

Project Introduction

In today’s complex healthcare environment clinicians face an increased risk of caring for patients with infectious diseases, as well as the use of specific low volume high risk procedure and products. When performing a patient care procedure, the goal is to have minimal manipulation of a product. Healthcare professionals can benefit by devices that are multi-use, simple and intuitive. If a product is too complex, the healthcare provider is often reluctant to utilize the product. Standardizing products allows mastery of a product.

Collecting a patient’s blood is a common procedure contributing to multiple measurable clinical outcomes and satisfaction scores in hospitals nationwide. The estimated cost of false positive blood cultures is 7-8 billion dollars every year. Vascular Integrity’s VI ByPass Syringe™ was designed to provide a simple solution for standardizing blood sampling collection including blood cultures and collection from existing lines. Ease of adoption and versatility differentiates this technology from other blood collection products and processes.

Purpose

The purpose of this product pilot was to measure the ease of use of a new blood collection device. Product compliance is crucial for optimal blood culture accuracy. Hospital initiatives in the reduction of false positive blood cultures patient satisfaction and workflow, while important, were not specifically addressed in the pilot.

Process

500 product samples were made available to University of Iowa and clinics. 9 blood-drawing sites were identified, and clinical instructors were identified within the hospital to cover specific areas. Areas included: SICU, MICU, Medical, Cancer Center, Phlebotomy, Orthopedic, Surgery and Emergency Departments.

Evaluations forms were collected during the clinical trial. End user nurses and phlebotomists completed these forms at their leisure to avoid interference with their professional duties. In addition to the end user evaluations, the clinical observers recorded additional detailed observations.

Traditional methods for comparison included a butterfly with a vacuum holder (BV), a Butterfly with a Syringe, (BS) and a Needle with a vacuum holder, (NV). Compete study documentation details every conceivable comparison/response.

Data Collection

Observer data collection		
Patient Information: Male _____ Female _____ Age _____ Diagnosis _____		
Type of blood draw: _____ readily available _____ Fair peripheral _____ poor peripheral		
Access location: _____ front of elbow _____ back of hand _____ Groin		
Gauge of needle: _____ 21ga _____ 23ga _____ 25ga _____ other		
Pre-fill syringe: _____ yes _____ No (if yes, with each successive blood draw? _____ Yes _____ No?		
Was sharps container within arm’s reach of the blood drawing site? _____ Yes _____ No Type used: _____ portable unit _____ wall unit		
Number of specimens collected. _____		
Blood culture obtained: _____ yes _____ no How Many? _____		
Central line use		
Type of catheter		
Art line: _____ Patient blood Pressure ____/____ Location: Radial artery _____ Dorsalis Pedis		
Central line: _____ Single lumen _____ Double lumen _____ Triple lumen		
Central line: _____ Single lumen _____ Double lumen _____ Triple lumen		
Location: Subclavian vein _____ Femoral Vein _____		
Remarks		
End User Questions		Circle yes or no Answer
Is the VI ByPass Syringe™ acceptable for use?		YES NO
How many times did you use the product?		More than 10 Less than 10
Did your patient make any comments?		YES NO
Was it easy to use?		YES NO
Was it easy to hold?		YES NO
Was it easy to Dispose of?		YES NO
Did the trial of the product affect your workflow?		YES NO

How would you rate the VI ByPass Syringe™ in comparison to the following ways to draw blood:			
	More difficult	No difference	Easier to Use
Needle w/vac	1	2	3
Butterfly w/vac	1	2	3
Butterfly w/syringe	1	2	3
Needle-stick safety			
Needle-stick safety rating compared to usual practice:	Safer	Same	Less safe

Summary of Study Results

Criteria	Professional	Rating
Safe	Nurses	100%
Easy	Nurses	90%
Successful blood draw	Nurses	89%

Discussion

Adoption rate was high. 84% (n=?) of participant in the product pilot were nurses and 16% (n=?) were phlebotomists. 80% of professional respondents found the VI ByPass Syringe™ acceptable for use. 90% found it easy to use, 100% found it easy to dispose of. 100% of respondents found the VI ByPass Syringe™ as safe as or safer than traditional blood drawing methods. Traditional methods included direct draw with Vacuum holder®, (DV) and with Syringe, (WS). When compared to the DV, 98% of end users found the VI ByPass Syringe™ easier to use or no difference. When compared to WS, 77% of end-users found the VI ByPass Syringe™ easier to use or no difference. The overall rating of the VI ByPass Syringe™ when compared to traditional blood draw methods was 86%.

Nurses accounted for 84.3% of the 32 professionals participating in the study group. All nurses perceived the VI ByPass Syringe to be as safe as or safer than traditional drawing methods, 69% of product uses were with various types of indwelling catheters, with 20.3% being from short PIV catheters. Blood collection using the VI ByPass Syringe™ was found to be particularly beneficial for collection from short length catheter peripheral IVs. The nurses with greater numbers of uses reported greater value and safety with use of the VI ByPass Syringe™.

While there was minimal to no learning curve in the adoption of the VI ByPass Syringe™ it was noted that failure to maintain patency (i.e., clamping the line) resulted in unsuccessful whole blood draw. As with all blood collection products, maintaining vessel patency was identified as the single most important detail in successful blood collection.

Conclusion

90% of nurse participants reported the VI ByPass Syringe™ was easy to use, intuitive and self-explanatory. The value of ease of adoption in emergency rooms, where procedures such as IV starts, routine labs and blood cultures need to be clustered to avoid multiple patient sticks, streamline workflow, and reduce costs will be further evaluated as the VI ByPass Syringe™ is adopted nationwide.

*Patent Pending

Reference: Vascular Integrity –*University of Iowa study on file

Vascular Integrity Irvine, CA www.vascularintegrity.com

¹ Vascular Logics is a fully owned brand name of Vascular Integrity