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P5 Methodology: A Novel Multidisciplinary Strategy to Improve Non-Hemodialysis Vascular Access Outcomes

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Abstract

Background: A methodology (P5) which includes a review of the promise, people, process, policy and products, was developed as a comprehensive quality improvement tool. The tool was implemented for non-hemodialysis midline and peripherally inserted central line catheters to identify opportunities for infection prevention performance improvement related to outcomes for patients in an acute care hospital.

Methods: The methods used were a comprehensive review, the setting of multiple goals for measures of success through the comparison of vascular access devices from two leading device manufacturers. The measures were a reduction in central line-associated bloodstream infections, use of tPA and triple lumen catheters.

Results: The successful implementation of P5 resulted in surpassing all measures including 98% reduction in triple lumen use, 100% reduction in additional midline usage for initiation of therapy, 96% reduction in tPA, and 53% reduction in central line-associated bloodstream infections.

Conclusion: The change in product was noted as a catalyst. The sustainability of the reductions was attributed to the successful implementation of the P5 methodology. Further research is needed to determine the applicability outside the non-hemodialysis vascular access scope.

Keywords: Non-hemodialysis; P5 methodology; Clinical outcomes

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Introduction

According to the Agency for Healthcare Research and Quality, it is vital to use a systematic, structured approach in order to succeed in improving patients' experiences [1]. Systematic approaches to improving care delivery guided by data are referred to as Quality Improvement (QI) and are designed to bring about immediate improvements in health delivery in particular settings [2].

There are a variety of methodologies used in Quality Improvement (QI) initiatives, including The Institute for Healthcare Improvement (IHI) Model for Improvement, Lean and Six Sigma [2-4]. Regardless of the methodology used, QI models share common features including emphasis on leadership to hold people accountable, clear goals, use of measurement and analysis to identify issues and guide decisions, emphasis on stakeholders as participants and audiences for the improvement processes, use of structured, iterative processes to implement improvement interventions, monitoring and data collection, and transparent metrics. It is critical to carefully choose strategies that have the best chance to improve patient interactions [1].

Recognizing that the majority of hospitalized patients require vascular access device placement to facilitate the delivery of care, insertion of these devices are not without risk [5-7]. It is crucial for institutions to understand their unique complication rates and patterns of utilization for various devices. Furthermore, it is essential to develop protocols, processes and practices aimed at reducing complications such as Central Line-Associated Bloodstream Infection (CLABSI) and thrombotic catheter dysfunction.

CLABSI are responsible for approximately 30% of all Healthcare-Associated Infection (HAI) related deaths [6]. CLABSI is a significant cause of morbidity and mortality in hospitalized patients [5]. Primary infection risks are associated with indwelling devices such as vascular access devices which increase the potential for a CLABSI. Infection risk correlates with an increasing number of device lumens [7]. Research demonstrates that the odds ratio for CLABSI increases by 50% with the use of a triple lumen PICC compared with a dual lumen [7].

Studies have shown that patients with sepsis often have central line-related thrombosis based on the presence of microbial

colonization on most vascular catheters within a fibrin sheath [8]. Catheter occlusions resulting from thrombosis are common in vascular access devices and require clearance with tissue Plasminogen Activator (tPA) which is a costly intervention [9]. If tPA does not clear the occlusion, then replacement of the catheter is required which exposes the patient to undue risk of an insertion related bloodstream infection [5].

Considering the charge that improving the quality of care of patients is a fundamental obligation of health care providers [10], our institution, Sunrise Hospital and Medical Center, assembled a multi-disciplinary team of stakeholders to evaluate vascular access products, practices and utilization patterns with the primary aim of determining and addressing device-associated complication rates, primarily CLABSI. The findings led to the development of a novel process and QI strategy specific to patients' vascular access needs called P5. The core pillars of the methodology include Promise, People, Process, Policy/Procedure and Products.

We are reporting on the development and implementation of the P5 methodology at our institution, a 690-bed acute care hospital. Additionally, we are reporting on the observational, retrospective clinical outcomes data resulting from the implementation of this QI initiative.

Methods and Design

The correlational approach to evaluating the P5 Pillars required quantitative evaluation of CLABSI cases and quantitative evaluation of tPA, midline, and PICC usage. The study period was January 1, 2018 through December 31, 2018. The primary research question was to determine the potential relationship between the device manufacturer and three areas of impact (device utilization, usage of tPA, and CLABSI).

The first pillar of P5, Promise, defined the primary purpose to identify potential weaknesses/limitations in vascular access care delivery and products and to develop a roadmap for the improvement. A secondary purpose of the initiative was to create an improvement platform that would be transferable to other QI projects across the organization.

The second pillar, People, was established to determine all the stakeholders whose participation was required for a comprehensive vascular access program review. Additionally, a review of stakeholder activities for the success of the program was evaluated. The team consisted of the Administrative Director of Critical Care (lead) along with Critical Care Management, Vascular Access Team (VAT) members, Infection Prevention Director, Chief Medical Officer, Clinical Practice Coordinators (educators) and supply chain staff. Outside stakeholders included the educators and vendors from the company currently supplying the PICCs and Midlines (heretofore referred to as Company A) along with a second company (heretofore referred to as Company B), chosen to provide another perspective for the full review. A third company was considered, but was eliminated early as a non-contender due to inability to meet the product needs of the facility for this type of device.

The third pillar, Process, consisted of evaluating criteria and process for ordering Central Venous Catheters (CVC), Peripherally Inserted Central Catheters (PICC), or midline catheters. A review of evidence-based practice was conducted using the Michigan Appropriateness Guide for Intravenous Catheter (MAGIC) tool developed by Chopra et al. [11].

The fourth pillar, Policy/Procedure was developed to provide for review of vascular access insertion and removal practices, as well as care and maintenance protocols to determine if evidence-based practices were being utilized. A specific focus of this review was to evaluate practices for removal of unnecessary lines and de-escalation of line referrals to the most appropriate access type (e.g. PICC vs. Midline). Additionally, a review of the pharmacy protocol was conducted to ensure that infusate type was considered in the process of appropriate device selection.

The fifth pillar, Products, was established to determine what products were available specific to PICC and midline device characteristics and manufacturers. At the time of the review, there was a single vendor (Company A) for PICC and midline products including 1) single-lumen midline full insertion kit, 2) single-lumen midline catheter only kit, and 3) dual and triple lumen maximum barrier full insertion PICC kit with tip location stylet.

Two catheter manufacturing companies (Bard Access Systems, Salt Lake City, UT, and Angio Dynamics, Inc., Latham, NY) were invited to provide a comprehensive review of the vascular access program at the hospital utilizing the P5 Methodology model. The companies were given a week of access on separate occasions during the same month to the facility's four-person Vascular Access Team to follow during vascular access device insertions, removals and maintenance. The companies were allowed access to ancillary department information and personnel including supply chain, pharmacy and nursing leadership.

Hospital policies were shared with each company to determine the need for any evidence-based changes. Finally, the vendors were allowed to present the findings and recommendations for any of the five layers of the P5 methodology. The devices under consideration were midlines (Power Glide by Bard Access Systems, Salt Lake City, UT and BioFlo by Angio Dynamics, Inc., Latham, NY) and peripherally inserted central catheters (PowerPicc Solo2 by Bard Access Systems, Salt Lake City, UT and BioFlo PASV PICC by Angio Dynamics, Inc., Latham, NY).

Methods for the statistical analysis for identifying the primary outcome of CLABSI was conducted through normal daily Infection Prevention surveillance activities as part of the facility's ongoing infection prevention program. The CLABSIs were identified using definitions as outlined by the Centers for Disease Control and Prevention National Healthcare Safety Network (NHSN) Patient Safety Component Manual [12]. The Chi-square test statistic was calculated using IBM SPSS Statistical Software Version 25.0 to validate that evidence was sufficient to reject the null hypothesis of no association between the device company and CLABSI or tPA at the significance level of a=0.05. A P-value <0.05 was considered statistically significant. The remainder of the statistical analysis was conducted using a simple quarter to prior quarter or year to prior year percentage change.

Results

Promise

The initiative was successful in identifying specific areas of improvement needed in the area of vascular access. The primary issue identified issue was central-line associated bloodstream infections. Additionally, evidence-based device selection, adherence to policies/procedures for catheter insertion, care and maintenance, and vascular access device efficacy and proper use were identified as areas of needed improvement.

Maintenance of PICCs and midlines were not consistently being adhered to for all bundle elements such as maintaining clean, dry and intact dressings for jugulars including antimicrobial disc placement. Insertion issues were identified with one of the PICC team members relative to sterile technique.

Utilization of multi-lumen lines being inserted was concerning based on the guideline to choose the least number of lumens for management of the patient [5]. Nine out of every ten PICCs inserted were triple lumen. The policies did not clearly define the evidence-based guidelines including proper line usage based on appropriate reason. The order sets were misleading and resulted in confusion and allowed for inappropriate vascular access choices. The need for order clarification by the PICC team and intervention by the physician was determined to be a source of delays and care.

The midline catheter utilized by the hospital at the time of the program inception had high technical insertion failure resulting in wastage of multiple catheters to gain venous access. These failures resulted in additional midline use of catheter only kits at a rate of over 100 per month. There was also an unacceptably high rate of failure to complete IV therapy using the midline device. Failures resulted in treatment delays associated with device replacement and also unnecessary procedures for patients. Failure reasons observed by team members (inserters and educators) were clotting or malfunction of the midline.

Furthermore, the device was not easily identifiable as a midline, which led to inappropriate device use. For these reasons, the midlines currently in use were a dissatisfier for the inserters, the physicians and the patients.

Based on these identified areas of improvement, outcomes measures were established in order to measure the success of the program in terms of patient safety, product utilization and cost-effectiveness **(Table 1).** Baseline data for the outcome measures were compiled from a retrospective review of CLABSI data from January 2018 through December 2018 and all other measures from prior calendar year 2017 compared to 2018.

Table 1: Quality improvement measures and outcomes for measure of success.

QI Improvement need identified	Outcome measure established	Result
High utilization of triple lumen PICC use	Reduce the use of triple lumen PICCs by 50% within 6 months	98% reduction
Inability to complete prescribed therapy with midline initially placed	Reduce the number of additional midlines needed to complete therapy by at least 25% within 6 months	100% reduction
High tPA usage	Decrease the usage of tPA by 60% within 6 months	96% reduction
CLABSI rate unacceptably high	Decrease the incidence of CLABSI related to PICCs within 6 months	53% reduction

People

The project team identified that re-validation of clinical competencies was needed in order to improve care. The PICC team skills were re-validated based on rigorous competency criteria [13]. Where new products were implemented as part of the program, members unable to achieve appropriate skills or to adjust to work flow changes using the new products were reassigned.

Additionally, the education and re-validation of clinical competencies for Registered Nurses (RNs) and Certified Nurse Assistants (CNAs) were accomplished through didactic and hands on education for dressing maintenance, sterile glove technique and vascular access continuation indications.

Daily conversations during leadership patient safety huddles amongst Nursing, Quality, and Executive leaders led with nursing personnel were highly encouraged to attempt to a de-escalation of any vascular access device when possible and prompt removal when no longer clinically indicated.

The PICC team job description was elevated to “Vascular Access Specialists” to encourage ongoing specialty knowledge achievement in the field of vascular access.

Process

In order to improve the criteria and process for ordering of vascular access devices, the order sets were revised to clarify and standardized to ensure appropriate guidance for the ordering provider based on an algorithmic approach. Variability in device selection and appropriate device utilization was eliminated.

Policies and procedures

Policy and procedure review resulted in a revision of the vascular access policy to reflect the most recent guidelines for appropriate device utilization based on infusate characteristics (vesicant, length of time or osmolarity) [9,11,13,14]. As a result of this review, procedures for insertion were updated based on evidence-based protocols including the elimination of X-ray by use of intracavitary technology where clinically indicated. The practice was being completed this way, but the policy was not updated to reflect this protocol. Finally, maximum barrier precautions for midline insertion as recommended by the Infusion Nursing Society (INS) Guidelines were integrated into protocol [14].

Products

As a result of the review of specific product type and manufacturer being used, and in order to meet the objectives of the P5 implementation, new products (Company B) were implemented and included 1) single and dual lumen midline maximum barrier

kit 2) single and dual lumen midline catheter only kit, and 3) single, dual and triple maximum barrier PICC kit. **Figure 1** outlines the timeline for the transition of products from Company A to Company B.

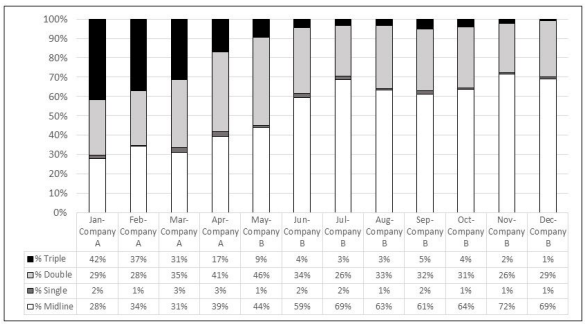

Figure 1 Product utilization by month for piccs (triple, dual, and single) and midline over 12 month period.

A novel anti-thrombogenic catheter technology, Endexo® present in Company B's PICC and midline catheters was a critical factor in choosing this product line. This was primarily because of the potential for cost savings through avoidance of complications. Additionally, the anti-thrombogenic property provided an opportunity to increase patient satisfaction through the reduction of catheter complications.

Based on the known increased risk of infection with each additional lumen in use (or not in use but present), the reduction of triple lumens was critical [9]. The use of triple lumen PICCs equaled 42% of the total PICCS and midlines in use at the start of the review in January 2018 as seen in **Figure 1**. Eight months post-change triple lumens represented approximately 1% of the total PICC insertions with a total count reduction of 216. The associated cost reduction for utilizing a double lumen PICC instead of a triple lumen during this period was almost $39,000.

Product utilization improved for midlines as a result of adherence to appropriate device selection protocols with an increase in midline insertions by 41%. The usage in 2017 for the original midlines was 1,341 single sterile midlines (non-kits). For the switch in 2018, the hospital purchased 48 single sterile midlines (non-kits) from Company B. No single sterile midlines were required for successful patient placement after the switch to Company B which resulted in a cost savings of almost $ 60,000.

The pharmaceutical consideration was related to the cost of using tPA. The tPA is used to assist with dissolving blood clots that may be blocking central venous catheters in an attempt to avoid the need to replace the line. The tPA administration was reduced from 55 to two between Quarter 1, 2018 and Quarter 4, 2018. This was a 96% reduction in use with a cost savings of approximately $ 18,000.

Clinical outcomes

The rate of PICC Line-related CLABSI for Company A was double the rate of Company B (3.09 versus 1.44 per 1,000 PICC Insertions) **(Table 2).** The overall reduction in PICC-related CLABSI was 53%. **Table 3** demonstrates that the relation between these variables was significant, X^2 (1, N=1917)=5.896, p=0.015. Patients with a catheter from Company B were significantly less likely to develop a CLABSI than were patients with a catheter from Company A.

The overall reduction in tPA-usage was more than 95% in the adult population. A chi-square test of independence was performed to examine the relationship between tPA use and device company. **Table 4** demonstrates that the relation between these variables was significant, X^2 (1, N=1917)=36.041, p<0.001. Patients with a catheter from Company B were significantly less likely to require tPA for line declotting than were patients with a catheter from Company A.

Table 2: Comparison of CLABSI rates based on insertions pre-change and post-change.

	#Weeks present in 2018	PICC Line related CLABSI	PICC insertion volume	Annualized insertion volume	CLABSI Rate per 1.000 PICC Line insertions
Company A	14	6	522	1939	3.09
Company B	38	2	1018	1393	1.44

Table 3: CLABSI versus device company SPSS output.

Clabsi developed*device company cross tabulation					
Count			Device Company		
			Company A	Company B	Total
Clabsi Developed		No	652	1257	1909
		Yes	6	2	8
Total			658	1259	1917
Chi-square tests					
	Value	df	Asymptotic significance (2-Sided)	Exact Sig. (2-Sided)	Exact Sig. (1-Sided)

Pearson Chi-Square	5.896[a]	1	0.015		
Continuity Correction[b]	4.223	1	0.04		
Likelihood Ratio	5.541	1	0.019		
Fisher's Exact Test				0.023	0.023
N of Valid Cases	1917				

[a]1 cells (25.0%) have expected count less than 5. The minimum expected count is 2.75.
[b]Computed only for a 2 × 2 table

Table 4: TPA usage versus device company SPSS output.

TPA used for the line?*device company cross tabulation					
Count		**Device company**		**Total**	
		Company A	**Company B**		
TPA Used for the line	No	651	1164	1815	
	Yes	7	95	102	
Total		658	1259	1917	
Chi-Square Tests					
	Value	**df**	**Asymptotic significance (2-sided)**	**Exact Sig. (2-Sided)**	**Exact Sig. (1-Sided)**
Pearson Chi-Square	36.041[a]	1	0		
Continuity Correction[b]	34.766	1	0		
Likelihood Ratio	45.744	1	0		
Fisher's Exact Test				0	0
N of Valid Cases	1917				

[a]0 cells (0.0%) have expected count less than 5. The minimum expected count is 35.01.
[b]Computed only for a 2 × 2 table

Discussion

As a result of this project, we were able to improve clinical outcomes in term of tPA usage and CLABSI associated with PICCs, and completion of therapy for midline devices. The outcomes included a reduction in CLABSI by almost 90% for adult patients with a PICC present (6 pre-change versus 2-post-change).

CLABSI was identified at significantly lower rates in patients with Company B catheter versus Company A catheter (p=015). The PICCs from Company A were inserted at a higher rate of 5.3 per day versus Company B at a rate of 3.8 per day **(Table 1).**

The reduction of tPA usage may have further contributed to the reduction of CLABSI in our project. In a study of 3,723, Thakarar et al. reported that an adjusted odds of developing a CLABSI was 3.59 times greater in those patients with PICCs who received tPA compare with those who did not (95% confidence interval (CI: 1.86-6.94) [9]. Furthermore, studies have shown that patients with sepsis often have central line-related thrombosis based on the presence of microbial colonization on most vascular catheters within a fibrin sheath [8].

Economic considerations related to product and pharmaceutical utilization were also an essential aspect of our project. The final triple lumen reduction was 98% by December, 2018 with a cost savings of approximately $ 39,000. The implementation of a stellar midline product resulted in an increase in usage of 41% and a 100% decrease of wasted nursing time with the product by the end of 2018.

Limitations

The research was limited to adult populations due to the devices under consideration. While this review resulted in a change of product which added value, it is conceivable that a consistent review of all other elements without a product change might have impacted the outcome measures.

Conclusion

This project represents a systematic, multi-disciplinary approach to improving the quality of care delivery related to vascular access in our institution. While each pillar of the P5 methodology was complex, the multi-disciplinary approach allowed success in achieving the outcomes of interest, primarily CLABSI reduction. It is conceivable that this framework for quality improvement related to vascular access outcomes may be reproducible by other institutions.

Implications for Practice

The P5 methodology can assist hospital administrators or

vascular access program managers with improving clinical and financial outcomes. The application of a single pillar may identify opportunities for improvement; however the implementation of all five pillars will maximize the overall potential program improvement possibilities. The framework for P5 methodology follows the Six Sigma quality improvement model: Plan, Do, Check, Act (PDCA) which encourages continuous evaluation.

Further Research or Scope

The scope of the project for future research could include external validation at other sites and in specific population needs such as pediatrics, oncology or dialysis.

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Conflicts of Interest and Source of Funding

None were declared for the authors.

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