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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
(PDSA) Cycle**

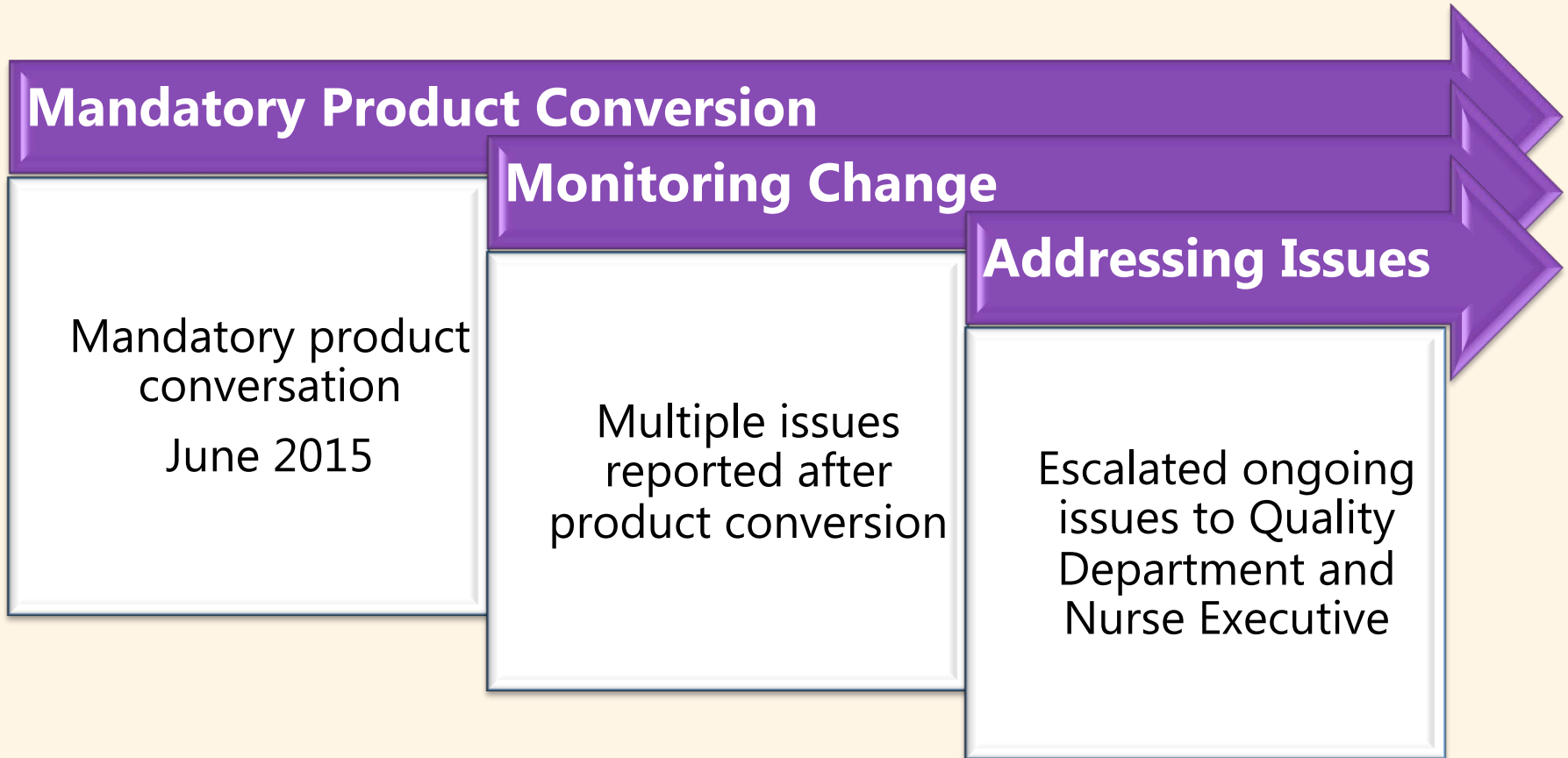
Heather Galang, MSN, RN-BC, CNL
Erica Lewis, PhD, RN

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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



Review of Literature

Open-System

Closed-System

***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.

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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

	(n)	(%)
Clinician Training	16	-
Inserting	9	56%
Consenting	7	44%
Enrollment	35	-
Saf-T Intima™	9	26%
Insyte Autoguard™	7	20%
Nexiva™	19	54%
Complications	6	17%
Unsuccessful Insertion	2	6%
Decline to Consent	1	3%
Unplanned Reinsertion	3	9%
Missing Data	20/980	2%
Electronic Health Record Data	6/140	4%
Clinician Questionnaire Data	4/770	1%
Patient Questionnaire Data	10/70	14%

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Pilot Lessons Learned & Clinical Implications

Lessons Learned	Clinical Implications
Slower than expected enrollment	<ul style="list-style-type: none"> ✓ Second training arranged to engage more clinicians ✓ Every 36-bed unit should train (2) inserting clinicians and (1) consenting clinician
Few returned Patient Questionnaires	<ul style="list-style-type: none"> ✓ 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	<ul style="list-style-type: none"> ✓ 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

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Questions?

**Heather Galang, MSN, RN-BC,
CNL**

galanghl@dukes.jmu.edu

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