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Pilot of a randomized trial comparing outcomes of three types of peripheral intravenous catheters (PIVC): Utilizing the Plan, Do, Study, Act Cycle

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Pilot of a Randomized Trial Comparing Outcomes of Three Types of Peripheral Intravenous Catheters (PIVC): Utilizing the Plan, Do, Study, Act Cycle

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Abstract

Peripheral intravenous catheters (PIVC) are used in high volume in acute and ambulatory settings. Due to high volume of use in patient care, complications from a PIVC can significantly impact patient experience. Literature indicates complications such as blood exposure, phlebitis, unplanned removal, infiltration, occlusion, dwell time, pain, and cost have serious consequences in patient care, leading to potential delays in treatment, patient discomfort, patient dissatisfaction, safety concerns, nursing interruptions, increased length of stay, and added costs. Gap analysis indicates additional research can prove beneficial for evidence-based care improvement. The authors propose using the plan, do, study, act to conduct a feasibility study of a multi-center, randomized-controlled trial (RCT), evaluating three different PIVC systems to compare outcomes. The purpose of this pilot was to determine the feasibility of assessing nurse and patient outcomes related to the use of three different types of PIVC, and to pilot implementation of a RCT prior to the expansion of the study to other facilities, which comparatively evaluated outcomes between two closed PIVC systems and an open PIVC system.

Keywords: intravenous catheter, randomized control trial, intravenous complications, PDSA, feasibility, closed PIVC, open PIVC, phlebitis

Introduction

On June 16, 2015, a 238-bed community hospital in the mid-Atlantic state changed products for peripheral intravenous catheters (PIVC) and began using the system product for the purpose of standardization of both product and practice. This facility was using a PIVC for over 20 years; an all in one closed-system device. The standardized product for the hospital system was an open-system device.

The Quality and Patient Safety Department (QPS) at the pilot site began receiving staff event reports and patient comment cards related to the new PIVC (G. Yost, personal communication, June 18, 2015). Patient comment cards were available in all outpatient areas as well as main lobbies throughout the hospital. Inpatient hospital consumer perception of providers and systems comments were submitted by patients. The majority of the submitted patient comment cards were from outpatient locations, including the Cancer Center, Treatment Center, and Outpatient Surgery units. Patients with reoccurring visits to these units shared their experience with the new PIVC compared to their experience with the previous product. The comments were reviewed and several of the themes that emerged from patients were: painful insertions, pain during dwell time, blood leakage (during insertion), multiple insertion attempts, and frequent PIVC replacement. Staff also began expressing concerns. The top immediate concerns reported by staff included blood exposure risk, multiple insertion attempts, and painful insertion reports from patients. Other staff concerns included kinking catheters, sheared catheter tips, tubing disconnects, leaking sites, PIVCs falling out, and continued pain during PIVC dwell time. There had been one needle-stick and one staff mucocutaneous blood exposure reported by Occupational Health related to the new catheters, compared

to no previously reported needle-sticks or exposures related to the previous PIVC, in the previous year (G. Yost, personal communication, June 18, 2015). By December 2015, the QPS department had received a total of 551 reported issues and 102 patient comment cards related to the PIVC product change.

In response to the feedback on the new product requiring additional sticks to obtain PIVC access, a data analysis of the mean number of PIVC insertion attempts was conducted. This provided establishment of a quantitative metric to evaluate. The data source was the electronic health record (EHR), PIVC insertion attempts, and documentation for PIVC therapy. Data included Emergency Department (ED), Cancer Center, Treatment Center, and inpatient patients. A retrospective data review of PIVC attempts from the timeframe of April 13 – June 15, 2015 was compared to the post-change timeframe of July 29 – September 30, 2015. Six weeks of data was purposely removed during the timeframe of June 16 – July 28, 2015 to account for the expected learning curve with the new product. Figure 1. displays the pre-mean and post-mean data of PIVC insertion attempts.

A two-sample *t*-test concluded that the mean PIVC attempts for the new PIVC was statistically significantly greater than the mean PIVC attempts of the previous PIVC with a *p*-value of <0.001. A two-sample standard deviation test concluded that the standard deviation of PIVC attempts for the new product was statistically significantly greater than the standard deviation of PIVC attempts of the previous product (closed PIVC system 1) with a *p*-value of <0.001. A two-sample % defective test with a defect defined as a PIVC attempt >1 concluded that the number of defects for the new product

was statistically significantly greater than the number of defects for the previous product with a *p*-value of <0.001.

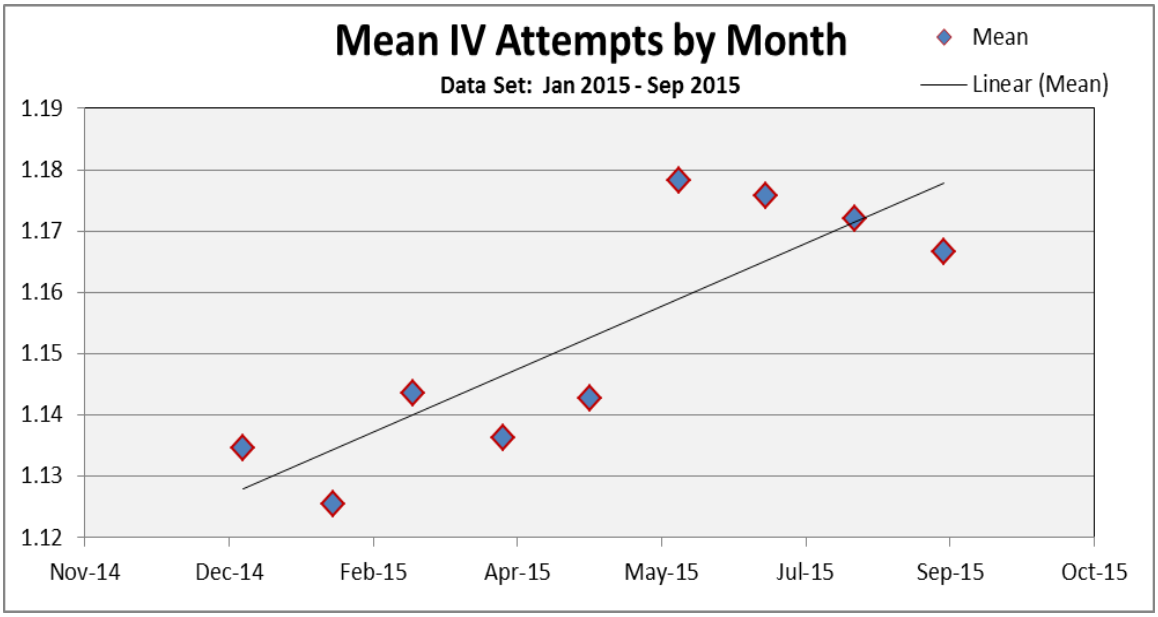

Figure 1. Mean PIVC attempts by month.

After evaluating the influx of comment cards reporting reduced patient and staff satisfaction, as well as evaluating the increased number of attempts required with the new PIVC, continued reporting of opportunities for improvement (OFI) reports occurred; even though, standard onsite training occurred. When OFI reports initially began, the facility immediately reached out to the other hospitals within their health system; however, no other hospitals were reporting similar events. Additionally, their patient comments did not reflect any dissatisfaction with the standardized PIVC a PIVC system the other eleven hospitals had been using for greater than 20 years. Senior Leadership then authorized additional training and coaching on insertion technique, which was conducted over two weeks, to evaluate whether problems reported and dissatisfaction were related to user error versus the PIVC itself. A representative from the vendor returned onsite in the fall of 2015 to initiate re-training and re-education for nurses, specifically on procedure and

technique. Safety reports and dissatisfaction continued to be reported. While numbers of nursing complaints began to drop, patient complaints continued (G.Yost, personal communication, July 29, 2016).

Cost was an additional concern. A detailed cost analysis was performed by the QPS Department, comparing the total cost of the previous closed-system versus the current open-system. The cost of the previous PIVC system included a closed system with the added option of a power-injectable product for PIVC situations in which a larger gauge is necessary for high flow. Twelve months of usage data for both previous products was obtained. Usage data for the new open-system was evaluated during the timeframe of August 2015 – November 2015, purposely excluding usage data during the first 2 months of start-up. Add on extension sets and clave usage was included in the analysis for both systems to account for the increase in add-on device expense with the use of the open-system without a built in extension set. An average daily cost for add-ons was calculated by taking the total number of add-on items and dividing by the total cost of add-on items for the above timeframes. The PIVC dressing usage and cost was included for both systems due to a change of product and increase in cost for the current system relative to the need for a more advanced securement dressing for the open-system. The cost and usage of an absorbent towel was included in the cost of the current system. This was an added product to the PIVC start kit due to blood leakage with an open-system. All usage and cost data were obtained from the materials management department and was rate adjusted to account for patient days. The daily usage and cost for each product were multiplied for a per day cost. The cost per day was extrapolated into a per month and a per year cost. The cost per year of the current open-system was

calculated at $573,262. The per year cost of the previous closed-system was calculated at $469,963. Inpatient census and outpatient encounters were evaluated and compared for both system timeframes to eliminate concerns of increased usage due to patient volume. The estimated 3% increase in patient volume could produce at most a $14,000 cost variance. This leaves an estimated $89,000 increase in the current open-system (G. Yost, personal communication, June 18, 2015). The analysis shows that the new open-system is more costly than the closed-system and that comparing the cost of only the PIVC fails to produce an accurate evaluation of total cost incurred when switching from a closed to an open system. The increase in cost can be primarily attributed to the increase in usage of add-on products along with the more advanced securement dressing and the added absorbent towel. Other indirect costs for analysis were excluded, such as bed linens, towels, gauze, scrubs, etc. Additionally, nursing time was excluded from this calculation, which, as indicated by an increased number of insertion attempts related to the new PIVC system, would also be increased. In conclusion, there are additional costs with the open-system some of which are not accounted for in this analysis.

Review of Literature

As issues remained in the clinical setting and re-training was completed, nurse leaders turned to the literature for further perspectives and guidance on types of PIVCs. A literature review was completed to establish the current available research related to open verses closed PIVCs and a table of evidence was compiled (Appendix I). Three randomized controlled trials (RCT) were available for review, indicating a need for continued research in this area of interest. A 2013 RCT with the aim to compare closed-system with open-system PIVCs, showed an increase in dwell time, a 29% decrease in

phlebitis rates and a 20% relative risk reduction of catheter-related infections with a closed-system (González López et al., 2013). A 2014 RCT compared an integrated closed-system with a built in stabilization platform to a conventional catheter with a blood control valve. This study concluded that there were significantly fewer catheter replacements due to catheter related complications in the integrated closed-system and that the pre-attached wing-shaped stabilization platform was the main contributor to this result (Tamura et al., 2014). The results from this study also suggested that longer dwell times offset the higher initial catheter costs of a closed-system. Bausone-Gazda, Lefaiver, & Walters (2010), conducted a RCT at a level one trauma, American Nurses Credentialing Center (ANCC) Magnet® designated, facility comparing a closed-system with a built in stabilization platform to an open-system catheter in which an add-on stabilization device was applied. This study concluded that the risk of securement related complications was reduced by 26% in the closed-system with the built in stabilization device, and findings were utilized to support the Infusion Nursing Standards of Practice for catheter stabilization (Bausone-Gazda, Lefaiver, & Walters, 2010). All three studies found evidence of benefit by utilizing a closed versus open PIVC system.

Blood exposure risk was a prominent concern for clinical staff and these concerns continued past the six week learning time period. Even after additional on-site PIVC insertion training, staff continued to report inability to occlude the vessel and prevent blood leakage during insertion for certain patients. A 2011 quantitative study focused on reducing blood exposure risk and cost associated with PIVC insertion (Richardson & Kaufman, 2011). In this study, when surveyed about traditional open-system PIVCs, 49% of nurses reported blood exposure 50% of the time; 20% stated they experienced

blood leakage 100% of the time; 10% stated they never experienced blood leakage (Richardson & Kaufman, 2011). Comparatively, nurses reported blood exposure 11% of the time with closed-system PIVCs (Richardson & Kaufman, 2011). In this same study, when asked about blood leakage onto scrubs, 50% of nurses who had blood leak onto their scrubs stated that they changed immediately; the other 50% attempted to clean up the blood from their scrubs. This study also highlighted research related to under reporting of blood exposure, stating in the United States, researchers have found this rate to be as high as 82% (Richardson & Kaufman, 2011).

Purpose Statement

The purpose of this pilot was to determine the feasibility of assessing nurse and patient outcomes related to the use of three different types of PIVC, and to pilot implementation of a RCT prior to the expansion of the study to other facilities, which comparatively evaluated outcomes between two closed PIVC systems, and an open peripheral intravenous system. The open PIVC system was the current standard of care at the pilot facility. The rationale for including the two closed PIVC systems in this study was that pilot facility had been using closed PIVC system 1 for over 20 years with no significant patient complaints or poor patient outcomes as described previously. It was also important to include a second closed PIVC system in the study. Closed PIVC system 2is the second generation to the closed PIVC system 1 and it has added power injectable capability, meaning it is able to support high-pressure injections up to 300psi; a requirement for injection of dye for computerized axial tomography (CAT) scans. The Shared Governance Council was involved in the decision and the council recommended that the closed PIVC system 2 be evaluated for effectiveness as well.

Variables studied were PIVC dwell time, blood exposure at insertion, effectiveness of insertion (flashback visualization, number of attempts), pain, needle-stick prevention feature, complications (phlebitis, dislodgment, infiltration, unintended removal), cost (device, add-on's and other applicable materials including clean up supplies), nurse satisfaction and patient satisfaction.

Problem Statement

PIVCs are used at a high volume in both the acute and ambulatory settings throughout acute care facilities. Due to the high volume of use and significance in patient care, failure and/or complications from a PIVC can have a significant impact. Quality improvement analysis, along with the literature review, indicated that complications such as infiltration, leaking, pain, phlebitis, reinsertions can have serious consequences in patient care, leading to potential delays in treatment, patient discomfort, patient dissatisfaction, safety concerns, nursing interruptions, increased length of stay, morbidity, and added costs (Bausone-Gazda, Leaiver, & Walters, 2010; Rickard et al., 2015). In a 2015 abstract for a three year RCT underway at a multi-center facility, the primary investigator (PI) explains that if PIVC failure rates can be reduced by 10%, this could prevent more than 30 million failures and reinsertions in the United States alone which would result in reductions in cost, nursing time, and improved patient experiences (Rickard et al., 2015). Additional research in this area can prove beneficial for evidence-based care improvement within the larger healthcare system, comprised of 11 other hospitals, and across the nation. Researchers are proposing to conduct a pilot of multi-center RCT to evaluate 3 different PIVCs with the purpose of comparing complications, blood exposure, nurse and patient satisfaction and potential cost implications. In order to

evaluate feasibility of such a study, evaluation of specific process measures was necessary.

Objectives and Aims

The purpose of this pilot was to determine the feasibility of assessing nurse and patient outcomes related to the use of three different types of PIVC, and to pilot implementation of a RCT prior to the expansion of the study to other facilities, which comparatively evaluated outcomes between the closed PIVC system 1 and closed PIVC system 2,, and the open PIVC system. The results of this pilot have informed the expansion of this study to a RCT multi-site design. Both process and outcome variables were collected in this pilot study. In relation to process, the following variables were studied: response rates, percentage of completed questionnaires, missing data elements, Clinician Training, feedback from clinician training, enrollment participation, and preliminary costs. The specific aims were as follows:

1. To examine feasibility of measuring the following items listed, by measuring the:
    a. Clinician and Patient Questionnaire response rate
    b. Percentage of Clinician and Patient Questionnaires that are complete
    b. Number of missing data elements for each study variable (i.e. number of data elements missing from electronic chart documentation and items on questionnaires)
2. Describe clinician training completion by the number of completed Clinician Training Forms
3. Describe themes in clinician evaluative comments about study training
4. Describe themes in patient comments about PIVC insertion

5. Describe enrollment participation by measuring the percent of patients declining to provide consent
6. Describe preliminary costs by calculating the number of products used at the time of insertion multiplied by product cost.

Guiding Framework (Theoretical Model)

Utilizing the Institute for Healthcare Improvement (IHI) (2016) test of change model, the plan, do, study, act cycle (PDSA cycle), a process evaluation was completed as part of the feasibility of the larger RCT study (Appendix J). The PDSA cycle is a tool and model used to direct quality improvement measures. The PDSA is a framework used to plan improvements, test the change, study results, and act on findings (IHI, 2016). Quality improvement (QI) and process evaluation are important to the RCT due to few publications and limited knowledge of variables being studied. Appendix H depicts the research conceptual model for the larger RCT. The PDSA model allowed for iterations to process as needed, as the RCT expanded to other sites, building on lessons learned from the feasibility study at the pilot study site. Using the PDSA cycle as part of the feasibility to the RCT study identified process specific problems (Bowen et al., 2009).

During the planning phase, a workgroup with representation from all RCT facilities, alongside the research team, began meeting to discuss the development of the study, including design, study variables, and outcomes. This group continued to meet weekly to develop education, communication, and clarify details of the project. Implementing the feasibility study site was the second phase of the PDSA cycle, where feasibility study outcomes (clinician and patient questionnaire response rate and percentage of complete questionnaires, number of missing data elements and completed

clinician training forms, thematic feedback from clinicians and patients, enrollment participation, and preliminary costs) were collected for evaluation and analysis. Analysis of these process measure outcomes helped guide expanding this study to the remaining study facilities, which was the third phase of the PDSA cycle. Finally, evaluating the findings and making adjustments to any processes within the study, as indicated, was the last step of the PDSA cycle.

Specific areas of process measure evaluation evaluated were acceptability (to what extent the process was appropriate), demand (to what extent the process was used), implementation (to what extent the process was delivered to participants), and practicality (to what extent this process was being carried out) (Bowen et al., 2009). After IRB approval and initiation of the project, data collected at the pilot study site was analyzed and studied, and used to refine processes that were expanded upon at the other RCT facilities.

Methods (Project and Study Design)

Setting & Resources

Using the PDSA cycle, process measures were evaluated, culminating in an experimental randomized controlled clinical trial (RCT). A 238-bed community hospital served as the pilot facility, with the first four weeks of the RCT comprising the data collection period for this pilot. A PIVC workgroup met weekly and was comprised of representatives from Quality, Risk & Legal, Nursing, Performance Improvement, Process Improvement, Data Analytics, and IV Therapy. The PDSA do and study phases of the change cycle included four-week data collection period that began after completion of clinician training at the pilot facility. Three PIVCs were studied, with the comparison

group being the open PIVC system. The intervention groups were the closed PIVC system 1 with the open PIVC system and closed PIVC system 2 with the open PIVC system.

Study Population

Participants were selected on a convenience basis from the inpatient and outpatient population based on the eligibility inclusion and exclusion criteria listed in Table 1. The number of enrolled patients after four weeks of data collection served as the pilot study population. The goal was to collect a total of 120 patients (40 enrolled patients for each PIVC) by the end of four weeks.

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria	Exclusion Criteria
▪ Inpatients or Outpatients ≥ 18 years old ▪ Available insertion site on the hand/forearm ▪ Demonstrates cooperation with medical devices and/or treatments ▪ Speaks and reads English ▪ Able to give Informed Consent	▪ Participating in another study or previously participated in this current study ▪ New PIVC site will be placed below an old infusion site or at an area of flexion ▪ Has a documented or known sensitivity to medical adhesive products ▪ Has dermatitis, burns, lesions, or tattoos at or near the insertion site ▪ Diaphoretic at the time of catheter insertion ▪ Requires application of topical antibiotics or ointments under dressing ▪ Has an IV site that requires a gauze pad or a tackifier ▪ Is pregnant ▪ Requires a 14 or 16 gauge PIVC ▪ Has a condition that in the opinion of the investigator or staff nurse would make the patient unsuitable for enrollment in this study

Once a patient was deemed eligible for participation, trained personnel in obtaining informed consent approached him or her to invite participation. After informed consent was obtained, participants were enrolled in the study. Participants were enrolled Monday thru Friday, during the hours of 0800 to 1630. Patients were enrolled during these hours due to additional resources being available to assist with obtaining consent as well as administrative tasks, such as returning study documents to the PI.

Randomization

A convenience sample of patients was used. After patients were identified as eligible for the study and informed consent obtained, the patient was randomly assigned to one of the three PIVCs. The participants study group were determined randomly using a six-sided dice from within the convenience sample of participants. Immediately after obtaining consent, the PIVC inserting clinician rolled the dice to determine random assignment. If the dice rolled a '1' or a '2', the patient received the open PIVC system 1. If the dice rolled a '3' or a '4', the patient received the open PIVC system 2. If the dice rolled a '5' or a '6', the patient received the closed PIVC system.

Insertion & Maintenance Procedures

PIVCs were inserted and maintained in accordance with guidelines from the Infusion Nurses Society (INS) (2016) and the Centers for Disease Control and Prevention (CDC, 2011). Clinicians inserting the study PIVC were trained and competencies verified for inserting and maintaining each of the three types of PIVCs. Figure 2. displays the enrollment and PIVC insertion process and was included as part of the clinician training.

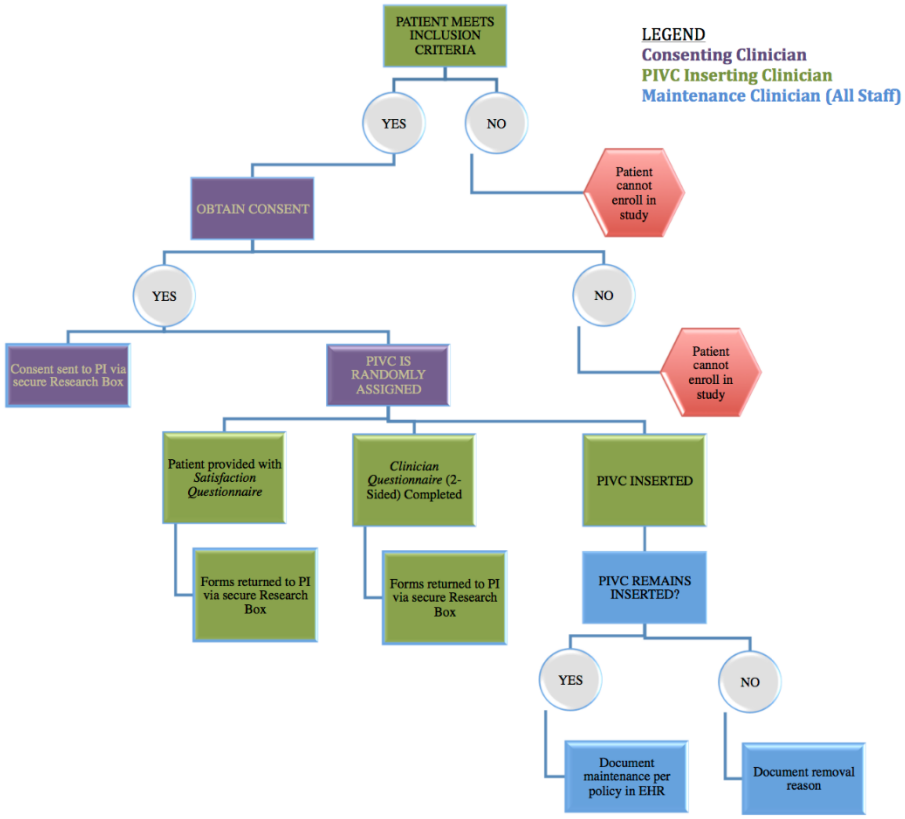

Figure 2. Clinician workflow for patient enrollment in PIVC Nursing Research Study.

Clinical Training & Education of Participating Staff

Clinician training on the insertion technique for each device was provided in addition to two weeks of practice in the clinical units/setting for each device (3 weeks total) before beginning service as an inserting clinician. Training was provided at no cost to the clinician (*i.e.*, was scheduled during work hours with coverage for the time the nurse spent away from the unit). The PI of the RCT was granted two awards, a $5,000 Research Fellowship and $2,000 Research Scholarship, which were to be utilized to cover study expenses. The Chief Nurse Executive (CNE) approved the cost of clinician training, and costs were absorbed by the monetary awards. To assist the individual units, the internal scholarship money was available to assist with costs related to study supplies, so that, products and supplies were not additional costs to units. Topics included in

clinician training were adverse event reporting, PIVC insertion policy, consent process, inclusion/exclusion criteria, PIVC data collection instruments, and hands-on return demonstration training. Clinicians completed demographic information and were signed off on review of policies, research design, and return demonstration for each of the above-mentioned topics. Clinicians participating in the study were paid for their time, and clinicians eligible for the hospital's recognition program received nursing research participatory points towards their clinical ladder portfolio.

Clinicians with experience and advanced skill, with regards to PIVC insertion, were recruited from each of the study units (ED, Cancer Center, Treatment Center, and Inpatient Nursing Units) and were invited to participate in the pilot study. Clinicians were defined as registered nurses (RNs) or unlicensed ED Technicians and were required to work a minimum of 20 hours per week. Enrollment was limited to day-time hours; therefore, in order to enroll patients routinely, clinicians were required to work the day-shift and work a minimum number of hours.

Data Collection

Data was collected using paper questionnaires (see Appendix E and F) along with data extraction from the EHR. Patient and Clinician Demographics that were collected are listed in Table 2. Items collected using paper questionnaire are marked (P) and from the EHR are marked (E). Clinician demographics were collected during the training sessions for the nurses. All patient identifiers were removed from the database by the PI for de-identification purposes before conducting analyses. A patient label was placed on the consent form with a corresponding participant identification (ID) code. Thereafter, only the participant ID code was used to label data collection tools. The list of patient

identifier and corresponding ID codes was kept in a password protected excel spreadsheet accessible only to the PI. The number of patients who refused consent was tracked for reporting purposes only.

Table 2. Patient and Clinician Demographics

Patient Demographics	Clinician Demographics
▪ Hospital Status (i.e. Outpatient vs. Inpatient) (E) ▪ Age (E) ▪ MR# (E) ▪ Encounter # (E) ▪ Gender (E) ▪ Admitting Dx (E) ▪ Principal Dx (E) ▪ Secondary Dx's (E) (grouped by Dx categories) ▪ Location (department) of insertion (P)	▪ Working Area (Unit/Department) (P) ▪ Years of IV Insertion Experience (P) ▪ IV Team Member - Yes/No? (P) ▪ RN, LPN, Tech (P)

Variables from the larger RCT were monitored for complete documentation in the feasibility study, and included blood leakage during insertion, effectiveness of insertion (number of attempts), complications (phlebitis, unplanned removal of PIVC, infiltration, occlusion), dwell time, pain unrelated to above variables, pain during insertion, removal reason, and cost will be collected electronically through the EHR. Variables collected electronically (from EHR, represented by "E" in Table 2.) and observed for completeness, included the following: blood leakage on insertion, insertion attempts, complications (phlebitis, unplanned removal of PIVC, infiltration, occlusion), dwell time, and removal reason. Variables collected manually (on paper, represented by "P" in Table 2.) and observed for completeness, included the following: insertion attempts, pain unrelated to variables and pain during insertion, and cost. Appendix B depicts each variable, its definition, and method of data collection (P) or (E). Missing data related to

the above mentioned variables were evaluated by the PI and research team. Problems identified with the completed documentation were discussed at the PIVC workgroup and solutions were developed and communicated by the PI and research team. Any recommended changes were discussed and considered for process adjustments.

Three PIVC products were used: the open PIVC system (18-24 gauge), and closed PIVC system 1 and 2 (18-24 gauge). Potential add-ons used is shown in Table 3.

Table 3. Add On Products

Add-On Item #	Description
187006	7"Pressure Infusion Ext Set
178699	Microbore Extension Set- 7 inch Non-DEHP
179277	Microclave Clear

The clinician questionnaire (completed after PIVC insertion) (Appendix F) and the patient questionnaire (completed after PIVC removal) (Appendix E) were collected by and monitored by the PI for response rate and percentage of completed forms. These questionnaires were created by adapting measures from the Emergency Care Research Institute (ECRI), the CDC, and consulting content experts, including staff nurses and quality and safety nurses. While no reliability and validity data exist for these measures, two nurse experts verified the content validity.

Data Analysis

Outcomes collected for this pilot were clinician and patient questionnaire response rate and percentage of completed questionnaires, number of missing data elements and completed clinician training forms, thematic feedback from clinicians and patients, enrollment participation, and preliminary costs. After data was collected from secure boxes on inserting units, data was entered into an excel file and verified. Paper

questionnaires were labeled with the participant's unique participant ID code (*not* the patient's medical record number label) for tracking purposes and collected in a secure lock box on each unit. Paper questionnaire data was transcribed and coded into an excel file managed by and accessible only to the PI and specified members of the research team. To reduce missing documents and data, the PI reviewed the enrolled participants EHR documentation and the questionnaires daily and made efforts to collect missing elements

EHR variables were extracted from the EHR for analysis using an internal reporting system called Clarity Reporting. Data was deidentified by removing medical record and encounter numbers prior to aggregation and analysis. Frequencies, descriptive statistics, incidence rates, and skewed data was analyzed. Analysis that revealed findings that suggested making a change to the study process were discussed and considered for process adjustments. Understanding process related problems improved implementation and expansion of this study at the other facilities. Any solutions, recommended changes, or major structural problems requiring process change, affecting the IRB protocol itself, necessitated obtaining appropriate permissions for IRB amendment approval, and were updated through all appropriate IRBs.

Human Subjects Protection

IRB approval was obtained and patients were provided information explaining the study. Consent was required and was obtained (Appendix C). Consent was provided by onsite, trained personnel. While in the study, participants were at very low risk for problems and were at no more risk than patients declining to participate in the study but whom have a PIVC inserted. Any questions regarding participation in the study were

answered prior to obtaining consent. If a patient declined to participate in the study, they continued to receive standard PIVC care. All excel files were kept on a secure, encrypted, password protected server accessible only to the PI. All protected health information was maintained in strict confidence as required by law.

Results

Descriptive Analysis

Summaries of quantitative descriptive results are described in Table 4. Sixteen (n=16) clinicians were trained for this pilot, which included inserting (n=9) and consenting (n=7) roles. There was some overlap of roles, as some inserting clinicians were also able to provide consent. Participant enrollment (n=35) over four weeks was much lower than anticipated. Anticipated enrollment was to enroll 40 participants per PIVC for a total enrollment of 120 participants. All participants that were agreeable to participate in the study completed the consenting process. One subject declined to participate after signing the consent form. There were a total of four (n=45) complications during the pilot. Complications seen during the pilot included unsuccessful insertion (n=1) and unplanned reinsertion (n=3).

Questionnaires were evaluated for percent returned (response rate) and percent completed (missing data) as shown in Table 5. One challenge was unreturned patient questionnaires (n=10), the highest contributing source of missing questionnaires. Of the 35 patient questionnaires distributed 10 (29%) were not returned. Of the patient questionnaires returned, 100% were entirely complete with all questions answered. The opposite problem occurred with clinician questionnaires. Clinician questionnaire response rate was 100%; however, several returned questionnaires were incomplete.

Table 6. displays the missing clinician and patient data from both the paper questionnaire

(1%) and the EHR data (4%).

Table 4. Quantitative Descriptive Results

	(n)	**(%)**
Clinician Training (Total Clinicians 16)	**16**	-
Inserting	9	56%
Consenting	7	44%
Enrollment (Total Insertions 35)	**35**	-
Closed PIVC system 1	9	26%
Closed PIVC system 2	19	54%
Open PIVC system	7	20%
Complications (Total Insertions 35)	**4**	**11.4%**
Unsuccessful Insertion	1	2.8%
Unplanned Reinsertion	3	8.6%

Table 5. Questionnaire Response Rate

	(n)	**(%)**
Clinicians	35/35	100%
Patients	25/35	71%

Table 6. Missing Data

	Number Missing/Total	**(%)**
Missing Data - Clinicians		
Paper Questionnaire		
Did blood leak out of the catheter during or after insertion?	*2/35*	*5.7%*
Patient will go home with PIVC inserted?	*2/35*	*5.7%*
EHR		
Missing PIVC Study Type – not present in EHR	*6/35*	*17.1%*
Missing Data - Patients	**0**	**0%**
While the PIVC was in place, what was your average pain level at the site of the PIVC?	*0*	*0%*
What was your overall level of satisfaction with the PIVC?	*0*	*0%*

Content Analysis

Qualitative feedback was obtained through patient and clinician questionnaires. These forms were collected by the PI and entered into an excel spreadsheet. Using Graneheim & Lundman's (2004) content analysis approach, feedback was broken down into the simplest like-comments (meaning unit), which was then condensed and turned into a code (p. 106-107). These codes were then grouped into similar categories as seen in Table 7. The categories were reviewed and grouped into common themes, which included closed PIVC system 1 Experience, closed PIVC system 2 Experience, open PIVC system Experience, Enrollment, and Clinician Role. These themes were less useful at identifying potential outcomes, but they were used to provide a framework for future qualitative content analysis as the study progresses (Graneheim & Lundman, 2004; Hsieh & Shannon, 2005).

PIVC Experience

Feedback for closed PIVC system 1included "more comfortable; placement is more comfortable" (n=3). Participants enrolled appeared to prefer this PIVC (n=2), and participants indicated it hurt less (n=4). Top closed PIVC system 2 feedback included participants reporting easier insertion (n=6), less pain (n=6), and "more secure, least complicated" in relation to device design (n=6). However, participants did indicate that the closed PIVC system 2 required restart or reinsertion (n=6). Participants commenting on the open PIVC system indicated that they observed bleeding (n=4), more pain (n=2), and reinsertion needed (n=4). Reports indicating that open PIVC system was their least favorite was also reported (n=3).

Enrollment

The majority of the feedback from clinicians indicated that they experienced the most difficulty in the pilot during the consenting process (n=9). Clinicians reported that many patients declined to participate at the time of consent or that patients were agreeable until the consent form was presented. Some clinicians reported other difficulty during the consent process with participants feeling overwhelmed, fearful to sign, or electing to not read the consent. Clinicians also reported insufficient numbers (n=7), mostly with difficulty in recruiting appropriate participants that met inclusion/exclusion criteria and that they found it difficult to complete the required paperwork.

Clinician Role

Patient feedback was overwhelmingly positive with regards to the staff working with them during their treatment. Patients noted their positive feedback on staff knowledge (n=12). Patients reported that "nurse medical advice has saved me pain and discomfort" and that "nurses work to provide best care possible". Staff reported that staffing issues (n=6) such as time off, departmental changes, and job transitions affected the clinician role in this pilot. Staff also felt that clinicians should be able to insert and consent (n=5) to help with the staff availability issues causing delay in the consent process (n=4). There was very little qualitative feedback from clinician training forms evaluating the initial training sessions. As this was a pilot study, there were few expectations about training and participating in the study. Clinicians provided no helpful evaluative feedback on training sessions; rather, they focused their comments by providing feedback in the clinician questionnaire.

Table 7. Content Analysis-Clinician and Participant Enrollment Feedback

Themes	Categories
Closed PIVC system 1	Insertion 5 Hurts Less 4 Comfort 3 Device Design 3 Prefers PIVC 2
Closed PIVC system 2	Reinsertion 6 Hurts Less 6 Device Design 6 Easy Insertion 6 More Comfortable 2 Prefers PIVC 2 Difficult Insertion 1 Does not Prefer 1 Easier to Move 1 Difficult to Move 1
Open PIVC system	Bleeding 4 Reinsertion 4 Does not Prefer 3 Hurts More 2 Prefers PIVC 1 No Bleeding 1
Enrollment	Difficulty During Consent 9 Insufficient Numbers 7
Clinician Role	Staff Knowledge 12 Staffing Issues 6 Clinician Training 5 Staff Availability 4 Staff Professionalism 2

Cost Analysis

After initiating this pilot, two significant operational events occurred. The first relates to the renegotiation of cost for the standard practice PIVC used, which led to a reduction in cost of about $0.15 per product. A second operational event to occur was to PIVC Start Kits. Each PIVC start kit had the surgical towel removed from the kit, decreasing the cost by about $0.30 per product. The surgical towel had been previously

used to help with the blood leakage reported on insertion. The surgical towel was replaced by a lower quality, cheaper product. While these changes are minor, they contribute to an overall reduction in cost and made analyzing cost between the three PIVCs more difficult. These changes occurred after presentation to the Nurse Executive Council in December 2015, but before beginning analysis of this pilot. Table 8. describes what cost would have been if products costs would have remained steady throughout the pilot. Product costs used in Table 7 are based on original figures provided by Materials Management at the pilot site. Individual product costs were multiplied by products used in the pilot to calculate total cost. Reinsertion costs were calculated based on a reported unplanned removal of the study PIVC, and totaled the sum of a standard PIVC insertion cost. Cost assumptions cannot be made using the pilot results; however, the framework for calculating total and reinsertion costs were used to inform the larger RCT.

Table 8. Cost Analysis – Summary of pilot costs and products used

By Individual Product	**Total Cost (USD)**
Add ons	
7" Pressure Infusion Extension Set ($1.85/product)	$7.40
Microbore Extension Set – 7in Non-DEHP ($1.20/product)	$4.80
Microclave ($0.80/product)	$27.20
PIVC	
Closed PIVC system 1 ($2.53/product)	$22.77
Closed PIVC system 2 ($3.69/product)	$84.87
Open PIVC system ($1.50/product)	$13.50
Start Kit	$44.10
By PIVC Insertion *(Total cost of insertion, including Add-ons, PIVC, and Start Kit)*	
Closed PIVC system 1 Insertion	$41.31
Closed PIVC system 1 Insertion	$125.61
Open PIVC system Insertion	$37.93
By Reinsertion Costs	

Closed PIVC system 1 Insertion	$4.64
Closed PIVC system 2 Insertion	$9.28
Open PIVC system Insertion	$0.00

Implications

Resource Allocation

The largest insight this pilot revealed was the slower than expected enrollment. Availability of inserting and consenting clinicians was part of the issue with slow enrollment. It was anticipated that the ED would enroll the most participants, and for this reason more inserting clinicians were trained in the ED than on inpatient units. However, due to staffing changes and workflow barriers, the ED was unable to enroll any during this pilot. The workflow in the ED prohibited the completion of additional consent form and questionnaires, a barrier to enrollment. A future recommendation would be to engage nursing leadership at the unit-level earlier in the designing phases to understand unit-level concerns and resource allocation. The availability of consenting clinicians also delayed the workflow for inserting clinicians. Ensuring at least two consenting clinicians per participating unit would help reduce the waiting time for enrollment. In addition to training more inserting clinicians, encouraging inserting clinicians to take human subjects in research training to be able to consent should be considered for the expansion of this study.

Missing Questionnaires

Missing patient questionnaires contributed to the largest category of missing questionnaires. After speaking with bedside nursing, their knowledge of the pilot study was limited. It was realized that communication to those participating in the study as

well as organization leadership had occurred, but limited information was provided to non-inserting and non-consenting front-line staff. Therefore, the importance of returning the patient questionnaire was not communicated from shift to shift, and as a result not returned to the PI. The PI established weekly rounding to reinforce the importance of returning patient questionnaires. After enrollment of a participant, the consenting clinician was also instructed to give verbal handoff to that subject's nurse, also reinforcing the importance of returning the patient questionnaire. To make the patient questionnaire more visible in the room, the PI instructed participating clinicians to utilize the whiteboard and magnets already present in the room. This kept the questionnaire visible to both the enrollee and nursing staff.

Missing Data

EHR data contributed as the largest source of missing data. After drilling down on the missing EHR data two things were determined regarding documentation. The first was that staff were not documenting the PIVC in the *PIVC Study Type* flowsheet. The clarity report was built to pull based on the presence of data in this field for all identified inserting clinicians. When this field was left blank, no information would flow into the clarity report, resulting in the need for manual abstraction. The second thing identified was that even when this field had correct documentation present, if the inserting clinician was not the one to document, no information would flow into the clarity report. It came to the team's attention that clinicians not identified as an inserting clinician for the study would assist the inserting clinicians by documenting for them. The clarity report was built to pull information documented by the inserting clinicians in the study only.

Education and awareness was quickly provided to the staff and participating clinicians on the importance of accurate documentation by inserting clinicians only.

Informing the Larger RCT

The results from this pilot have informed and provided recommended changes to the larger RCT and are summarized in Table 9. Understanding the workflow, process, and needed resources has revealed clearer expectations for the continuation and expansion of the study. After analyzing the pace of enrollment and resources needed, recommendations for additional inpatient clinicians to be trained in both insertion and consenting was identified. Strategically placing consenting clinicians will be important for ease of enrollment. Furthermore, recognizing the unit-level resource limitations will help to identify appropriate enrollment locations. Lastly, the work done to establish a framework for future content analysis was developed as a result of this pilot.

Table 9. Lessons Learned and Clinical Implications

Lessons Learned	Clinical Implications
Slower than expected enrollment	✓ Second training arranged to engage more clinicians
	✓ Every 36-bed unit should train (2) inserting clinicians and (1) consenting clinician
Few returned Patient Questionnaires	✓ Utilize patient room whiteboards and magnets to increase returned documents
	✓ Weekly rounding to reinforce importance of returned documents
Pilot informed recommended changes for larger RCT	✓ Framework for future Content Analysis was developed
	✓ Avoid areas where consent process may delay care
	✓ Engage with leadership in planning phase to help with communication and resource allocation

Strengths and Limitations

This pilot used the PDSA cycle as the guiding framework for study implementation. Using this process was a practical way of determining the feasibility of such a large study design in the context of a complex organizational structure. The study design for the larger RCT is the first of its kind; therefore, this pilot has positively informed the continuation and expansion of the larger RCT. The lessons learned and analysis from this pilot provides a framework for future data analysis.

This pilot was limited to four weeks of data collection, which may not have been enough time to truly understand all of the barriers and processes needing improvement. With a slower than expected enrollment rate and low participation from units involved, a longer time period for the pilot may have been beneficial. Another limitation to this pilot is the shifting and renegotiation of prices for products used within the study. Obtaining pricing information, along with renegotiated cost/product across the healthcare system, has caused considerable difficulty in completing a cost analysis.

Conclusion

The pilot of a RCT comparing outcomes of three different PIVCs was successfully completed and has constructively informed the larger RCT. The PDSA cycle is an effective guiding framework to understand the process for implementing the larger RCT study design. The steps in the PDSA cycle provided structure to the PI to plan, implement, analyze, and act upon the proposed study. The pilot results suggest that enrollment to this study is slow due to limited availability of consenting clinicians and that resource allocation, in general, is a barrier to this study. Enrollment is not feasible in areas where workflow is time sensitive and pace of work cannot accommodate a delay in

patient care. While results from this pilot were limited to identification of process improvement opportunities, the results of this pilot suggest that there is need for continued enrollment, because it is still unclear which PIVC is best in terms of complications, satisfaction, and cost. The recommendation from this pilot study will be to continue enrollment at the pilot site and to expand to the other proposed hospitals, building on lessons learned from the pilot.

Appendices

Appendix A – Add on Products
Appendix B – Data Glossary
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Appendix I – Table of Evidence – Systematic Review
Appendix J – Theoretical Model (PDSA Cycle)

Appendix A – Add on Products

Table 3. Add on Products

Add-On Item #	Description
187006	7"Pressure Infusion Ext Set
178699	Microbore Extension Set- 7 inch Non-DEHP
179277	Microclave Clear

Appendix B – Data Glossary

Term	**Definition**	**Measurement Definitions**
Add-Ons (P)	Per INS Standards of Practice (2016), adds on are defined as devices that minimize manipulation and reduce multiple components, such as single and multi-lumen extension sets and/or needleless connectors (INS, 2016). Add-ons should be considered only for clinical indications (INS, 2016).	Used at time of insertion.
Adverse Event	According to the Sentara Healthcare (SHC) Incident and Event Reporting Risk Management Policy, any event unrelated to the ordinary course of the patient's hospitalization, will be reported according to SHC policy.	Incident and Event Reporting SHC Policy (5/2015)
Adverse Event (Serious)	As defined by the pilot facility's IRB, Serious Adverse Events include any experience that is fatal or life threatening, is permanently or significantly disabling, requires inpatient hospitalization or prolongation of hospitalization, a congenital anomaly/birth defect or is medically significant. Adverse events related to this study are to be reported to the IRB, according to IRB policy.	Institutional Review Board
Closed PIVC system 1	Closed PIVC System without stabilization, available in 18-24 gauge; however, is not power injectable and has no large bore catheter available.	N/A
Open PIVC system	Open PIVC System without stabilization, available in 14-24 gauge, and has power injectable capability and a large bore catheter is available.	N/A
Closed PIVC system 2	Closed PIVC System with built-in stabilization, available in 18-24 gauge, and has power injectable capability (with exception of 24 gauge), but has no large bore catheter available.	N/A
Blood exposure (E)	"Occupational exposure to blood borne pathogens related to leakage, spill, or splash of blood through needlesticks or cuts from other sharp instruments contaminated with an infected patient's blood or through contact of the eye, nose, mouth, or skin with a patient's blood"11.	2016 INS Policies & Procedures
Blood leakage (P)	Blood leakage will be defined as blood leaking from the catheter onto an area unexpectedly. For example, blood leaking onto intact skin, staff clothing, bed linen, or patient clothing would be considered blood leakage.	
Clinician	Registered Nurse (RN), Licensed Practical Nurse (LPN), or Technician.	
Closed System	Closed systems are PIVCs that may not require add ons during the insertion process. The add ons and PIVC are one product, and come packaged as one unit together.	

Term	Definition	Measurement Definitions
Data Safety Monitoring Process	According to the Sentara Healthcare (SHC) Incident and Event Reporting Risk Management Policy, any event unrelated to the ordinary course of the patient's hospitalization, will be reported according to SHC policy. According to the policy, incident reporting is not a part of the medical record, and is not to contain information related to the hospitalization or treatment of any patient in the ordinary course of hospitalization of such patient. Staff members with the best first-hand knowledge of what occurred should complete an incident and event report, according to policy and job aides. Investigation will be initiated, as appropriate, within 24 hours of receipt of the incident/event report, or notification of the event.	Incident and Event Reporting SHC Policy (5/2015)
Diaphoretic	Profuse sweating, which may interfere with the adhesion of study PIVC dressings.	
Dwell time (E)	The amount of time a catheter is dwelling in the vein (INS, 2016). Recommendation from INS (2016) is a dwell time no longer than 96 hours.	Measured in Hours
Infiltration (E)	Inadvertent administration of a nonvesicant solution or medication into surrounding tissue (INS, 2016). Infiltration will be classified according to the INS, as follows: 0, no symptoms/signs; 1+, skin blanched, edema <1 inch, cool to touch, with or without pain; 2+, skin blanched, edema 1-6 inches, cool to touch, with or without pain; 3+, skin blanched/translucent, gross edema >6 inches, cold to touch, mild-moderate pain, possible numbness; and 4+, skin blanched, translucent, skin tight/leaking/discolored, bruised, swollen, gross edema >6 inches, deep pitting tissue edema, circulatory impairment, moderate-severe pain, infiltration of any amount of blood product, irritant, or vesicant (INS, 2016; INS, 2006).	2016 INS Policies & Procedures; 2006 INS Standards of Practice
Informed Consent	Informed consent is required for human subject participation in research according to federal rules and regulations (INS, 2016).	N/A
Inpatient Population (E)	Inpatient is defined as an inpatient admission to an inpatient unit.	Point of Entry
Occlusion (E)	The inability to flush the catheter without resistance and the inability to yield a blood return (INS, 2016).	2016 INS Policies & Procedures
Open System	Open systems are PIVCs that require add ons to be added as part of the insertion process. The add ons and PIVC are separate products, and do not come packaged together.	
Outpatient Population (E)	Outpatient is defined as patients being treated in the Treatment Center, Cancer Center, ED, or designated as Observation Status.	Point of Entry

Term	Definition	Measurement Definitions
Pain: during insertion (P)	Standard Analog Scale 0-10 Scale or Wong Faces Scale	
Pain: unrelated complication variables (P)	Standard Analog Scale 0-10 Scale or Wong Faces Scale	
Patient Identifiers (E)	Patient identifying information, which may include age, gender, or visit number.	
Patient Satisfaction (P)	Satisfaction with the insertion process; evaluation of insertion and dwell time.	
Phlebitis (E)	Mechanical causes of phlebitis result in vein wall irritation can be caused by multiple manipulations of infusion delivery system, large catheter gauge size, catheter material and diameter, failure to stabilize catheter adequately, failure to stabilize the joint if insertion site in or near a joint must be used. Signs and symptoms of phlebitis include pain/tenderness at site, erythema, warmth, swelling, induration, purulent drainage, palpable venous cord (INS, 2016). Phlebitis will be classified according to the INS, as follows: 0, no symptoms/signs; 1+, redness with/without pain; 2+, redness and/or swelling accompanied with pain; and 3+, redness and/or swelling accompanied with pain (INS, 2016).	Phlebitis Classification Scale; 2016 INS Policies & Procedures
Unplanned Removal of PIVC (E)	Early removal of catheter unrelated to treatment plan (INS, 2016)	2016 INS Policies & Procedures

Appendix C – Informed Consent

FORM DATE: 20160729 CONSENT FORM VERSION: 20160729

Subject Consent Form

STUDY TITLE

A randomized trial comparing outcomes of three types of peripheral intravenous catheters (PIVC)

INVESTIGATORS

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Heather Galang, MSN, CNL-BC, Sentara Rockingham Memorial Hospital
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Laura Yoder, PhD, RN, Eastern Mennonite University
Kathie Zimbro, PhD, RN, Sentara Healthcare

SPONSOR

The costs of this study, including administrative fees paid to the investigator(s), are being paid by Sentara Healthcare, and Becton Dickinson, who made the BD Insyte Autogard, BD Saf-T Intima, and BD Nexiva being studied.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out which peripheral intravenous catheter (PIVC) has the best results in terms of fewest complications, patient satisfaction, nurse satisfaction, and cost. Each device is already approved for use in clinical settings, but we don't know which will have the best results in these areas.

WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate in this research project because you are 18 years or older, you have not participated in this study before, you have the need for a peripheral intravenous catheter to be placed in your arm, wrist, or forearm for the purposes of usual care, you can cooperate with usual medical devices and treatments, and are capable of giving informed consent. This is a research study. This study includes only people who choose to take part. You will receive the care you need whether you choose to be a part of the study or not. Please take your time to make your decision and feel free to ask any questions you might have.

WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?

At this local site about 600 people will take part in this study. A total of about 2,400 people are expected to take part in this study at four sites throughout the State of Virginia. We will need you to be in the study for up to 10 days.

WHEN SHOULD YOU NOT TAKE PART?

If you have any of the following conditions or are taking any of the medications listed below, you should not take part in this study:

- Pregnant
- A PIVC already placed above the site where a new PIVC would be placed
- Known sensitivity to medical adhesive products
- Dermatitis, burns, lesions, or tattoos at or near the insertion site
- Diaphoretic (sweaty, moist) skin at time of insertion
- Require application of topical antibiotics or ointments under the PIVC dressing
- An IV site that required a gauze pad or a tackifier

WHAT IS INVOLVED IN THE STUDY?

You will be "randomized" into one of the study groups described below. This means that you will be assigned into a group by chance. It is like throwing dice. A computer program may do this - neither you nor the investigator will choose what group you will be in. You will have a 1 in 3 chance of being placed in any group. People in each group will get one of three different types of the smallest intravenous catheters that get placed in a hand, wrist, or forearm.

The three types of medically approved intravenous catheters are:
- BD Insyte Autogard: has an open end that must be capped or attached to tubing
- BD Saf-T Intima: has a closed end and short tubing already attached
- BD Nexiva: has a closed end, short tubing attached

Regardless which type of catheter you receive, the following are standard procedures that will be done because you will be in this study:
1. A tourniquet will be applied to your arm to aid in finding an appropriate vein for insertion.
2. Your skin will be cleaned at the insertion site with an antiseptic.
3. The nurse will don clean gloves and open the PIVC insertion supplies and prepare them.
4. The nurse will insert the catheter into your vein and then release the tourniquet.
5. The nurse will then add any needed tubing or caps.
6. The nurse will secure the PIVC with tape and a clear dressing and flush the PIVC with sterile saline solution.

The whole procedure will take between 5 and 20 minutes. You will be given a bracelet to wear during the study, identifying which PIVC is being studied. There are no experimental procedures being tested in this study. After the PIVC is removed, you will be asked to complete a short questionnaire about your experience with the PIVC. It will take no more than 10 minutes for you to complete. The bracelet, identifying participation in the study, will be removed at the same time the PIVC is removed.

WHAT ARE THE RISKS OF THE STUDY?

The risks of participating in this study are similar to the risks you would experience during your normal care. By participating in this study, your PIVC insertion risks do not change. While in the study, you are at very low risk for the problems listed below. You should discuss these with the investigator and/or your regular doctor or healthcare provider. Other treatments may be given to make problems less serious and make you more comfortable. Most problems go away shortly after the peripheral intravenous catheter is removed, but in rare cases the problem can be serious, long lasting and/or permanent. There is a risk of fainting during PIVC insertion, infection, bruising, swelling and pain at the site of the PIVC.

Risks and problems related to the different types of peripheral intravenous catheters we are studying include:
- Phlebitis
- Occlusion
- Blood loss
- Infiltration
- Pain
- Unplanned removal
- Leaking at insertion site
- Leaking at tubing connections
- Need for additional, unplanned PIVC

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private. There also may be other risks that are unknown and we cannot predict. For more information about risks and side effects, ask the investigator or contact Sentara Healthcare

FORM DATE: 20160729 CONSENT FORM VERSION: 20160729

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. There is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people who need to have a peripheral intravenous catheter inserted in the future.

WHAT OTHER OPTIONS DO YOU HAVE?

You may receive the standard care BD Insyte PIVC even if you do not take part in the study. Please talk to your regular doctor or health care provider about these and other options.

WHAT ABOUT CONFIDENTIALITY?

In conducting this research study, it may be necessary for the research team to send information about you and your health to persons in other organizations. For example, the investigator or members of her research team will report the results of your study-related questionnaire results and PIVC outcomes to Sentara Healthcare, the sponsor of the study. This information may include what we call "protected health information (PHI)," which includes personal information about you. It will be shared with others only as described below:
We will collect information such as your name, age, gender, your survey answers, comments from your nurse, and documented problems from your records. This data will be stored within an onsite password protected server. All electronic data will be deidentified prior to aggregation and analysis. Consent forms and paper data collection tools will be stored in a locked file in the office of the PI. The consent form will be assigned a unique participant code, which will be used for the deidentified study data. All personal identifiers will be removed from the data when it is placed into the final report for internal review and publication.

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
  You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about you before the date you cancelled will not be used. To cancel your approval, you must notify Heather Galang, MSN, RN-BC, CNL in writing at Sentara RMH Medical Center, 2010 Health Campus Drive, Rockingham, Virginia 22801.
- Your approval for the sharing of personal information about you for this study expires at the end of the study.
- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.

Any research information in your medical record will become a permanent part of that document. Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Eastern Virginia Medical School Institutional Review Board, Sentara Rockingham Memorial Hospital Institutional Review Board, and Sentara Martha Jefferson Hospital Institutional Review Board. Information learned from this research may be used in reports, presentations, publications, or to guide future research. None of these will personally identify you.

WHAT WILL PARTICIPATION IN THE STUDY COST OR PAY?

There are no additional costs to you associated with taking part in this study.

WHAT IF YOU GET INJURED?

In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by Sentara Norfolk General, Sentara RMH, Sentara MJH, or Sentara CarePlex and paid for by you. Further medical care and/or hospitalization resulting from this injury or illness will be charged to you.

Eastern Virginia Medical School and Sentara CarePlex Hospital, Sentara RMH, Sentara MJH and Sentara Norfolk General Hospital will not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you. The investigator may decide to take you off this study if you cancel your approval or it is in the best interest of your health or new information becomes available. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus:

- The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases; and,
- Those test results will be released to the person who was exposed and to the health department as required by Virginia law.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigator, Heather Galang, MSN, RN-BC, CNL at 540-689-1548 or Gina Yost, BSN, RN at 540-689-1000. For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (540) 689-2368.

If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Heather Galang, MSN, RN-BC, CNL at 540-689-1548. You may also contact Dr. Stewart Pollock, chairman of the Sentara RMH Medical Center Institutional Review Board, at (540) 689-2368.

SIGNATURE			
You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study and accept the risks.			
_____ Signature of Participant	_____ Typed or Printed Name	_____ Relationship to Subject	___/___/___ MM/DD/YY

WITNESS (required for oral presentations)		
This signature must be present if the consent was presented orally to a subject in any manner. The witness may not be an individual named as an investigator or a person authorized to negotiate informed consent.		

_____ Signature of Witness ☐ Witnessed Consent Process	_____ Typed or Printed Name	__/__ /__ MM/ DD/ YY

STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

_____ Signature of Investigator or Approved Designee	____ / ____ / ____ MM/ DD/ YY

Sufficient space for the IRB stamp should be included on the 1st page or on the last page of the consent form.

Appendix D – Patient & Clinician Demographics

Table 2. Patient and Clinician Demographics

Patient Demographics	Clinician Demographics
▪ Hospital Status (i.e. Outpatient vs. Inpatient) (E) ▪ Age (E) ▪ MR# (E) ▪ Encounter # (E) ▪ Gender (E) ▪ Admitting Dx (E) ▪ Principal Dx (E) ▪ Secondary Dx's (E) (grouped by Dx categories) ▪ Location (department) of insertion (P)	▪ Working Area (Unit/Department) (P) ▪ Years of IV Insertion Experience (P) ▪ IV Team Member - Yes/No? (P) ▪ RN, LPN, Tech (P)

Appendix E – Patient Questionnaire

Completed after removal, up to a week to obtain

PIVC Study – Patient Questionnaire

Instructions: After the study peripheral intravenous catheter (PIVC) is removed, please mark your evaluation of the study PIVC below.

1. While the PIVC was in place, what was your average pain level <u>at the site of the PIVC</u>? Circle the number on the scale where 0 is no pain and 10 is the worst pain you can imagine.

0	1	2	3	4	5	6	7	8	9	10
No Pain										Severe Pain

2. What was your overall level of satisfaction with the PIVC?

1--	2	3	4	5	6	7	8	9	10 –
Extremely dissatisfied									Extremely satisfied

3. Comments:

Appendix F –Clinician Questionnaire (Front Side)

PIVC Study – Clinician Questionnaire

Completion of this questionnaire implies voluntary participation in the PIVC study and informed consent. Your personal information will not be linked with this questionnaire.

Insertion Date: _____ Insertion Time:_____

Insertion Facility: ☐SRMH ☐ SMJH ☐SCH

How many insertion attempts for success? 1 2 3 4 5
other:_____

How many staff attempted insertion? 1 2 3

Did blood leak out of the catheter during or after insertion? Yes No

Blood leaked onto:☐ Patient ☐ Staff ☐ Patient clothing ☐ Staff clothing ☐ Bed Linen ☐Other:____

Cleaning supplies used: ☐ Additional Gauze ☐ Linen Towel ☐Disinfectant wipe ☐Other:____

Patient will go home with PIVC inserted: ☐Yes ☐ No

What was the patient's pain rating during insertion?

Circle the number on the scale where 0 is no pain and 10 is the worst pain imaginable.

0 No Pain 1 2 3 4 5 6 7 8 9 10 Severe Pain

Insertion Questions	Disagree…….Agree				
The flashback visualization was effective in assisting with insertion	1	2	3	4	5
Sharpness of needle is acceptable					
The catheter threads easily without kinking or bending					
The device is easy to use and does not affect my ability to start IV					
The needle safety feature operates reliably					
The use of this product requires you to use the needle safety feature					
The product stops the flow of blood after the needle is removed					
The user does not have to wipe blood from the patient's skin surface surrounding IV site after insertion					
The user does not need extensive training for the product to be operated correctly					
Patient discomfort is not increased with use of this catheter					

Additional comments:

Participant's ID Code - Label

Appendix F –Clinician Questionnaire (Back Side)

Check IV Type and Number Used at start of IV:

☐ **Insyte Autoguard (Non-winged, Non-BC)**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other _____

☐ **Nexiva (Single Port)**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other _____

☐ **Saf-T-Intima**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other _____

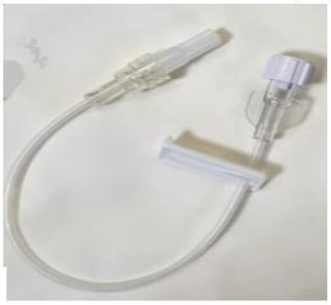
Check all Add-On components used at start of IV:

☐ **MicroClave**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other _____

☐ **Microbore Extension set- 7 Inch**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other ___



☐ **7 Inch Pressure Rated Extension Set w/attached MicroClave**

Used ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Other _____

Participant's ID Code - Label

Created 4/29/16 for Sentara RMH Medical Center
Revised 6/28/16

Appendix G –Clinician Training

PIVC Study – Clinician Training
Completion of this training implies voluntary participation in the PIVC study and informed consent. Your personal information will not be linked with this questionnaire.

Years of IV Insertion Experience:
< 1 year 1-3 years 3-6 years 6-10 years > 10 years

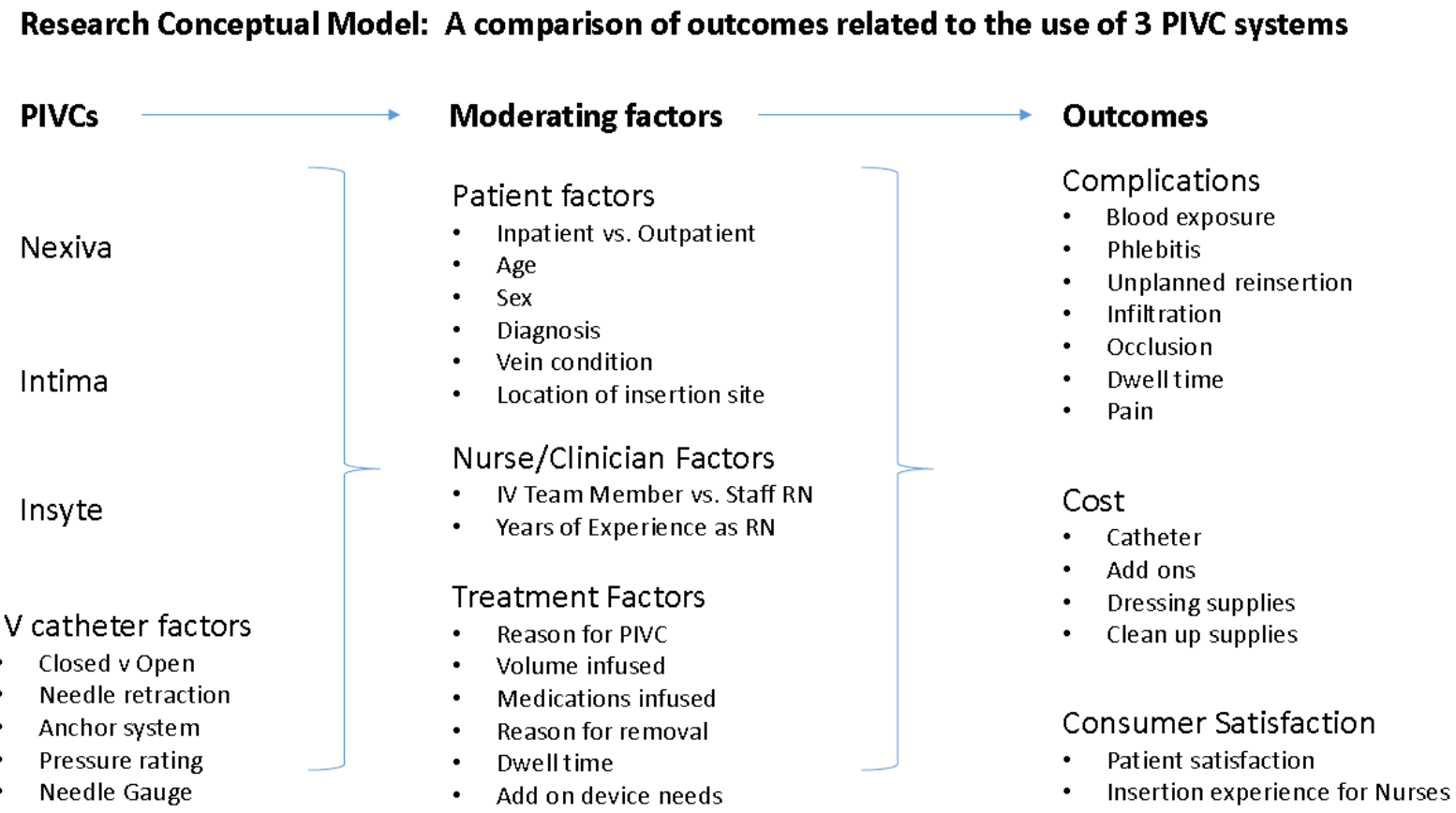
Please check the box next to your primary working unit:
ED Treatment Center Cancer Center Inpatient Nursing Unit

Are you a member of the IV Therapy Team? Yes No

On a scale from 1 to 10, 1 being very low self-confidence **with the skill of inserting PIVCs**, and 10 being very high self-confidence with inserting PIVCs, **where would you rate yourself today**? (circle one)
1 2 3 4 5 6 7 8 9 10
Low self-confidence High self-confidence

Training Topics	Review of Policy Completed	Return Demonstration Completed
Reporting Adverse Events		
PIVC Insertion Policy		
Consent Process		
Inclusion / Exclusion Criteria		
PIVC Study Data Collection Instruments		
Onsite PIVC Training		

Appendix H – Conceptual Model



Appendix I – Table of Evidence – Systematic Review

Table 1. Table of Evidence - Open vs. Closed Peripheral Intravenous Catheter Systems

Author (Year)	Research Design	Level of Evidence*	Sample and Sample Size	Intervention	Instruments	Results/Stats Evidence	Summary/ Conclusion
Bausone-Gazda, D. (2010)	RCT	II	Convenience Sample collected from 302 medical-surgical patients from 9/2008-12/2009, by VAD RNs in a Level 1 Trauma Magnet Designated Facility. Investigational Group (n=150) and control group (n=152) IRB approval obtained, and written informed consent obtained from study participants.	Subjects were randomly placed into the control group (receiving the nonwinged B. Braun Introcan Safety Catheter without built-in stabilization) or the investigational group (receiving the BD Nexiva Closed IV Catheter System with built in stabilization). Randomization was computer generated.	Control catheter - Nonwinged B. Braun Introcan Safety Catheter Investigational catheter – BD Nexiva Closed IV Catheter System	Investigational catheter significantly noninferior to the control catheter. Cox Regression Model HR 0.740 (90% CI: 0.530-1.034) Reducing complications by 26% when using the investigational catheter. Nurse satisfaction significantly improved with the use of the investigational catheter (56% compared to 36%, P≤ 0.001). *Statistical Method:* Cox Regression Analysis	With regards to stabilization, the investigational catheter reduced stabilization-related complications by 26%, and was as effective, if not more so, in terms of location-related complications, than the control catheter. Furthermore, Nurse satisfaction significantly increased with use of the investigational catheter. Findings support INS recommendation to use a catheter including a stabilization platform with dressing designed for stabilization.
Gonzalez Lopez, J.L. et al, (2013)	Prospective RCT	II	952 catheters (513 inpatients) - all patients ≥ 18 receiving PIVC at	PIVCs inserted and maintained in accordance with CDC guidelines.	Compact closed System Catheter (COS) – BD Nexvia	*Results:* Using COS PIVCs provides a RRR of 29%	With use of the COS PIVCs, indwell times were significantly longer with phlebitis and infiltration

Continued on next page

Author (Year)	Research Design	Level of Evidence*	Sample and Sample Size	Intervention	Instruments	Results/Stats Evidence	Summary/ Conclusion
			one of three wards in Madrid, Spain between March and July 2008; target sample was 1200 catheters to evaluate. 126 nurses on the three wards comprised the field researchers. Written informed consent obtained from study participants.	Both PIVCs were examined for effectiveness, efficacy, safety, and efficiency. Dwell time and complication rates were collected for evaluation. Randomization was computer generated.	Mounted open System Catheter (MOS) – B. Braun Vasocan Safety Catheter	of CRC compared to MOS PIVCs (CI 95%; p<0.001) MOS and COS PIVCs received no needle stick injuries during the study, proving that both are passive safety devices. Median time for indwell times before adverse event was significantly higher for COS group than the MOS group (P=0.003) Significant reduction in phlebitis rates of 29% (P=0.004) when using COS PIVCs. Total complications of COS PIVCs per 1000 catheter-days (109.87) was significantly lower than the MOS PIVCs per	rates being simultaneously, significantly lower. While ease of use of the MOS PIVCs was of significance, attributed to nurses being familiar with the MOS system, less COS PIVCs needed to be removed due to CRC. Overall total complications were less in the COS PIVCs group, than the MOS PIVCs group, indicating fewer complications from the closed catheter group versus the open catheter group.

Continued on next page

Author (Year)	Research Design	Level of Evidence*	Sample and Sample Size	Intervention	Instruments	Results/Stats Evidence	Summary/ Conclusion
						100 catheter-days (135.57) (P<0,001). *Statistical Methods:* Qualitative Variables analyzed using Chi Square or Fisher's Exact Tests Quantitative Variables analyzed using student's t-test.	
Richardson, D. et al, (2011)	Non-Experimental ; Qualitative	VI	104 nurses were recruited through telephone interviews and placed intone of two groups, based on SPIVC used at their facility.	Online survey conducted with Purchasing Agents and Materials Managers Telephone Interviews conducted with nurses and nurse managers. Nurses recruited were placed into either Traditional SPIVC (open) or Blood-	• Online Survey • Telephone Interview	*Qualitative Results:* 49% of nurse respondents using traditional SPIVCs indicated blood exposure 50% of the time 89% of nurse respondents using blood-contained SPIVCs indicated no blood exposure 89% of the time.	Nurses that use blood-contained SPIVC are less likely to experience blood exposures, if at all.

Continued on next page

Author (Year)	Research Design	Level of Evidence*	Sample and Sample Size	Intervention	Instruments	Results/Stats Evidence	Summary/ Conclusion
				contained SPIVC (closed) groups and their telephone interview data was aggregated.			
Tamura, N. et al, (2014)	Semi-Random Control Trial	II	359-Patients ≥ 20 years old, needing PIV for more than 72 hours. Exclusion criteria: pregnant women, skin inflammation, burns, lesions, or tattoos near the insertion site, patients receiving anticancer therapy, patients with limited insertion sites, and those requiring specialized dressings. Written informed consent obtained from study participants.	Patients were divided into two groups to receive the CICS (n=194) or traditional catheter (open) (n=165), according to study month. i.e. patients enrolled in months 1, 3, and 5 received the CICS; those enrolled in months 2, 4, and 6 received the conventional catheter. Nurses were trained in use of CICS and were required to successfully use the CICS in at least	Catheters: Variable CICS – BD Nexiva Catheter Conventional catheter – Medikit Company Objective observations and use of INS 4-point scale, recommended for Phlebitis classification.	*Results:* Restart rates were significantly lower in the CICS group, than with the traditional catheter (open). Reason for removal • Bending/Kinking (p=0.0060) • Displacement/Losening of the fixation site (p=0.0060) • Extravasation (p=0.009) *Statistical Methods:* Descriptive Statistics Fisher's Exact Test Kaplan-Meier Analysis	There are no significant differences in incidence rates of adverse events between CICS and traditional catheters; however, restart rates are significantly lower in the CICS group. CICS wing-shaped stabilization platform was considered a contributing factor for the reason replacement rates were lower in the CICS group. This study supports using CICS to meet the CDC and INS recommendations.

Continued on next page

Author (Year)	Research Design	Level of Evidence*	Sample and Sample Size	Intervention	Instruments	Results/Stats Evidence	Summary/ Conclusion
				five patients prior to start of the study.			

CDC= Centers for Disease Control; **CI=** Confidence Interval; **CICS=** closed intravenous catheter system; **COS=** Closed System; **COSMOS=** Closed System/Open System Study; **CRC=** Catheter-related Complications; **ED=** Emergency Room; **HR=** Hazard Ratio; **INS=** Infusion Nurses Society; **MOS=** Open System; **OR=** Operating Room; **PIVC=** Peripheral intravenous catheter; **PIV=** Peripheral intravenous catheter; **PPS=** per protocol set; **RCT=** Randomized Controlled Trial; **RRR=** Relative Risk Reduction; **SPIVC=** short traditional intravenous catheter; **VAD=** Venous Access device

*Melnyk and Fineout-Overholt [3] used to determine level of evidence

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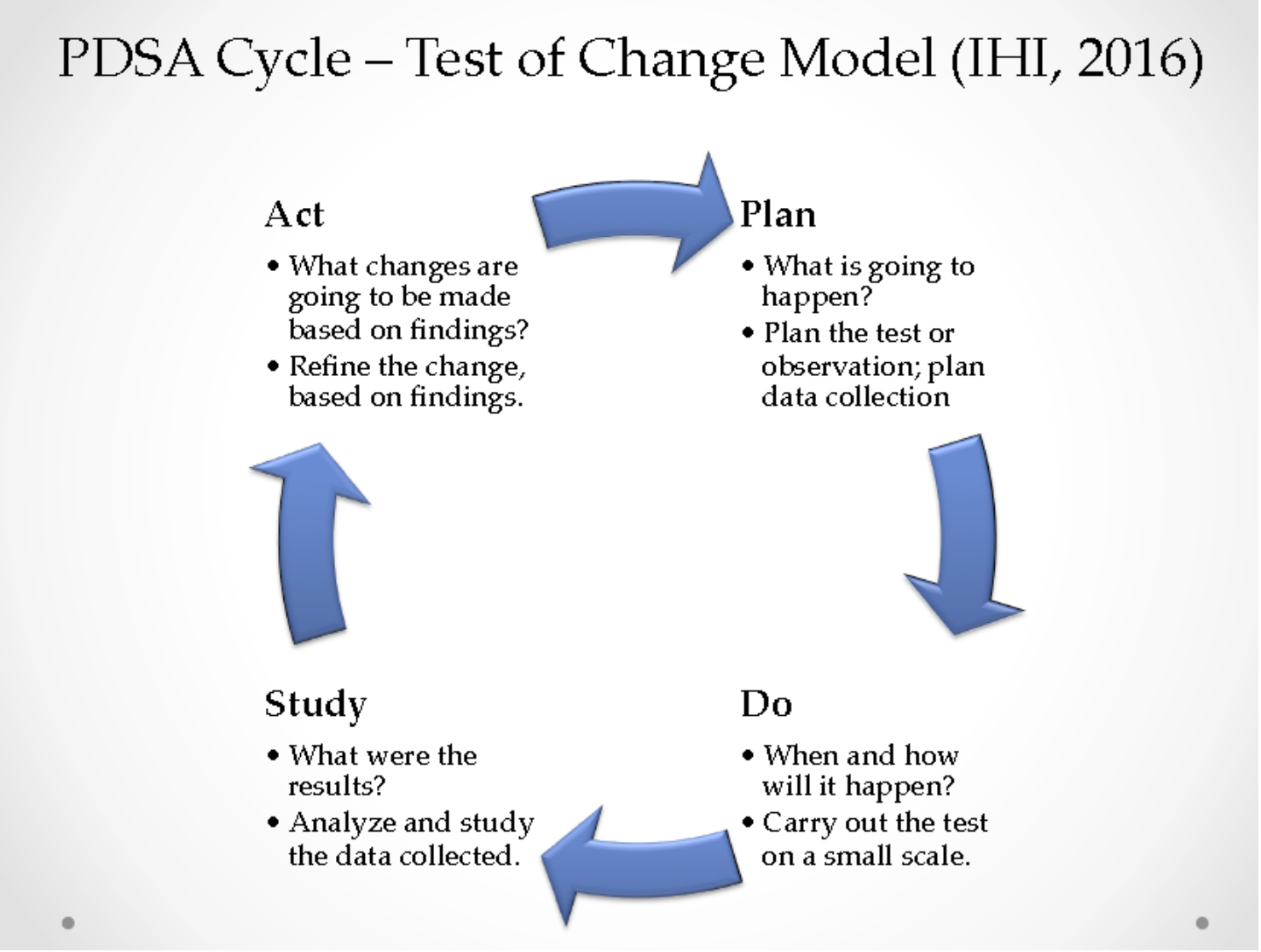
Appendix J – Theoretical Model (PDSA Cycle)



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