an increased risk to patients because of their complexity" (Helman, S, Lisanti, A., Adams, A., Field, C., & Davis, K., 2016, p. 33). Confidence in performing skills comes with repetition and practice of those skills; this theory of skill acquisition is the foundation for Benner's theory of Novice to Expert (1984) for nursing practice. If skills are seldom used, the nurse will most likely not build the confidence required to deliver safe care (Banks, Gilmartin, & Fink, 2010); therefore, confidence must play a major role in competence (see Appendix A: Concept Model).

Problem Recognition and Definition

Purpose

The purpose of this study was to investigate the relationship between skill practice and perceived confidence in performing high-risk, low-volume patient care skills and whether simulation can be effectively substituted for actual patient care experiences. The results could potentially drive change in how Professional Nurse Staff Development training is delivered.

Problem Statement

The current healthcare environment is one of high-acuity and shorter lengths of stay (LOS), creating high-risk low-volume situations for patient care and increased risk for poor patient outcomes (Lucas, 2013). A lack of patient experiences for nurses to regularly perform

newly obtained high-risk patient skills, creates a quandary of how achieving skill mastery and then maintaining ongoing competency will be accomplished (Helman, S, Lisanti, A., Adams, A., Field, C., & Davis, K., 2016). The National Council of State Boards of Nursing (NCSBN) (Hayden, Smiley, Alexander, Kardong-Edgren, & Jefferies, 2015) reported, human patient simulators can be used effectively to fill patient care experience gaps.

PICO

The PICO mnemonic is used to frame a research question and represents the four most important elements; population, intervention, comparison, and outcome. (Polit, 2010).

Population: Experienced ICU nurses

Intervention: Simulation scenario practice utilizing a high-fidelity manikin

Comparison: Three practice scenarios in which participants identified and acted upon a patient complication of intra-aortic balloon pump (IABP) therapy.

Outcome: Improved self-perceptions related to confidence of high-risk low volume IABP patient care skills.

Question: Will repeat simulation practice improve the experienced ICU nurses' self-perceptions related to confidence in performing high risk low-volume IABP patient care skills?

Significance, Scope, and Rationale

It is not clear why simulation is seldom utilized for professional nurses' education compared to the utilization for pre-licensure education. Perhaps, the educators using simulation in professional nurse staff development are not publishing their findings as often as academia (Hallenbeck, 2013). Either way, there is very little published research regarding use of simulation with this population.

Traditionally, professional nurses are given an education piece then a competency checklist is completed while an educator evaluates a return demonstration. This checklist goes

into the nurse's education file and she or he is deemed competent (Wright, 2007). Unfortunately, a checklist measures one moment in time, without frequent practice it does not mean the nurse is competent to provide such care over time (Benner, 1984). Iatrogenic mishaps have become the third leading cause of death in the US (Makary, 2016), educators must work to find alternative teaching and learning modalities that support safe and competent care.

Theoretical Foundation

Bandura's Social Learning theory is founded in the idea people learn through observing others. This theory describes three basic models of observational learning;

1. "A Live Model, which includes an actual person performing a behavior.
2. A Verbal Instruction Model, which involves telling of details and descriptions of a behavior.
3. A Symbolic Model, which includes either a real or fictional character demonstrating the behavior via movies, books, television, radio, online media and other media sources" (Sincero, 2008, ¶3).

This project utilized all three modeling techniques for observational learning. The didactic video presented verbal instruction on the possible side effects of IABP therapy and then describes the desired actions or behaviors of the nurse in response. In addition, there was a video of a nurse completing a head-to-toe assessment on a standardized patient to model the desired actions of the nurse in assessing this type of patient. Lastly, the project includes a symbolic model; a high-fidelity human patient simulator for the nurse to practice the newly learned skills on.

Benner's theory of Novice to Expert (1982) utilized the Dreyfus model of skill acquisition and applied it for clinical competence in nursing. Benner's theory speaks to the confidence is gained by the nurse in repeating patient care skills; she states, "the novice nurse

lacks the confidence to demonstrate safe practice" (Benner, p. 406). If experiences for such patient care skills are not available for the nurse, the NCSBN tells us we could we could safely use simulation to develop the confidence Benner touts is necessary to deliver safe care.

Adult Learning principles were also utilized for this project by offering different modalities and then reinforcing the new education with hands-on practice. A study by Curran, Fleet, and Greene (2012) found research supports resuscitation skills can begin to deteriorate in as little as two weeks when adults are not provided with hands-on practice time outside of the classroom. In Ericsson's theory of deliberate practice for expert performance he discusses the difference of every day and professional development skill acquisition. According to this theory every day skills are obtained quickly; however professional skills achievement may take "years or even decades of experience" (Ericsson, 2004, p. S70).

Literature Selection

Journal articles were retrieved from five separate databases using the key words simulation, staff development, competency assessment, and IABP. A total of 30 articles were retrieved; CINAHL yielded 13 articles, EBSCO Host yielded five, Academic Search Premier yielded nine articles, Journals at Ovid yielded two articles and Science Direct yielded one article. Because so few recent articles were found, some articles older than five years were included. The evidence was distilled using Houser's (2011) levels of evidence. The majorities of articles reviewed were evidence level VII, non-research and based on opinion (Table 1). (Appendix A: Systematic Review).

Table 1. Levels of Evidence

Adapted from Melnyk & Fineout-Overholt (2005) Levels of Evidence.

Strength	Level	Design	# Articles Returned

High	**Level I**	Evidence from a systematic review of all relevant randomized controlled trials (RCT's), or evidence-based clinical practice guidelines based on systematic reviews of RCT's.	1
	Level II	Evidence from at least one well-designed RCT	1
	Level III	Evidence obtained from well-designed controlled trials without randomization, quasi-experimental.	4
	Level IV	Evidence from well-designed case-control and cohort studies	1
	Level V	Evidence from systematic reviews of descriptive and qualitative studies.	0
	Level VI	Evidence from a single descriptive or qualitative study.	8
Low	**Level VII**	Evidence from the opinion of authorities and/or reports of expert committees.	15

Scope

An abundance of publications was retrieved on the successful use of simulation in pre-licensure nursing education but very little on its use in post-licensure education for competency maintenance of rarely used patient care skills. This acute lack of evidence on simulation use for Professional Nurse Staff Development was one of the driving forces for this study.

Review of Evidence

Background of the Problem

Donna Wright (2007) touts nurses do not lose under-utilized skills over time; she compares the retention of skills to those of riding a bike. While this may be true for skills the nurse has performed over and over again, this is not necessarily the case for newly acquired skills (Benner, 1984).

Simulation use in nursing can be traced back as early as 1847 including mechanical manikins, task trainers, fully jointed skeletons, and anatomical models. The first full size manikin was produced in 1911 for use in nursing education. (Hayden, Smiley, Alexander,

Kardong-Edgren & Jeffries, 2015). Nursing schools traditionally use simulation for pre-licensure training and the NCSBN (National Council of State Boards of Nursing) recently endorsed replacing up to 50% of clinical time with simulation (Hayden et al., 2015). Simulation has been embraced early on for nursing schools, anesthesia, and for medicine; however, the evidence of simulation use in Professional Nurse Staff Development is lacking.

As patient acuity rises, and lengths of stay shorten, high-risk low volume patient care situations present themselves. Traditionally nurses are taught new skills, a competency evaluation is completed, and the organization deems the nurse competent to perform the new skill (Wright, 2007). Unfortunately, long periods of time may go by before the nurse is able to perform this new skill and when an opportunity does present itself the nurse may shy away because he or she does not feel confident to provide such care (Lucas, 2013). This lack of patient care experiences presents a high-risk situation for patient safety and the opportunity for developing confidence in the newly acquired skill much more challenging.

Systematic Review of the Literature

The databases offer a plethora of publications about the use of simulation in nursing education for students. Unfortunately, there are very few publications on the use of simulation for experienced nurses. Lucas (2013) writes about the limited literature regarding high-fidelity simulation (HFS) and its potential use in staff development. This author further discusses how HFS offers opportunities for use in continued competency and confidence building by offering experiential learning for nurses within a controlled environment. Lucas states nothing can replace real patient experiences however; HFS can closely model them and offer opportunities to practice thus increasing confidence and competence.

Search results in the databases returned a publication on the use of HFS to improve nursing competency in critical care. This prospective open-label study by Abe, Kawahara,

Yamashina, and, Tsuboi (2013) was conducted in Japan with 24 experienced nurses. Utilizing Benner's Novice to Expert theory each nurse was rotated through repeated simulation stations and their clinical performance was evaluated using a rubric before and after sessions. The participants also completed a self-assessment using the Teamwork Activity Inventory Nursing Scale (TAINS) to assess their nontechnical skills. Study results failed to show a relationship between the groups with rubric scores however; the data analysis did uncover a statistical difference in the confidence as a team member score.

Blum, Borglund, and Parcells (2010) published a research study using the Lasater Clinical Judgment Rubric to evaluate the impact of HFS on confidence and competence in nursing students. Using a quasi-experimental design, they studied 53 nursing students of which 16 were placed in a control group and received traditional education. Over 13 weeks the students were evaluated by instructors using the rubric and upon data analysis there was no statistical difference between the two groups; however, the authors report a trend of improved confidence in the simulation group.

In a 2008 quasi-experimental, pre-test and post-test study, Brannan, White, and Bezanson studied the effect of learning on nursing students utilizing different instructional methods. One group of students received instructional method with a human patient simulator and the other group received instruction in a traditional classroom setting. These researchers used two separate tools to evaluate the participants; one to measure knowledge and clinical performance and the other, a Likert scale, to measure confidence. The data analysis failed to show a difference in confidence between the two groups however; it did show confidence levels significantly improved in both groups with the practice of skills.

Smith and Roehrs (2009) used a descriptive correlation study design to examine the effects of simulation experiences on student satisfaction and self-confidence. This study utilized

two instruments from the National League for Nursing for assessment of the 68 participants. Data analysis failed to show a statistical significance for the outcomes of satisfaction and self-confidence. The researchers felt the demographics for the participants may have been a factor however upon further inspection they found no significance for the demographics.

Yuan, Williams, and Fang (2012) offer a systematic review of 24 publications published between 2000-2011 on the topic of HFS and impact on student confidence and competence. They report in the results of a meta-analysis, high-quality random control trials with large sample sizes are lacking. They also report the qualitative studies reviewed offered more positive results; however, the evidence to support HFS to improve student confidence remains insufficient.

In all of the articles reviewed, authors discuss the limitations of their research and the need for further study. The lack of literature on the use of simulation in staff development and the abstruse results for research with nursing students clearly demonstrates the need for further study with larger sample sizes.

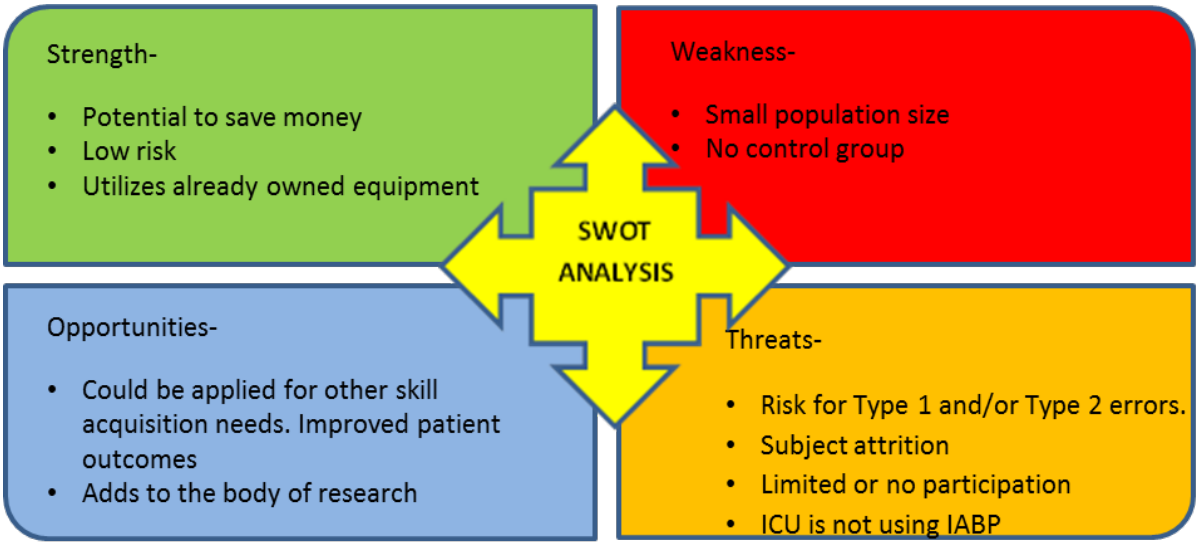
Project Plan and Evaluation

Market/Risk Analysis

First introduced in the 1960's by Albert Humphrey, the SWOT framework provides an opportunity to identify internal forces: strengths and weaknesses and external forces: opportunities and threats (Mind Tools, 2015). The major strength of this project is the return on investment; with a small initial investment this project stands to save millions of dollars (Fig. 2). (Lucas, 2013). In addition, this project provides a safe environment for learning where mistakes can be made utilizing simulation and without patient risk (Helman, S, Lisanti, A., Adams, A., Field, C., & Davis, K., 2016). The weaknesses include a small population number, attrition or limited participation, and no control group which can all result in Type 1 and Type 2 errors which are potential threats (Polit, 2010) (Fig. 1). This project provides ample opportunities to

provide a template for other high-risk low volume patient care skill needs and growing the body of current research.

Fig. 1. Project Strengths, Weaknesses, Opportunities, Threats (SWOT)



Driving and Restraining Forces

This project began with a request from the field; the facility was looking for education and learning opportunities for staff nurses and intra-aortic balloon pump (IABP) also called counterpulsation, patient care skills. After completing a formal needs assessment at this facility and then querying other like facilities, it became overwhelmingly clear the staff nurses wanted and needed a modality to develop and maintain IABP patient care skills.

Some of the restraining forces for this project included the closure of the Internal Review Board (IRB) at the intended study facility. This closed IRB caused a delay in study completion; forcing completion at an alternate facility. This delay and change in venue may have negatively affected study participation.

Need, Resources, and Sustainability

This project uses a high-fidelity simulator (HFS) previously purchased and maintained for each facility under the Veterans Health Administration (VHA) national simulation program.

The seven-year shelf life of this HFS was factored into the purchase and sustainment and is utilized by many different disciplines. Nursing uses this $100,000 manikin approximately 10% of the time; this would be a $1400 annual cost for sustainability. The intra-aortic balloon costs approximately $200 and can last several years depending on use and storage. The patient care items required for fidelity are inexpensive and only cost about $50 total; they can be re-used throughout the training. IABP patient care has not changed in the past 25 or more years so the chances of needing to update the didactic video would be small (Piper & Bowden, 2013). Sustainment for this project would be less than $2000 annually (see Appendix C: Budget & Resources).

Feasibility/Risks/Unintended Consequences

To test the feasibility of this study, a pilot study was completed. This pilot allowed the project team to test the study components with a group of participants and then make necessary adjustments based on feedback. One unanticipated risk encountered during the pilot was the acute exacerbation of a participant's post-traumatic stress disorder. When we provided the scenario to the participant, he disclosed he had just returned to work after a life-threatening experience much like the scenario. The project team stopped the simulation and excluded him from continuing. They provided follow-up care for this participant at the facility. This feedback was utilized for participant prepping for the study to mitigate this risk.

Stakeholders and Project Team

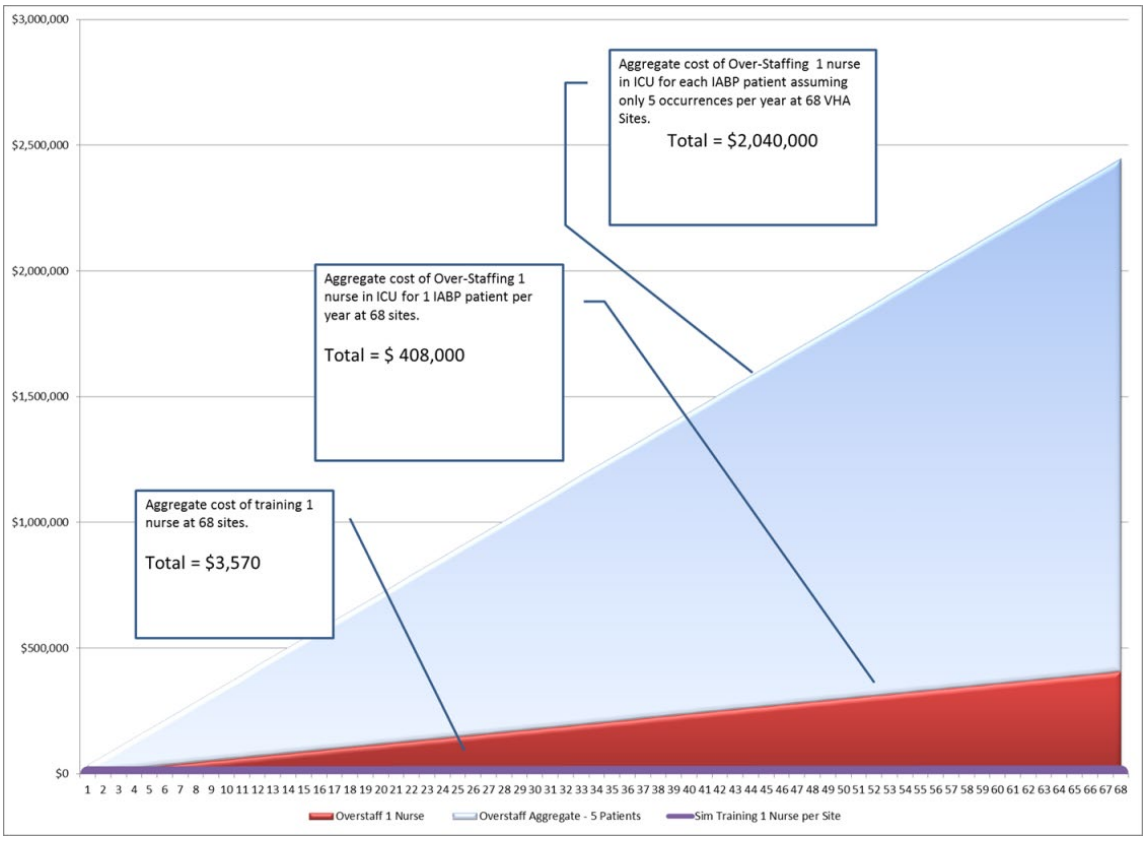
Stakeholders are defined as "persons or groups that have a vested interest in a clinical decision and the evidence that supports that decision" (AHRQ, 2014, ¶4). The stakeholders for this project include, the patient or Veteran is the primary stakeholder; receiving competent care helps prevent poor patient outcomes. The nurses delivering the hands-on care; the more we can improve confidence and competence the better our patient outcomes should be. Providers need

concise and relevant information to plot a course of patient care and this project reinforces the importance of good interdisciplinary communication. The facility is ultimately responsible for the competence of the staff they employ and overall patient safety. Lastly, tax payers; the Veterans Health Administration is funded with tax payer dollars and that investment should be maximized and utilized wisely. The project team includes the following: the DNP student as the Team Lead, Project Mentor: Dr. Janet Sprehe, a Simulation Technician, intensive care unit (ICU) Staff nurses, ICU Nurse Educator: Kathleen Manley, and the Project Chair: Dr. Cris Finn.

Cost-Benefit Analysis

Currently, the ICU staffs an additional nurse on each shift to provide hands-on practice for those nurses needing experience. This extra nurse works with the IABP super-user providing 2:1 care for this patient. The average staff nurse in the VHA makes approximately $35/hour; there is a 35% off shift and weekend differential. The average IABP patient receives treatment for three to six days; some longer. Considering these factors and the average Length of Stay (LOS) for an IABP patient in the non-surgical ICU average staffing cost is around $12,000 per IABP patient which is an additional $6000 cost for extra staffing. Utilizing an HFS manikin for this high-risk patient care skill practice could alleviate the need for over staffing; saving thousands of dollars per patient and millions of dollars annually (Cost Benefit Analysis, Fig. 2). Other benefits include improved skill set for the staff nurses which have the potential for improving patient outcomes. If successful, this model could be used for other high-risk low volume patient care skills.

Figure 2. Cost-Benefit Analysis



Mission/Vision/Goals

The mission of this project was to highlight the implications for simulation use in Professional Nurse Staff Development for maintaining high-risk low-volume patient care skills. The vision of this project was to drive change in the current approach to competency maintenance for Professional Nurse Staff Development because of the potential impact it has on improving patient outcomes and patient safety. The goal of this project was to define the relationship between confidence and competence and additionally to create a training template that could be used for any high-risk low-volume patient care skill without the need to remove nursing staff from the patient care area to attend a simulation center. This project looked to change the way educators approach competency maintenance for Professional Nurse Staff Development.

Project Goals/Objectives

Process/Outcomes Objectives. The participants of this project completed a one-hour eLearning course that provides a review of patient anatomy related to IABP therapy; it discusses the three most common complications patient's experience when receiving IABP therapy and the appropriate nursing interventions for each. After completing the didactic training, the participants completed three brief patient care scenarios with an HFS based on the didactic learning they completed. This project utilized a pre-post evaluation process to evaluate the participant's self-perceived level of confidence, comfort with the nurse role, and level of competence in providing the practiced patient care skills.

Program Objectives.

1. Participants perceived confidence level will be increased as evidenced by improved scores in the post simulation evaluation.
2. Participants perceived comfort level in knowing their nursing role will be increased as evidenced by improved scores in the post simulation evaluation.
3. Participants perceived level of competence will be increased as evidenced by improved scores in the post simulation evaluation.

Logic Model

The inputs for this project (see Appendix D: Logic Model) include the team members and equipment needed for implementation; constraints include having ICU bed space available, patient acuity at the time for staff to step away from patient care, staffing in general, facility buy-in, and distance away from researcher. Activities include coordinating with the ICU and recruitment for participation, coordinating simulation time with the staff, and obtaining needed equipment. The outputs included providing advanced training for participants. Short term outcomes included confidence improvement, decreased anxiety, and improved patient outcomes,

long term included nurses being more likely to seek out high-risk patient care opportunities and improved interdisciplinary communication in the ICU. Improved patient outcomes and patient safety along with a financial savings will provide a positive impact on the facility.

Population/Sampling Parameters

The population for this study was experienced ICU nurses, having at least one year of ICU experience and who completed initial counterpulsation training but had limited experiences in caring for these patients. The sampling for this project utilized a convenience sample from those who met the inclusion criteria from the current ICU staff. Because this project has a specific inclusion criterion, the facility nurse educator sent alerts to the staff nurses meeting the inclusion requirements. Recruitment was completed one month prior to planned data collection and data collection occurred during a one-month time frame (see Appendix E: Timeline).

Setting

Data collection occurred in the Cardiac Care Unit (CCU) of a complex care VA medical center in the Southern United States. These 12 beds, level 1A critical care unit, averages one to two IABP patients annually. The HFS was brought into the CCU and utilized a patient bed space without disrupting patient care. This in-situ approach eased participant completion by not taxing staff coverage and Veteran care.

Design Methodology and Measurements

This was a descriptive study involving pre- and post- simulation measures of self-confidence, comfort with the nurse's role in delivering the care, and self-perceived level of competency, to provide care for a patient receiving counterpulsation therapy. Each participant completed an online training module which reviewed the three most common IABP patient complications (Piper & Bowden, 2013) and the necessary nursing interventions required for each. After completing the didactic training, each participant was scheduled to complete 3, 10-

minute scenario practice sessions. The pre- and post-evaluations utilized a seven-point Likert scale, where 0 equaled none and 7 equaled most. The evaluation tool used the Likert scale to self-assess participant perceptions related to three questions:

1. I Feel confident about my role in patient care for this scenario
2. I feel comfortable with my role in providing patient care for this scenario
3. I feel competent to provide this level of care for a real patient

Prior to starting the scenario sessions, each participant completed a pre-evaluation to score their level of self-perceptions for the Likert scale questions. After each 10-minute scenario, the participants completed a post-evaluation to score their level of self-perceptions for the same questions. (Appendix F: Evaluation Questionnaire).

Instrumentation Validity/Reliability and Intended Statistics

Reliability is defined as the degree to which a tool actually measures what it was intended to measure (Polit, 2010). According to Allen and Seaman (2007), Likert Scales have been used for research data collection since the 1930's and proven valid and reliable. These authors recommend using a seven-point scale to provide the highest level of reliability (Allen & Seaman). The measurement tool utilized for this study was tested during the pilot study and resulted in a 0.923 Cronbach's Alpha score for reliability.

In an effort to manage the simulation scenario as a variable for outcomes, the simulation scenarios were reviewed by eight subject matter experts (SME) for content validity. The SME's have either presented or published in simulation and utilized a rating tool developed by the Cleveland Clinic tested for validity and reliability.

Descriptive statistics were utilized to describe, compare, and characterize the relationship between the data (Polit, 2010). Utilizing a confidence value of 0.05, a paired T-tail comparison

and a Pearson Correlation was used to analyze the interval data. The IBM SPSS software was used to calculate the statistical measures.

Data Collection and Treatment Procedures/Protocol

Prior to the study completion a pilot was completed with the nursing staff at the facility who originally requested the training. This pilot was completed to ensure validity and reliability of the planned data collection process. During the pilot eight nurses started and completed the didactic training. One participant did not meet the exclusion criteria and was not progressed to scenario completion. One participant did not continue. During the pilot, focus group feedback from participants revealed they were not familiar with the capabilities of the HFS and this unfamiliarity impacted their interactions and interventions.

For the study, thirteen participants were recruited. The eLearning module was assigned in the facility learning management system. Several issues were experienced with access to the eLearning training video which took several weeks to correct. Of the original participants recruited, five completed the didactic training and three completed the practice scenarios for data collection.

The scenario participants received an introduction to the HFS and its modeling capabilities such as peripheral pulse palpation and breath sound auscultation. Each participant completed the pre-evaluation and placed it blindly into an opaque envelope. After each scenario the participant completed a post-evaluation, each was placed blindly into the envelope and then sealed in their presence.

Protection of Human Rights

Veterans' Health Administration (VHA) Internal Review Board (IRB) (see Appendix G: IRB) and Regis University IRB approval (see Appendix H: IRB) was obtained prior to study commencement. Data was scrubbed of participant identifiers; sealed packets with all required

documents were labeled with an alphanumeric code and provided to the participants randomly. As participants completed the evaluations; they were sealed in envelopes for further protection of anonymity. All electronic files were password protected to maintain privacy.

Subjects were pre-briefed on project goals and that results would not be used for disciplinary reasons. Disclosures were provided as well as consent forms in which subjects were made aware, they could drop out at any time without repercussions and/or have negative affect on work status. (See Appendix I: Consent Form). Collaborative Institutional Training Initiative (CITI) training was completed and current for all study team members (See Appendix J &K: CITI).

Project Findings and Results

Study Results

The pre- and post-evaluation tool compared participants level of self-perceptions related to confidence in sub categories of comfort with their role and competence in completing the IABP patient care skill before and after the HFS practice. A total of 12 measurements were collected from each participant which were analyzed using the Statistical Package for the Social Science (IBM Corporation).

Program Objectives:

1. Participants perceived confidence level will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean score for this question on the pre-evaluation was 2.33 and the mean post-evaluation score for scenario one was 4.67, the mean post-evaluation score for scenario two was 5.67, and the mean post-evaluation score for scenario three was 6.0 (See Table 2). However, even with this noted increase in mean scores between pre- and post-evaluations the two-tailed test showed no statistical significance

identified between the pre-evaluation and post-evaluation scores for perceived confidence (See Table 4). In the Pearson Correlation calculation, a high correlation between the pre-evaluation and post-evaluation scores for question one was noted for scenario one only (See Table 3).

Table 2. Study Mean Scores

Pre-evaluation Mean scores	Mean	Mean Post Scenario 1	Mean Post scenario 2	Mean Post scenario 3
Question 1	2.33	4.67	5.67	6.0
Question 2	2.00	5.00	5.33	5.67
Question 3	1.33	5.00	5.00	5.33

2. Participants perceived comfort level in knowing their nursing role will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean score for question two on the pre-evaluation was 2.0 and the mean score for post-evaluation scenario one was 5.0. The mean post-evaluation score for scenario two was 5.33, and the post-evaluation mean score for scenario 3 5.67 (See Table 2). There was statistical significance noted for scenario two and three between the pre-evaluation and post-evaluation scores for perceived comfort in knowing their nursing role with *p* values of .010 and .008 respectively (See Table 4). The IBM SPSS software used did not report a calculation for the pairing between pre-question two and post question two for scenario one, even when it was repeated. The Pearson Correlation calculation for question two showed a high correlation between the pre-evaluation and post-evaluation scores for all three scenarios; scenario one showed a perfect 1.000 correlation score (See Table 3).

Table 3. Pearson Correlation Values-Study

Pre-Evaluation	Post Scenario 1			Post Scenario 2			Post Scenario 3		
	Q 1	Q2	Q 3	Q1	Q2	Q3	Q1	Q2	Q3
Question 1	.971								
Question 2		1.000			.982			.866	
Question 3			.866			.866			.996

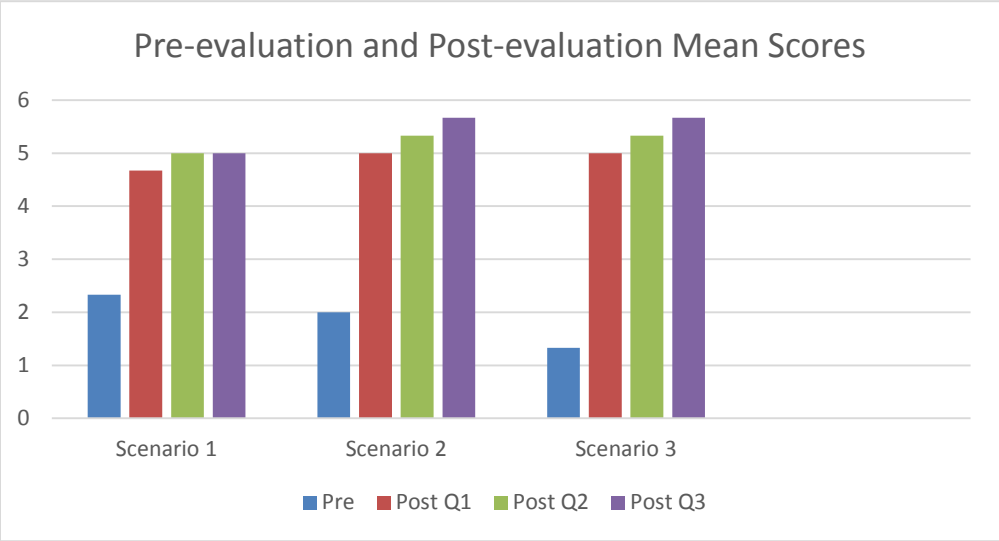
3. Participants perceived level of competence will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean pre-evaluation score for question three was 1.33. The mean post-evaluation score for scenario one was 5.0 (See Table 2). The mean post-evaluation score for scenario two was 5.0 and for scenario three it was 5.33. Although there was a marked increase between all of the pre- and post-evaluation scores, statistical significance was only noted for scenarios one and three for perceived level of competence with *p* values of .008 and .020 respectively (See Table 4). The Pearson Correlation showed a pre-evaluation and post-evaluation correlation for scenario one and three (See Table 3), (See Graph 1 Study Mean Scores).

Table 4.2-tailed Test-Study

*****The correlation and t cannot be computed because the standard error of the difference is 0.

Pre-Evaluation	Post Scenario 1			Post Scenario 2			Post Scenario 3		
	Q 1	Q2	Q 3	Q1	Q2	Q3	Q1	Q2	Q3
Question 1	.118			.109			.053		
Question 2		*			0.10			.008	
Question 3			.008			.053			.020

Graph 1. Study Mean Scores



Pilot Results

1. Participants perceived confidence level will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean score for this question on the pre-evaluation was 0.83 and the mean post-evaluation score for scenario one was 3.17, the mean post-evaluation score for scenario two was 4.17, and the mean post-evaluation score for scenario three was 5.17 (See Table 5). The two-tailed test identified a statistical significance between the pre-evaluation and post-evaluation scores for perceived confidence noting *p* values of <0.05 for all three scenarios (See Table 6). In the Pearson Correlation calculation, no significant pairing values were noted between the pre-evaluation and post-evaluation scores this object.

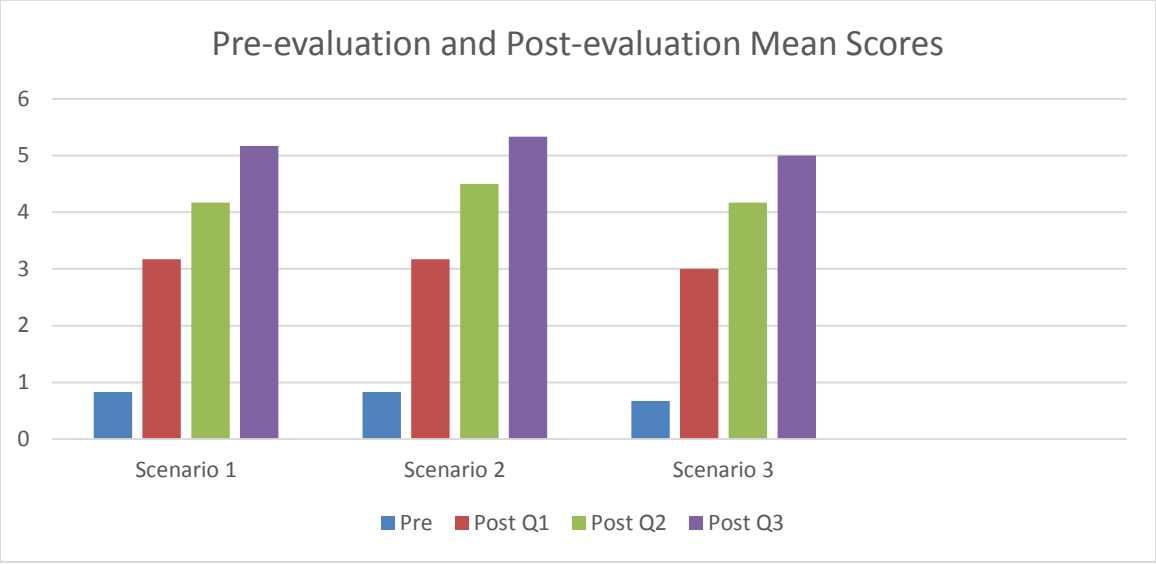
Table 5. Pilot Mean Scores

Pre-evaluation Mean scores	Mean	Mean Post Scenario 1	Mean Post scenario 2	Mean Post scenario 3

Question 1	.83	3.17	4.17	5.17
Question 2	.83	3.17	4.50	5.33
Question 3	.67	3.00	4.17	5.00

2. Participants perceived comfort level in knowing their nursing role will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean score for question two on the pre-evaluation was 0.83 and the mean score for post-evaluation scenario one was 3.17. The mean post-evaluation score for scenario two was 4.50, and the post-evaluation mean score for scenario three was 5.33 (See Table 5). The two-tailed test identified statistical significance between the pre-evaluation and post-evaluation scores for this objective with p values of <0.05 for all three scenarios (See Table 6). The Pearson Correlation calculation for question two did not show any significant correlations between the pre-evaluation and post-evaluation scores for all three scenarios (See Graph 2. Pilot Mean Scores).

Graph 2. Pilot Mean Scores



3. Participants perceived level of competence will be increased after each practice scenario as evidenced by improved scores in the post simulation evaluation. The mean pre-evaluation score for question three was 0.67. The mean post-evaluation score for scenario one was 3.0. The mean post-evaluation score for scenario two was 4.17 and for scenario three it was 5.00 (see Table 5). The two-tailed test showed statistical significance between pre-evaluation and post-evaluation scores for this objective with p values <0.05 (See Table 6). The Pearson Correlation showed no significant paired correlations between the pre-evaluation and post-evaluation

Table 6. 2-tailed Test-Pilot

Pre-Evaluation	Post Scenario 1			Post Scenario 2			Post Scenario 3		
	Q 1	Q2	Q 3	Q1	Q2	Q3	Q1	Q2	Q3
Question 1	.009			.003			.000		
Question 2		.001			.000			.000	
Question 3			.009			.000			.000

EBP Discussion

Will repeat simulation practice improve the experienced ICU nurses' self-perceptions related to confidence in performing high risk low-volume IABP patient care skills? The mean scores for both the pilot and study results showed a marked increase between pre-evaluation and post-evaluation self- assessment scores for all participants. It is reasoned the sample size for the study was too small to indicate a statistical significance in the scores for perceived confidence level; however, the data did demonstrate a statistical significance between the pre and post scores for self-perception of comfort with nursing role and level of competence. Although the increased

mean scores for the post-evaluations cannot be solely attributed to the simulation practice scenarios, the findings do support using high-fidelity simulation to improve nurses' self-perceptions related to confidence in high-risk low-volume patient care skills.

Limitations

This study was conducted at one facility, which may affect generalizability. There was a 77% attrition rate with this study and the number of participants who completed was low. This attrition rate may be attributed to the difficulties in accessing the eLearning module and the inability to repair this access issue in a timely manner. Unlike the pilot for this study, buy-in from facility leadership was lacking. The pilot was completed in a setting where the facility leadership was well-known to the researcher and completion of the pilot was collaborative between the Chief Nurse, ICU nurse-manager, ICU Nurse Educator and the project team. Accommodations were made by their leadership for staff participation.

The study setting lacked collaboration with the nurse manager as the position was vacant when planning began and had only recently been filled before study completion. When the researcher met with the new nurse manager to brief her on the planned study, she stated they rarely accept IABP patient's in their unit and it was not applicable for her nurses. When told her nurses expressed the desire to participate in the learning experience the researcher was told they really do not have time for that.

Because of distance, the majority of communication between the project team and recruits was through email which was ineffective due to slow response times from the recruits. On the day of the study, the participants stated they were too busy to step away for scenario completion. On the day of study completion, the HFS was not able to be programmed and the element of fidelity was lost. This loss of fidelity may have affected the measurements of self-confidence.

Recommendations

The positive results in the pilot express several key factors. First, more research is needed with a larger sample. Second, buy-in is key for successful participation and adequate data collection. During the recruitment phase of the study, the participants were excited to participate however, somewhere between the delays in access to the training module and the scenario data collection, their enthusiasm was waived. Perhaps the loss of enthusiasm is a symptom of a larger issue. Perhaps our Professional Nurses want to participate in training events but are not adequately accommodated by leadership to do so. As the nursing shortage increases the opportunities for time away from the bedside decreases. Patient acuity rises as does the nurse patient ratio. We, as educators, must find a better way to reach this underserved population. With further research, this could drive change in how high-risk low volume patient care skills are maintained to positively impact patient outcomes.

Conclusion

Although the data reports failed to demonstrate a statistical significance between simulated patient care practice and improved levels of self-confidence, looking at the mean score changes tell us the participants perceptions were improved. Unfortunately, due to a small sample size the data was unable to support this assumption.

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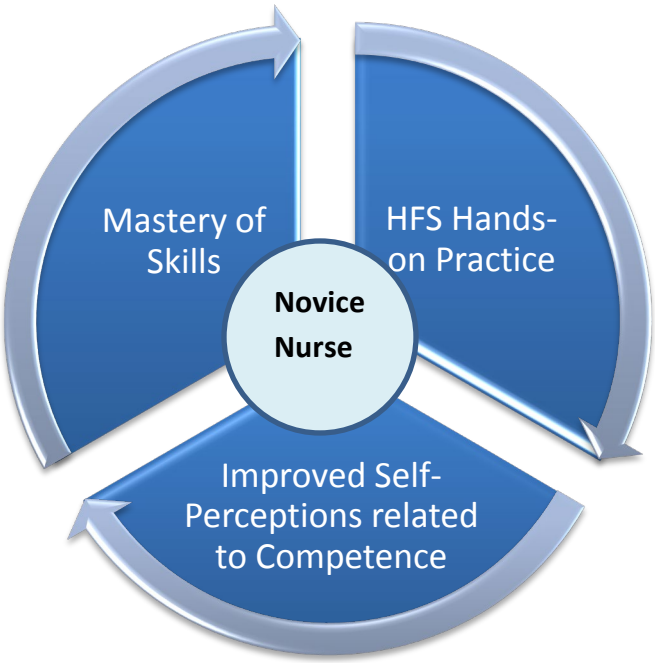
Appendix A: Concept Model



Appendix B: Systematic Review Evidence Table Format [adapted with permission from Thompson, C. (2011). Evidence table format for a systematic review. In J. Houser & K. S. Oman (Eds.), Evidence-based practice: An implementation guide for healthcare organizations (p. 155). Sudbury, MA: Jones and Bartlett.]

Article/Journal	1. Comparison of self-assessed competence and experience among critical care nurses/*Journal of Nursing Managemen*t	2. Intraaortic balloon pump: Incidence and predictors of complications in the Florence Registry/*Clinical Cardiology*
Author/Year	Jerry O'Leary/2012	Valente, S., et al./2012
Database/Keywords	CINAHL/Nursing Competency, confidence	EbscoHost/Intraaortic balloon pump (IABP) complications
Research Design	Descriptive study	Prospective study
Level of Evidence	VI One tertiary care hospital	VI One acute care hospital
Study Aim/Purpose	The study was designed to address critical care nurses' self-assessed competence.	To prospectively assess the incidence and predictors of complications in IABP patients.
Population/Sample size Criteria/Power	Population included 329 critical care nurses/Sample size totaled 101 responders	ICU patients in cardiogenic shock/481
Methods/Study Appraisal Synthesis Methods	Questionnaires were distributed to the 329 nurses/Data was analyzed using Statistical Package for Social Sciences (SPSS) version 16.0. Descriptive and correlational statistics were both used.	Multivariate logistic regression
Study tool/instrument validity/reliability	Utilized Nurse Confidence Scale (NCS) developed and utilized by another author. Copyright permission was obtained. The overall Cronbach alpha for the tool is 0.97.	Researcher created database/Not discussed
Primary Outcome Measures/Results	The total NCS scores ranged from 41-100 with a mean of 76.85 (SD 12.01). The mean scores and standard deviation for the seven competence categories ranged from 81.97 (SD 13.01) for managing situations to 71.38 (SD 16.12) for therapeutic interventions. The correlation between nursing experience and the total NCS score was r=0.27 (P<0.05).	Measured predictors of complications: inotrope use, nadir platelet count, admission lactate/100 of the 481 patients died (20.8%). All of the predictors measured all showed a positive correlation with P values <0.05 and confidence intervals of 95%.
Conclusions/Implications	Researcher concluded that study showed a positive correlation between experience and level of self-perceived competence thus supporting Benners' theory of needing 5 years' experience to reach proficient skill level./The	The researchers concluded that the degree of hemodynamic instability and platelet count were independent predictors of IABP complications and higher ICU mortality. In the past registries were used and subsequently the most common IABP

	assessment of clinical competence can recognize and reward performance, develop educational initiatives, identify need for change in practice and promote further research.	complications of limb ischemia and and major bleeding dropped to <3%. Although not stated directly, the author eludes to this registry having the same type of impact on complications.
Strengths/Limitations	Utilized a previously tested tool with an adequate score for validity. Sample provided an adequate distribution of age and years of experience. Convenience sample used; one facility among a workgroup with similar skills. Self-assessed competence cannot be directly related to actual care provided.	Large population of patients. Many variables for IABP complications were not measured such as comorbidities. Convenience sampling was used and no control or comparison group.
Funding Source	No sources of funding other than the author.	Not disclosed
Comments		
Article/Journal	3. The intra-aortic balloon pump: A nursing care study/*British Journal of Cardiac Nursing*	4. A survey of nurses' perceived competence and educational needs in performing resuscitation/*Journal of Continuing Education in Nursing*
Author/Year	Piper, R. & Bowden, T./2013	Roh, Y., Issenberg, B., Chung, H., Kim, S., & Lim, T./2013
Database/Keywords	EbscoHost/IABP Nursing	EbscoHost/Nursing competency
Research Design	Non-research Case Study	Cross-sectional descriptive survey
Level of Evidence	VII-Evidence from opinion of authority	IV Well designed case-control
Study Aim/Purpose	Describe appropriate nursing care of this patient population	To identify perceived competence and educational needs and to examine the factors that influenced perceived competence in resuscitation skills.
Population/Sample size Criteria/Power	One ICU patient/No sample size	Hospital nurses from non-critical care areas at 11 separate hospitals in one city/502/Power of 0.95 using F test.
Methods/Study Appraisal Synthesis Methods	None	Utilized a convenience sampling method. original 540 questionnaires returned 98% and 29 were excluded for incomplete data =502. Utilized a 5-point Likert scale. Descriptive statistics and regression analysis were calculated using SPSS software. Multiple linear regression analysis with stepwise method to identify factors of influence.
Study tool/instrument validity/reliability	None	Researcher designed tool based on 3 previously utilized and published tools. Chronbach's alpha was 0.947 for the total scale
Primary Outcome Measures/Results	None/Educational article for appropriate nursing interventions for the IABP patient	Nurses rates self confidence in post-resuscitation care at the lowest. Factors showing a positive correlation in influencing perceived competence in resuscitation included work duration,

		usefulness of simulation and recent code experience with P values <0.001. Work duration was more significant than the other variables.
Conclusions/Implications	IABP is a high-risk patient intervention appropriate nursing care is vital for improved patient outcomes	Effective instructional strategies are needed to ensure high-quality resuscitation performed by staff nurses. Perceived competence in this area was found to be suboptimal. Authors recommend a simulation-based resuscitation training curriculum.
Strengths/Limitations	Well referenced nursing interventions/Not a study, low level of evidence	Large sample size from multiple locations/Self-reported data rather than objective structured evaluation, researcher notes evidence of feeling confident and expressing confidence were not necessarily the same on using the self-evaluation. Also discuss ethnic limitations due to the level of modesty in that culture.
Funding Source	Not stated	Not disclosed
Comments		
Article/Journal	5. Promoting continuing competence and confidence in nurses through high-fidelity simulation-based learning/*The Journal of Continuing Education in Nursing*	6. Intensive care unit nurses' evaluation of simulation used for team training/ *British Association of Critical Care*
Author/Year	Lucas, A./2013	Ballangrud, R., Hall-Lord, ML., Hedelin, B., & Persenius, M./2013
Database/Keywords	CINAHL/Competency, confidence, simulation	CINAHL/Simulation, team training, nurses, intensive care, patient safety
Research Design	Non-research article	Questionnaire evaluation
Level of Evidence	VII Professional opinion of authority	VI Single descriptive study
Study Aim/Purpose	Describe how high-fidelity simulation can be used to enhance patient safety.	To implement a simulation-based training program and to investigate ICU nurses' evaluation of the simulation.
Population/Sample size Criteria/Power	None	ICU RN's from 7 separate hospitals/Convenience sample of 63/RN's who wanted to participate/Not disclosed
Methods/Study Appraisal Synthesis Methods	None	Questionnaire, 5 item Likert scale/ Measured nurse's satisfaction rates with simulation training
Study tool/instrument validity/reliability	None	NLN Nursing Education Simulation Framework, Satisfaction with Learning, the Self-Confidence in Learning Scale, and the Education Practices Simulation Scale/Chronbach's *alpha* for all ranged from .70-.93 Simulation design scale to evaluate simulation design/development
Primary Outcome Measures/Results	None	Nurses were highly satisfied with simulation-based training Descriptive statistics displaying frequencies, percentages, means, and standard deviations/Statistical significance

Conclusions/Implications	Nurses of all competency levels would benefit from simulation scenarios where they can practice the skills needed to strengthen clinical performance in a safe environment.	High degree of satisfaction and positivity reflected in evaluations. Years of experience in ICU and previous simulation experience may influence satisfaction level.
Strengths/Limitations	Well referenced information/Non-research; opinion only	Valid and reliable tools, validated scenarios/Small sample size, no control group
Funding Source	Not disclosed	Laerdal Foundation for Acute Medicine
Comments		Team training scenarios
Article/Journal	7. Effectiveness of high-fidelity simulation for pediatric staff nurse education/*Pediatric Nursing*	8. Simulation basics: How to conduct a high-fidelity simulation/*AACN Advanced Critical Care*
Author/Year	Bultas, M., Hassler, M., Ercole, P., & Rea, G./2014	Willhaus, J./2016
Database/Keywords	CINAHL/Simulation, nursing, staff development, competency	CINAHL/Simulation, staff development, simulation operations
Research Design	Pre-test Post-test control group	Non-research
Level of Evidence	III Quasi-experimental	VII Expert opinion
Study Aim/Purpose	Determine if HFS, compared to a task trainer would improve the nurses' ability to identify and act when a patient deteriorates.	How to make a thoughtfully developed HFS scenario and conduct the simulation equally as thoughtful
Population/Sample size Criteria/Power	Pediatric non-critical care nurses from one facility/33/More than 6 months experience having completed prior training in NRP or PALS/Not disclosed	None
Methods/Study Appraisal Synthesis Methods	Pre-test Post Test, participants were randomly assigned to the study group or control group. All subjects received didactic training then were skill checked in their assigned group. The written exam scores were collected immediately after training and then again after 6 months.	None
Study tool/instrument validity/reliability	AHA PEARS written exam, PEARS skill check sheet was adapted by the author to include point values for content items. The Mayo High Performance Teamwork Scale / "Satisfactory construct validity"	None
Primary Outcome Measures/Results	Work location and years of experience were not statistically significant. Exam scores declined for both groups (p=0.537. Teamwork rating increased for the 6 month (p=0.001) ANOVA, Man-Whitney U, Pearson's Chi-square, Fisher's exact	None
Conclusions/Implications	HFS was effective as a teaching method, there was little difference between the two groups on the written exams, The HFS teamwork scenario scores were significantly higher for the experimental group and they performed better recognizing and intervening with patient decline. /Adds to	Proper planning preceding the simulation is paramount for success. Facilitators must give thought not only to what they want to teach but how to engage the learners. Recommend using trained raters for high-stakes simulation

	the body of research, Showed that using HFS as an adjunct to continuing education increased the maintenance of knowledge.	
Strengths/Limitations	Random assignment using a control group, used one tool with proven construct validity/Small sample size, used two non-validated tools, participant attrition	Well referenced/Non-research, EBP only.
Funding Source	St. Louis Children's Hospital Foundation Collaborative Nursing Faculty-Staff Research Grant	None disclosed
Comments	Teamwork scenarios	
Article/Journal	9. Just-in-time training for high-risk low-volume therapies/ *Journal of Nursing Care Quality*	10. Using simulation to expose shortcomings in clinical learning objectives/*Nursing Education Perspectives*
Author/Year	Helman, S., Lisanti, A., Adams, A., & Davis, K. /2016	Leach, J./2014
Database/Keywords	Ebscohost/Competency, high-risk, staff development	Academic Search Premier
Research Design	Quality improvement	Quality improvement
Level of Evidence	VII: Expert Opinion	VII: Expert opinion
Study Aim/Purpose	To create just-in-time training to support high-risk low-volume treatment (HRLVT)	To develop a tool capable of objectively measuring the learners ability to assess and interpret vital signs utilizing simulation.
Population/Sample size Criteria/Power	BSN Nurses in cardiac care unit/None	234 baccalaureate nursing students
Methods/Study Appraisal Synthesis Methods	Charge nurse reviewed JITT checklist with each nurse providing HRLVT providing peer feedback. Participants also completed a satisfaction survey.	Evaluated learner assessment ability in group prior to instituting simulation and then evaluated group of learners after instituting simulation.
Study tool/instrument validity/reliability	None	None
Primary Outcome Measures/Results	83% of participants agreed to feeling more comfortable caring for patient's receiving HRLVT. Numbers of poor patient outcomes decreased after the implementation of the JTT.	Group exposed to simulation performed better assessment than group who did not experience simulation.
Conclusions/Implications	The data support the central tenets of the synergy model that when nursing competencies are in alignment with complex patient characteristics, improved care occurs. Attending an annual skill fair is not sufficient frequency to maintain nursing competency. Model could be applied to any HRLVT.	Use of simulation improved the learners' assessment ability.
Strengths/Limitations	No discussion regarding tool for evaluation, V/R, One facility, non-research design.	Large sample size/Opinion only, multiple variable for test group, did not re-test sample.
Funding Source	None disclosed	None disclosed
Comments		

Article/Journal	11. Recognition of physical deterioration in patients with mental health problems: The role of simulation in knowledge and skill development/*Journal of Psychiatric and Mental Health Nursing.*	12. Nurse experts jump start clinical simulation in rehabilitation nursing/*Nursing Education Perspectives*
Author/Year	Unsworth, J., McKeever, M., & Keelher, M./2012	Brickner, D., & Pardee, C./
Database/Keywords	Academic Search Premier/Simulation, nursing, skill acquisition	Academic Search Premier/Simulation, Nursing education
Research Design	Qualitative; Focus Group	Quality improvement
Level of Evidence	VI: Evidence form a single qualitative study	VII: Expert opinion
Study Aim/Purpose	To design and deliver simulation scenarios to develop the skills and knowledge of mental health nursing students in the recognition and management of physical deterioration.	A high-fidelity simulation project was implemented to educate new graduate nurses on the appropriate spinal cord injury patient care.
Population/Sample size Criteria/Power	Mental Health nursing students/15	New graduate nurses working in a spinal cord injury rehabilitation unit/Not disclosed
Methods/Study Appraisal Synthesis Methods	Students were exposed to simulation scenarios and the invited to participate in a focus group.	Nurses were exposed to simulation scenarios and the completed an evaluation reflecting their reactions to the training.
Study tool/instrument validity/reliability	Content analysis for themes; 8 stage process of data reduction/Utilized OSCE tool: V&R not disclosed	Five-point Likert scale/ V&R not disclosed
Primary Outcome Measures/Results	Four main themes: bridging the gap, learning inter-professionally, authenticity, and reflection & learning	Most participants agreed (mean >4.0) that they felt comfortable learning through simulation and that simulation enhanced their learning.
Conclusions/Implications	Intermediate fidelity simulation is a useful catalyst to learning about physical deterioration.	Learners reported improved confidence in caring for the patient population after the simulation experience.
Strengths/Limitations	Utilized previously proven data collection tool/Small sample size, convenience sample	/Sample size not disclosed, no control group for comparison, many variables.
Funding Source	None disclosed	None disclosed
Comments		
Article/Journal	13. Effect of improving the realism of simulated clinical judgement tasks on nurses' overconfidence and under confidence: Evidence from a comparative confidence calibration analysis/*International Journal of Nursing Studies*	14. Intensive care nurses' perceptions of simulation-based team training for building patient safety in intensive care: A descriptive qualitative study/*Intensive and Critical Care Nursing*
Author/Year	Yang, H., Thompson, C., & Bland, M./2012	Ballangrud, R., Hall-Lord, M., Persenius, M., & Hedelin, B./2014
Database/Keywords	Academic Search Premier/Simulation, confidence, nursing education	Academic Search Premier/Nursing, Simulation training
Research Design	Comparative confidence calibration analysis	Qualitative descriptive design
Level of Evidence	VI: Single descriptive study	VI: Single descriptive study

Study Aim/Purpose	To test the effect of improved realism of clinical judgement tasks on confidence calibration performance	To describe the intensive care nurses' perceptions of simulation-based team training for building patient safety in the ICU.
Population/Sample size Criteria/Power	Nurses & nursing students/97 participants from one large university medical center Convenience sampling	Nurses from 7 different ICU's/18 Strategic sampling with regard to variation in gender, age, area of in ICU, education level, years as an RN, years as a post graduate ICU nurse, scenario roles and simulation experience.
Methods/Study Appraisal Synthesis Methods	Participants were exposed to paper-based scenarios and then high-fidelity scenarios. Participants were asked to record dichotomous judgements of yes or no for being at risk for critical event. Confidence ratings were assigned on a 0-100 scale.	Individual interviews conducted by a single interviewer which were recorded and transcribed verbatim. Manifest inductive content analysis was implemented including preparation, organization, and reporting phases.
Study tool/instrument validity/reliability	Not disclosed	Dialogue with follow up questions which were not disclosed by the author Utilized Lincoln & Guba's (1985) criteria for credibility, dependability, confirmability, and transferability to ensure trustworthiness.
Primary Outcome Measures/Results	Three calibration statistics used: calibration score, over/under confidence measure, and resolution score. Responses were depicted on a scatterplot with squared deviations away from the 45-degree line. Participants were significantly less accurate in the high-fidelity scenarios than the paper.	One main category was identified from three generic categories and six sub-categories.
Conclusions/Implications	Improving realism did not improve performance. Judgmental miscalibration of confidence in nurses may be a systematic cognitive bias that realism cannot correct for.	Training increases awareness of clinical practice and acknowledges the importance of structured work in teams/Realistic training contributes to safe care, reflection and openness motivates learning, and finding a common understanding of team performance.
Strengths/Limitations	Adequate sample size/Sample size included both nurses and students in order to create a large enough size. Comparison between judgement for experienced and non-experienced participants would be difficult to compare. Did not discuss limitations.	Sample size from multiple locations with a variety of ages, gender, and levels of experience, author discussed study limitations/Small sample size, poor gender mix of participants
Funding Source	Not disclosed	Laerdal Foundation for Acute Medicine
Comments		
Article/Journal	15. Reflective debriefing to promote novice nurses' clinical judgment after high=fidelity clinical simulation: A pilot study/*Canadian Association of Critical Care Nurses*	16. Case-based learning and simulation: Useful, tools to enhance nurses' education? Nonrandomized controlled trial/*Journal of Nursing Scholarship*
Author/Year	Lavoie, P., Pepin, J., & Boyer, L./2013	Raurell-Torreda, M., Olivet-Pujol, J., Romero-Collado, A., Malagon-Aguilera, M., Patino-Maso, J., & Baltasar-Baque, A./2014
Database/Keywords	Academic Search Premier/Clinical judgment, clinical reasoning, high-fidelity clinical simulation	Academic Search Premier/Nurse education, simulation, clinical evaluation

Research Design	Educational project	Non-randomized controlled trial
Level of Evidence	VII: Expert opinion	III: Quasiexperimental
Study Aim/Purpose	To evaluate whether reflection after simulation could improve nurses' clinical judgment in complex situations.	To compare skills acquired by undergraduate nursing students enrolled in a medical-surgical course.
Population/Sample size Criteria/Power	Novice ICU nurses/5 Convenience sample of nurses in orientation	Undergraduate nursing students and nurses with clinical experience/101 & 59 respectively Convenience sampling of students enrolled in Adult Practice 1
Methods/Study Appraisal Synthesis Methods	Open ended questionnaire completed immediately post simulation practice	Scores on an objective structured clinical examination (OSCE) using a human patient simulator and cases validated by the NLN were compared for the undergraduate control and intervention groups, and for the experienced nurses.
Study tool/instrument validity/reliability	Not disclosed Authors disclose that the tool has not been previously tested	OSCE tool Well documented validity and reliability
Primary Outcome Measures/Results	Participants reported that reflection contributed to their care prioritization and organization, their nursing assessment capacities, and their global clinical judgment in the situation.	Control group scored significantly lower than the intervention group on patient assessment and no differences were observed in the remaining categories. There was significant difference between undergraduate nurses and the experienced nurses in patient evaluation and appropriate nursing interventions.
Conclusions/Implications	That high-fidelity simulation combined with debriefing improves clinical performance and judgment.	Case-based learning helps the students identify in the scenario the important signs and symptoms that indicate a problem, complication, or need for care, as well as the confounders that add information irrelevant to the scenario.
Strengths/Limitations	Authors discussed limitations/Small sample size, no control group, tool used not tested for validity and/or reliability	Large sample size, well designed, used previously validated tool and scenarios/One location, different instructors for each group, one data collector without intraclass correlation of scores.
Funding Source	Not disclosed	Not disclosed
Comments		
Article/Journal	17. Simulation in nursing practice: The impact on patient care/*Journal of Issues in Nursing*	18. The template of events for applied and critical healthcare simulation (TEACH Sim): A tool for systematic simulation scenario design/*Society for Simulation in Healthcare*
Author/Year	Aebersold, M. & Tschannen, D./2013	Benishek, L., Lazzara, E., Gaught, W., Arcaro, L., Okuda, Y., & Salas, E./2015
Database/Keywords	Academic Search Premier/Nursing practice, simulation, staff development, competency	Academic Search Premier/Nursing practice, simulation, staff development, competency, scenario development
Research Design	Quality improvement	Quality improvement
Level of Evidence	VII: Expert opinion	VII: Expert opinion
Study Aim/Purpose	To provide a review of the current uses of simulation in the nursing practice environment with several exemplars and offer recommendations to develop a simulation program.	Article describes existing scenario templates, explores considerations for choosing a template, and introduces the Template of Events for Applied and Critical Healthcare Simulation (TEACH Sim).
Population/Sample size	None	None

Criteria/Power		
Methods/Study Appraisal Synthesis Methods	None	None
Study tool/instrument validity/reliability	None	None
Primary Outcome Measures/Results	None	None
Conclusions/Implications	Simulation provides a suitable methodology for deliberately performing skills necessary to be an effective practicing nurse. Simulation can provide an effective mechanism for improving competency in a given area.	The TEACH Sim template assists in systematic development of simulation scenarios that meet learning objectives through scripted events aimed at eliciting learner responses and corresponding knowledge, skills, and attitudes.
Strengths/Limitations	Well-resourced information with a systematic review/Non-research	Well-sources information/Non-research
Funding Source	Not disclosed	Not disclosed
Comments		
Article/Journal	19. Randomized, controlled trial of the effectiveness of simulation education: A 24-month follow-up study in a clinical setting/*Association for Professionals in Infection Control and Epidemiology*.	20. Using simulation and virtual reality technology to assess continuing nurse competency in the long-term acute care setting/*Journal for Nurses in Staff Development*
Author/Year	Jansson, M., Syrjala, H., Ohtonen, P., Merilainen, M., Kyngas, H., & Ala-Kokko, T./2016	Landry, M., Oberleitner, M., Landry, H., & Borazjani, J./2006
Database/Keywords	CINAHL/Simulation, nursing, staff development, competency	Journals at Ovid
Research Design	Longitudinal, single-center, parallel, randomized control trial with repeated measurements	Quality improvement
Level of Evidence	II: One randomized control study	VII: Expert opinion
Study Aim/Purpose	The aim of the present trial was to evaluate the longitudinal effects of simulation education in the nursing management of patients receiving invasive ventilation.	To develop a simulation education program for staff nurses in an attempt to meet the Joint Commission requirement for a systematic and measurable assessment of competence.
Population/Sample size Criteria/Power	ICU nurses who had previously participated in the original randomized control study/30 of the 40 previous study participants	75 nurses completed two-day event
Methods/Study Appraisal Synthesis Methods	A computerized randomization was used for assignment of participants. Each group received simulation training with a high-fidelity manikin. The study group received debriefing and feedback. 24-months later the participants of the original study were evaluated on the skills learned in the simulations.	Exit evaluation and a written exam
Study tool/instrument validity/reliability	The method was guided by a validated (S-CVI 0.99), highly structured 86-item Ventilator Bundle Observation Schedule (VBOS). If participants adhered to a recommended practice, they were assigned 1 point, yielding a skill score range of 0-60.	None

Primary Outcome Measures/Results	Adherence to care guidelines improved for both groups over time however the only statistical difference between the two groups was at 6 months and disappeared by 24 months.	Evaluation results were highly favorable that the nurses' felt the sessions were effective for learning. The facility reported that the session was a cost effective and expedient way to evaluate the continuing competency of large numbers of nurses while adhering to Joint Commission Standards.
Conclusions/Implications	Simulation education may have some advantages over other teaching methods depending on the context, topic, and method. Previous studies have demonstrated more long-lasting improvements in learning and clinical outcomes.	See above
Strengths/Limitations	High level evidence study/Attrition of participants for longitudinal study, only 17 of the original completed the study.	Large sample size/No control group, one facility, competency measurement tool validity and reliability not disclosed.
Funding Source	Not disclosed	Not disclosed
Comments		*** Older article
Article/Journal	21. The effects of clinical experience on nurses' critical event risk assessment judgements in paper based and high fidelity simulated conditions: A comparative judgement analysis/*International Journal of Nursing Studies*	22. Early identification of physiologic deterioration by acute care nurses/*Clinical Nurse Specialist*
Author/Year	Yang, H. & Thompson, C./2011	Ozekcin, L., Tuite, P., Willner, K., & Hravnak, M./2015
Database/Keywords	Science Direct/Clinical experience, simulation, nursing	Journals at Ovid/Simulation, nursing education, staff development
Research Design	Two phase judgement analysis: Phase one nurses were exposed to written case simulations and phase two the same nurses participated in physical case simulations.	Quality improvement
Level of Evidence	VI: Single descriptive study	VI: Single descriptive study
Study Aim/Purpose	To examine whether improving fidelity via physical clinical simulation impacts on the apparent benefits of clinical experience on nurses' judgement performance.	To improve acute care nurses' ability to assess deteriorating patients, recognize signs of instability and immediate critical treatment, and escalate care in a timely manner.
Population/Sample size Criteria/Power	63 nursing students and 34 experienced nurses Convenience sample from one facility and one local nursing school	35 acute care nurses Convenience sampling of RN's with 6 months experience at one facility
Methods/Study Appraisal Synthesis Methods	Participants made risk assessment judgements (at risk or not as risk) in relation to the scenarios presented. Scenarios were randomly assigned from a dataset of real patient case records and nurses were evaluated on achievement, consistency, and clinical information use.	Nurses were divided onto 10 simulation groups who were then exposed to a two-phase education program-e-learning module followed by simulation scenarios. Education effectiveness was assessed by knowledge and performance of critical activities for instability recognition. The simulations were followed by a debriefing of the participants.
Study tool/instrument validity/reliability	Brunswick Lens Model of Judgement	e-learning was evaluated using a pre-test/post-test Self-developed tool; no validity/reliability data Post course Likert scale for learning evaluation

Primary Outcome Measures/Results	No significant differences in judgement were observed between the novice and experienced nurses in either paper or physical simulation.	A paired-sample t test demonstrated that the mean pretest score increased after the two-phase education was applied.
Conclusions/Implications	Experience made no difference in nurses' judgement achievement in either low-fidelity paper scenarios or higher fidelity setting of the clinical simulation unit.	Use of e-learning, simulation and organized debriefing can improve instability recognition.
Strengths/Limitations	Adequate sample size/convenience sampling, no control group, one facility & one school, many variables	Adequate sample size/Convenience sample, no control group, self-developed tool without V/R testing
Funding Source	No external funding disclosed	None disclosed
Comments		*****Very similar to my project
Article/Journal	23. Use of high-fidelity simulation for staff education development: A systematic review of the literature/*Journal for Nurses in Staff Development*	24. Simulation in nursing staff development: A concept analysis/*Journal for Nurses in Staff Development*
Author/Year	Hallenbeck, V./2012	Nickerson, M., Morrison, B., & Pollard, M./2011
Database/Keywords	CINAHL/Simulation, nursing, staff development	CINAHL/Simulation, nursing, staff development
Research Design	Systematic review	Analysis; Quality improvement
Level of Evidence	I: Evidence from a systematic review of all relevant evidence-based clinical practice guidelines	VII: Expert opinion
Study Aim/Purpose	To review publish research from a five-year period and evaluate the evidence collected	To analyze the concept of simulation, use in professional nurse staff development
Population/Sample size Criteria/Power	None	None
Methods/Study Appraisal Synthesis Methods	Table format for evidence appraisal	None
Study tool/instrument validity/reliability	Table of evidence included but no reference to the type of table or V/R for the tool used	None
Primary Outcome Measures/Results	The research related to the use of high-fidelity simulation (HFS) with practicing nurses is very limited, with currently only one randomized study having been published.	None
Conclusions/Implications	Use of HFS in staff development has the potential for meeting many learning needs. However, there is a need for more research in this area with this population.	Simulation is best incorporated where the learner has theoretical information and needs to understand how to best apply this to actual practice.
Strengths/Limitations	High level of research/Limited published research to review	Well supported references, reviewed many articles/Few articles directly related to this population
Funding Source	None disclosed	None disclosed
Comments	***Supports my project need	***Supports my project need
Article/Journal	25. The simulation revolution: What are the implications for nurses in staff development? /*Journal for Nurses in Staff Development*	26. Implementation of simulation to improve staff nurse education/ *Journal for Nurses in Staff Development*

Author/Year	Leigh,G./2011	Hommes, T./2014
Database/Keywords	CINAHL/Simulation, nursing, staff development	CINAHL/Simulation, nursing, staff development
Research Design	Quality improvement	Quality improvement:
Level of Evidence	VII: Expert opinion	VII: Expert opinion
Study Aim/Purpose	To explore the strategies that staff development educators can incorporate to improve educational activities by adopting high-fidelity patient simulation.	To implement a simulation curriculum during the nursing orientation process at a Midwestern, rural community hospital.
Population/Sample size Criteria/Power	None	None
Methods/Study Appraisal Synthesis Methods	None	None
Study tool/instrument validity/reliability	None	Presurvey-postsurvey using a 12 item Likert scale; 6 to measure competence and six to measure confidence Tested for face validity by the project director's advisor and by five content experts.
Primary Outcome Measures/Results	None	All participants had an increase in perceived confidence and perceived competence from the presurvey to the postsurvey
Conclusions/Implications	High-fidelity simulation is an expectation of the new generation of nurses; the question is not whether to adopt simulation into staff development but rather when.	Although the outcome evaluation for this project identified an increase in confidence and competence for NGN's, causality could not be determined because of the project design.
Strengths/Limitations	Well referenced opinion/Opinion only	Well referenced/Utilized author created tool, poorly designed for descriptive data correlation.
Funding Source	None disclosed	None disclosed
Comments		
Article/Journal	27. Education methods for maintaining nursing competency in low-volume, high-risk procedures in the rural setting: Bridging the theory to practice gap/*Journal for Nurses in Staff Development*	28. A regional simulation center partnership: Collaboration to improve staff and student competency/*The Journal for Continuing Education in Nursing*
Author/Year	Bank, C., Gilmartin, H., Fink, R./2010	Sportsman, S., Bolton, C., Bradshaw, P., Close, D., Townley, N., & Watson, M./2009
Database/Keywords	CINAHL/Simulation, nursing, staff development	CINAHL/Simulation, nursing, staff development
Research Design	Quasi-experimental	Quality improvement
Level of Evidence	III	VII: Expert Opinion
Study Aim/Purpose	To evaluate the effectiveness of a focused, multifaceted, evidence-based education intervention on registered nurses' knowledge and perceived competence of the maintenance of CVAD's, a low frequency, high-risk procedure at the institution.	To describe the benefits of creating a collaborative approach to simulation education and evaluation.
Population/Sample size Criteria/Power	RN's employed at the rural health facility/146 Convenience sampling	

Methods/Study Appraisal Synthesis Methods	Pretest-posttest design to study the effects of the multifaceted educational intervention. Self-study learning module followed by skills lab evaluation 2 weeks later. An additional posttest was completed 3 months later.	None
Study tool/instrument validity/reliability	25 item knowledge test, adapted from Coopersmith et al. (2002) with updated questions to meet the query. 5-point Likert scale was used to assess the nurses' comfort level with the skill and other demographics.	None
Primary Outcome Measures/Results	The mean knowledge test scores improved over time with a p <.001. For evaluation of education modalities; learners most preferred the skills lab. Confidence in skill performance also improved from pre-intervention to post intervention.	None
Conclusions/Implications	A multifaceted intervention is suggested as a superior method of educating nursing staff.	Authors tout that clinical competence is improved because simulations allows for practice of high risk low volume skills in an environment without risk to the patient. Program has led to new discussion about competency assessments and requirements at their facility.
Strengths/Limitations	Large sample size/Unknown reliability and validity of tool used, instrument included both nominal and interval-level variables. Lack of a clear definition for competence in nursing.	Non-research, no tool to evaluate or measure claim of improved competency.
Funding Source	None disclosed	None-disclosed
Comments	***Similar design to my project	
Article/Journal	29. Reducing avoidable deaths from failure to rescue: A discussion paper/*British Journal of Nursing*	30. The effectiveness of and satisfaction with high-fidelity simulation to teach cardiac surgical resuscitation skills to nurses./ *Intensive and Critical Care Nursing*
Author/Year	Waldie, J., Tee, S., & Day, T./2016	McRae, M., Chan, A., Hulett, R., Lee, A., & Coleman, B./2017
Database/Keywords	CINAHL/Simulation, nursing, staff development	EbscoHost/Nursing education, Simulation
Research Design	Quality improvement	Descriptive study, quasi-experimental
Level of Evidence	VII: Expert opinion	III
Study Aim/Purpose	Proposes a radical new approach to the monitoring and governance of services, and the education and training of nurses to meet failure to rescue requirements.	To test the effect of simulation on the self-confidence of nurses to perform cardiac surgical resuscitation skills and the nurses' satisfaction with the simulation experience.
Population/Sample size Criteria/Power	None	60 ICU nurses/ convenience sample
Methods/Study Appraisal Synthesis Methods	None	Pre-post simulation measures of self-confidence and then a post satisfaction survey at the end.
Study tool/instrument validity/reliability	None	Satisfaction with Simulation Experience Scale (SSES) Chronbach alpha 0.77. Self-confidence tool was researcher developed and does not disclose validity or reliability.

Primary Outcome Measures/Results	None	Self confidence levels to perform skills was significantly higher after simulation with a p value <0.001
Conclusions/Implications	Discusses need for implementation of a framework however this has not actually been done. Discusses potential impact on nurses' ability to recognize and rescue the deteriorating patient.	Findings support the use of high-fidelity simulation to increase self-confidence to perform the high-risk patient care skills.
Strengths/Limitations	Discussion only; no measured outcomes	Large sample size/ one location, No control group, no randomization
Funding Source	Not disclosed	None disclosed
Comments		**Applicable to my study

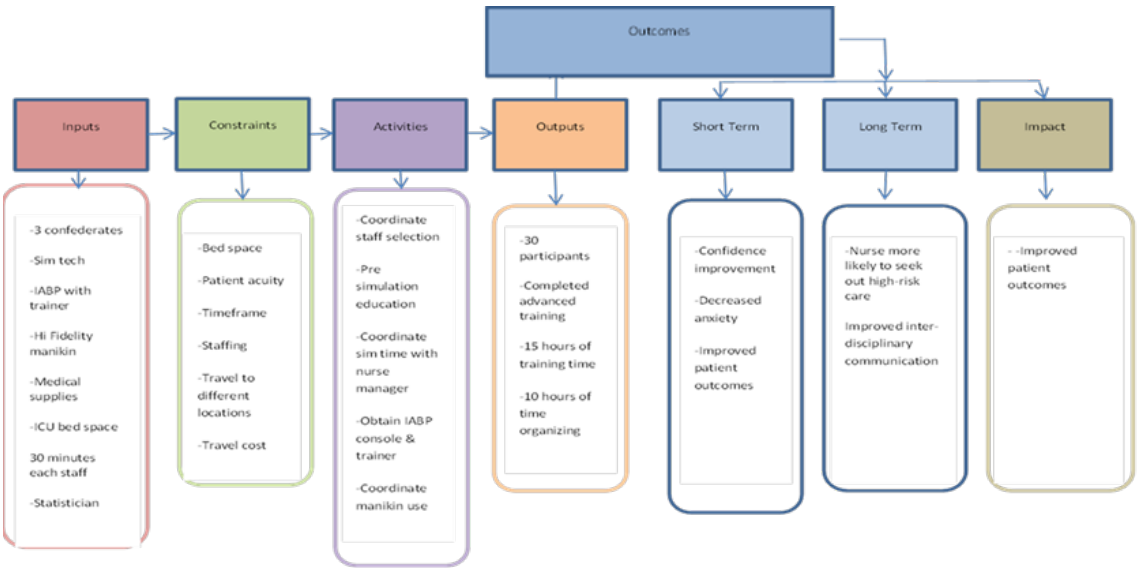
Appendix C: Budget & Resources

This project utilized equipment already in possession by the VHA facility.

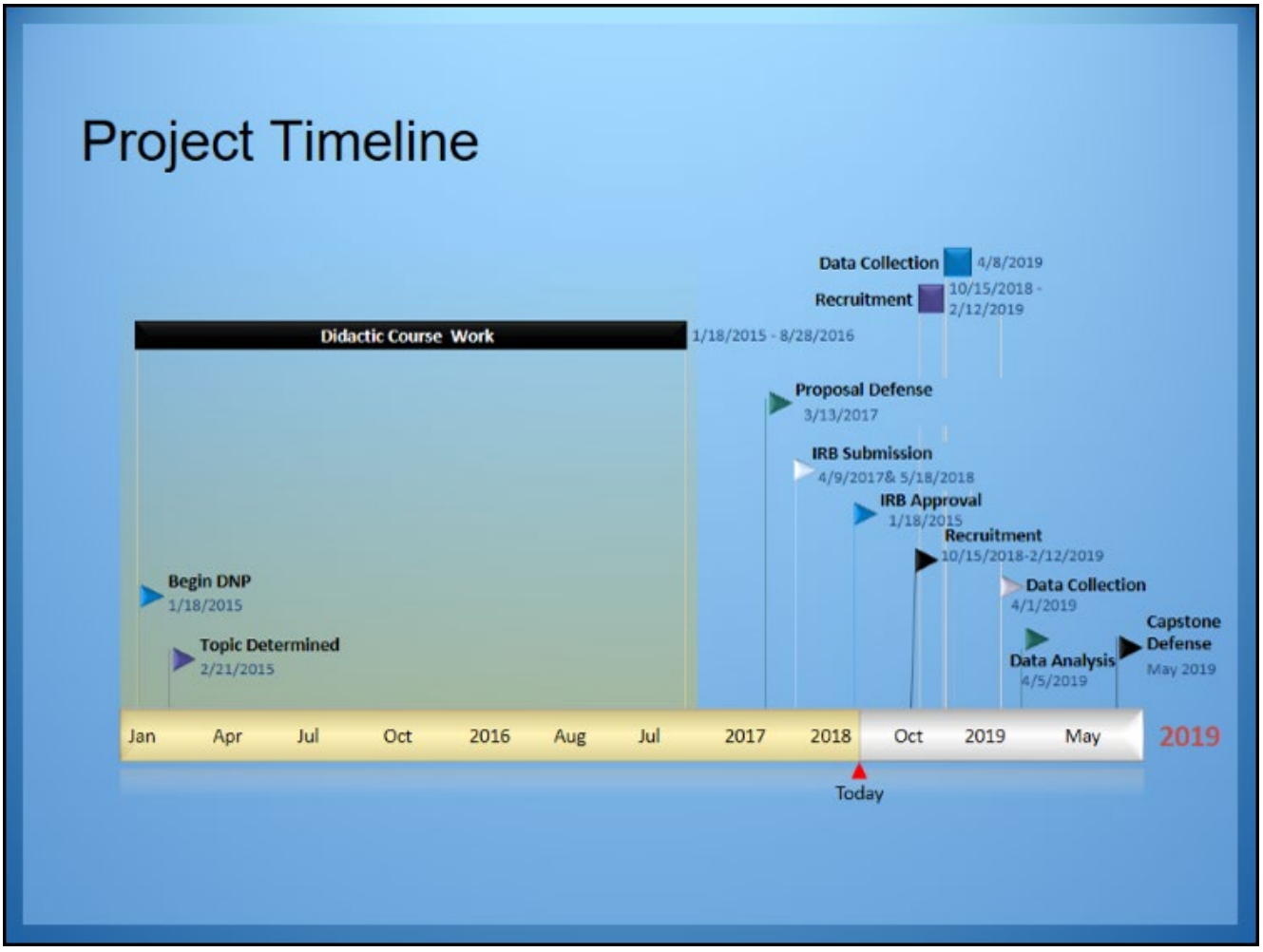
Cost to the facility: manpower to run the scenario practice sessions, including the simulation staff and ICU staff.

	Staff Nurse	Sim Nurse/Tech
Wages/Hr	$35	$35
Hours required	1.5	0.5
Setup/Take down/Prep		1.0
Total per nurse	$52.50	$52.50

Appendix D: Logic Model



Appendix E: Timeline



Appendix F: Evaluation Tool/Instrument

Pre/Post Scenario Evaluation ___

Complete one survey after completing each scenario

Learner:

Using the scale below please rate your feelings.

After completing this scenario….

A. I feel confident about my role in patient care for this scenario

_____

B. I feel comfortable with my role in providing patient care for this scenario

_____

C. I feel competent to provide this level of care for a real patient

_____

Rating Scale:

0-None

1-Very little

2-

3-

4- Moderate

5-

6-

7-Severe

Appendix G IRB Approval Letter VHA

VHA Operations Activities That May Constitute Research

VHA Handbook 1058.05 establishes procedures for determining whether a VHA operations activity constitutes research and establishes procedures for verifying and documenting the non-research status of certain VA operations. This form has been developed to assist program offices and services to determine if an operations activity constitutes research. The ACOS/R&D can provide assistance in determining if an activity constitutes research. (See definitions on page 2)

Section 1: Project and Reviewer Identification

Program Office	Hospital Education/Simulation
Title of Project/Operations Activity	The Effect of Intra-Aortic Balloon Pump Simulation on the Experienced ICU Nurse.
Project Manager	Janet Sprehe DNP-APN-BC & Tracey Robilotto DNP(c)
Reviewer	Robert R. Campbell JD MPH PhD. Acting ACOS/R&D

Section 2: Operations Activity Review

	NO	YES
1. Is the Operations Activity **designed** (and/or implemented) for **internal VA purposes in support of the VA mission(s)**?	☐	☒
2. Are the activity's **findings designed to be used by and within VA** (or by entities responsible for overseeing VA)?	☐	☒
3. Is the activity **designed** for the purpose of contributing to **generalizable knowledge**?	☒	☐
4. Is the activity **designed** for the purpose of expanding the **knowledge base** of a **scientific discipline** or scholarly field of study?	☒	☐
5. Is the activity funded or supported **as research**?	☒	☐
6. Is the activity a **clinical investigation** as defined under Food and Drug Administration **(FDA) regulations**?	☒	☐
7. Does the activity include **double-blind interventions**?	☒	☐
8. Does the activity include **placebo controls**?	☒	☐
9. Does the activity include **prospective patient-level randomization** to a clinical intervention **not tailored to individual patient benefit**?	☒	☐
10. Has the activity been **supplemented or modified before, during, or after implementation** in order to produce information to expand **the knowledge base of a scientific discipline** or scholarly field of study or otherwise **contribute to generalizable knowledge**?	☒	☐
11. Has the purpose of the activity **changed** so that it is **now designed or intended** to expand the **knowledge base of a scientific discipline** or scholarly field of study or otherwise **contribute to generalizable knowledge**?	☒	☐

investigation to ensure reliable outcomes. Systematic investigation does not, in and of itself, define research. ***NOTE:*** *Examples of systematic investigations that may or may not constitute research, include (but are not limited to) activities involving questionnaires or surveys; observations; focus groups; interviews; analyses of existing data; analyses of biological specimens; medical chart reviews; epidemiologic reviews or analyses; program evaluations; and quality assessment, quality improvement, and quality management.*

Department of
Veterans Affairs

Memorandum

Date: January 19, 2018

From: Janet Sprehe, DNP, APN-BC, CVRN, RN-BC & Tracey Robilotto DNP (C)

Subject: Operations Activity concurrence and support

To: Research Service

The attached project entitled "The Effect of Intra-Aortic Balloon Pump Simulation on the Experienced ICU Nurse "is submitted for your review and concurrence.

After your review, please sign below. Your signature indicates that you concur with this project being conducted under your supervision as an Operations Activity at the James A. Haley Veterans' Hospital.

☒ I concur and support this project as an Operations Activity.

☐ I do not concur.

☐ I concur with the following stipulations:

Signature: CO Date: 1/17/18

Printed Name: Colleen Jakey

Attachment: Project

Comments:		

Section 3: Operations Activity Reviewer Determination

Key for Black and White Forms

Green boxes: Question 1-Yes, Question 2-Yes, Questions 3-11-No

Red boxes: Question 1-No, Question 2-No, Questions 3-11-Yes

The Reviewer makes one of the following final determinations:	
☒	If all the green boxes above are checked, this operations activity is **NOT** research and Institutional Review Board (IRB) approval is **not** required. Documentation of non-research status is (i) required prior to peer –reviewed publication and (ii) encouraged whenever non-research status may be questioned.
☐	If any of the red boxes above are checked, this operations activity constitutes research and Institutional Review Board (IRB) approval is required.
☐	Defer for Review by ACOS/R&D. Reasons for Deferral are indicated below.

Reasons for Deferral:

Signature of Reviewer **Date** 1/23/18

Definitions:

Generalizable Knowledge: For purposes of this VHA Handbook 1058.05, generalizable knowledge is information that expands the knowledge base of a scientific discipline or other scholarly field of study. Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, systematic investigations designed to produce information to expand the knowledge base of a scientific discipline or other scholarly field of study constitutes research.

Clinical investigations: As defined under Food and Drug Administration (FDA) regulations clinical investigators include studies of FDA-regulated drugs, devices, and biologics, regardless of whether the investigation or comparison requires an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE), and regardless of whether the investigation or comparison involves approved or unapproved (i.e., off-label) uses.

Systematic Investigation: A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic

Appendix H: IRB Regis University

REGIS UNIVERSITY

REGIS.EDU

Institutional Review Board

DATE:	July 10, 2018
TO:	Tracey Robilotto, MSN
FROM:	Regis University Human Subjects IRB
PROJECT TITLE:	[1053721-1] The effect of Intra-Aortic Balloon Pump simulation on the Experienced ICU Nurse.
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF EXEMPT STATUS
DECISION DATE:	July 10, 2018
REVIEW CATEGORY:	Exemption category # *(2)*

Thank you for your submission of New Project materials for this project. The Regis University Human Subjects IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations 45.CFR46.101(b).

We will retain a copy of this correspondence within our records.

If you have any questions, please contact the Institutional Review Board at irb@regis.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Regis University Human Subjects IRB's records.

Appendix I: Consent Form

DESCRIPTION: You are invited to participate in **a research study** on simulation use in Professional Nurse Staff Development. The **purpose** of this study is to measure the level of self-perceived confidence after practicing high-risk low-volume patient care skills on a high fidelity patient simulator. You will be asked to complete an eLearning education program and then complete three 10 minute simulation practice sessions in the ICU. You will be asked to complete a pre and post-test with the eLearning component and then a self -evaluation before and after each of the simulation practice sessions.

TIME INVOLVEMENT: Your participation will take approximately 1.5 hours.

RISKS AND BENEFITS: The risks associated with this study are not expected to be beyond those of usual daily living. **We cannot and do not guarantee or promise that you will receive any benefits from this study.** Your decision whether or not to participate in this study will not affect your employment. Results from this study will not be used for any disciplinary implications.

PAYMENTS: You will not receive compensation for participation and participation will occur during regular work hours.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your **participation is voluntary** and you have the **right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled**. **The alternative is not to participate.** You have the right to refuse to answer particular questions. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. Identities of participants will not be disclosed.

CONTACT INFORMATION:
Questions: If you have any questions, concerns or complaints about this research, its procedures, risks and benefits, contact the Project Director, Tracey Robilotto, 407-497-0978

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Regis University Institutional Review Board (IRB) to speak to someone independent of the research team at (xxx)-xxx-xxxx.

The extra copy of this signed and dated consent form is for you to keep.

SIGNATURE _____ DATE _____

Print name of participant _____

Appendix J: CITI Training Certificate Robilotto

CITI PROGRAM

Completion Date 07-Mar-2018
Expiration Date 06-Mar-2021
Record ID 25177967

This is to certify that:

tracey robilotto

Has completed the following CITI Program course:

Human Research	(Curriculum Group)
Social Behavioral Research Investigators and Key Personnel	(Course Learner Group)
2 - Refresher Course	(Stage)

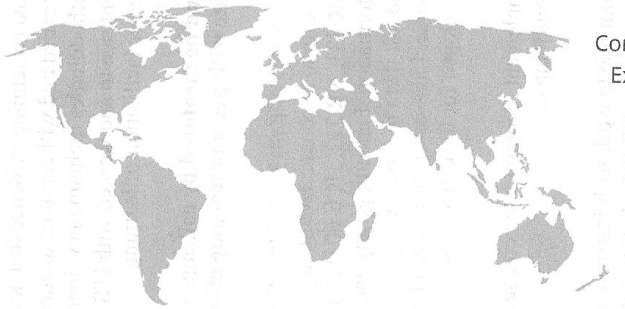
Under requirements set by:

Regis University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w6d597cfd-2b49-4a49-bc15-71629fc4afe5-25177967

CITI PROGRAM



Completion Date 07-Mar-2018
Expiration Date 06-Mar-2021
Record ID 25177966

This is to certify that:

tracey robilotto

Has completed the following CITI Program course:

Human Research (Curriculum Group)
Biomedical Research Investigators and Key Personnel (Course Learner Group)
3 - Refresher Course (Stage)

Under requirements set by:

Regis University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wf5a08dd5-f63c-473b-a5ab-87f53807ea71-25177966

CITI PROGRAM

Completion Date 23-May-2016
Expiration Date 23-May-2019
Record ID 19494787

This is to certify that:

janet sprehe

Has completed the following CITI Program course:

Human Research (Curriculum Group)
VA Human Subjects Protection (Course Learner Group)
3 - Refresher Course (Stage)

Under requirements set by:

Tampa, FL-673

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w30a659f1-291a-4c1d-a52e-9a83881d4741-19494787

Appendix K: CITI Training Certificate Finn

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Christine Finn (ID: 237192)
- **Institution Affiliation:** Regis University (ID: 745)
- **Institution Email:** cfinn@regis.edu
- **Institution Unit:** nursing
- **Phone:** 719-661-6750

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social Behavioral Research Investigators and Key Personnel
- **Stage:** Stage 2 - Refresher Course

- **Record ID:** 24605500
- **Completion Date:** 15-Sep-2017
- **Expiration Date:** 14-Sep-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
SBE Refresher 1 - Instructions (ID: 943)	15-Sep-2017	No Quiz
SBE Refresher 1 – History and Ethical Principles (ID: 936)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality (ID: 15035)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Assessing Risk (ID: 15034)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research with Prisoners (ID: 939)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research with Children (ID: 15036)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – International Research (ID: 15028)	15-Sep-2017	2/2 (100%)
Biomed Refresher 1 - Instructions (ID: 960)	15-Sep-2017	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?ka01e9f18-50c0-4f62-94a4-9867c18eb665-24605500

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Christine Finn (ID: 237192)
- **Institution Affiliation:** Regis University (ID: 745)
- **Institution Email:** cfinn@regis.edu
- **Institution Unit:** nursing
- **Phone:** 719-661-6750

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social Behavioral Research Investigators and Key Personnel
- **Stage:** Stage 2 - Refresher Course

- **Record ID:** 24605500
- **Report Date:** 09-Jan-2019
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
SBE Refresher 1 – History and Ethical Principles (ID: 936)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 - Instructions (ID: 943)	15-Sep-2017	No Quiz
Biomed Refresher 1 - Instructions (ID: 960)	15-Sep-2017	No Quiz
SBE Refresher 1 – Federal Regulations for Protecting Research Subjects (ID: 937)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Informed Consent (ID: 938)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research with Prisoners (ID: 939)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research in Educational Settings (ID: 940)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – International Research (ID: 15028)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Defining Research with Human Subjects (ID: 15029)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Assessing Risk (ID: 15034)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Privacy and Confidentiality (ID: 15035)	15-Sep-2017	2/2 (100%)
SBE Refresher 1 – Research with Children (ID: 15036)	15-Sep-2017	2/2 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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