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

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Objectives

1. Identify clinical events leading up to pilot design.
2. Describe pilot design, results, and lessons learned.
3. Understand how a Doctorate of Nursing Practice student led an interdisciplinary team through the process of designing a randomized controlled trial.
Introduction: Problem Identification

Mandatory Product Conversion
Mandatory product conversation
June 2015

Monitoring Change
Multiple issues reported after product conversion

Addressing Issues
Escalated ongoing issues to Quality Department and Nurse Executive
Review of Literature

*Phlebitis  (González et al, 2013)

*Infection  (González et al, 2013)

Blood Exposure  
  (Richardson et al, 2011) (Delisio, 2012)

*Unplanned Reinsertions  
  (Tamura et al, 2014)

*Complications  
  (Bausone-Gazda et al, 2010)

*Dwell Time  
  (González et al, 2013)

*Studied with an integrated closed system with stabilization platform
Problem Statement

• There is no clinical trial evaluating the Insyte Autoguard ™ (open PIVC) in comparison to the Saf-T Intima ™ and Nexiva ™ (closed PIVCs)

• There is no clinical trial evaluating these PIVCs in terms of patient satisfaction, complications of care, and cost; making it difficult to ascertain which of the three PIVC systems are best for patients.
Pilot Guiding Model

PLAN
- Establish Workgroup
- Literature Review
- Study Design
- Resource Allocation
- IRB Approval

DO
- Implement trial of randomized control trial (RCT)
- Pilot Data Collection

STUDY
- Descriptive & Content Analysis

ACT
- Process adjustments for continuation of larger RCT
Pilot Results

Table 1. Pilot Quantitative Descriptive Results

<table>
<thead>
<tr>
<th>Category</th>
<th>(n)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinician Training</strong></td>
<td>16</td>
<td>-</td>
</tr>
<tr>
<td>Inserting</td>
<td>9</td>
<td>56%</td>
</tr>
<tr>
<td>Consenting</td>
<td>7</td>
<td>44%</td>
</tr>
<tr>
<td><strong>Enrollment</strong></td>
<td>35</td>
<td>-</td>
</tr>
<tr>
<td>Saf-T Intima ™</td>
<td>9</td>
<td>26%</td>
</tr>
<tr>
<td>Insyte Autoguard ™</td>
<td>7</td>
<td>20%</td>
</tr>
<tr>
<td>Nexiva ™</td>
<td>19</td>
<td>54%</td>
</tr>
<tr>
<td><strong>Complications</strong></td>
<td>6</td>
<td>17%</td>
</tr>
<tr>
<td>Unsuccessful Insertion</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Decline to Consent</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Unplanned Reinsertion</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Missing Data</strong></td>
<td>20/980</td>
<td>2%</td>
</tr>
<tr>
<td>Electronic Health Record Data</td>
<td>6/140</td>
<td>4%</td>
</tr>
<tr>
<td>Clinician Questionnaire Data</td>
<td>4/770</td>
<td>1%</td>
</tr>
<tr>
<td>Patient Questionnaire Data</td>
<td>10/70</td>
<td>14%</td>
</tr>
</tbody>
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## Pilot Lessons Learned & Clinical Implications

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


References


Questions?
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