Evidence-based Protocol for Malfunctioning Totally Implanted Venous Access Devices

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Abstract

Background: Fundamental to chemotherapy infusion, all venous access lines must always produce brisk blood return before treatment may begin. Occlusions occur in 14-67% of central venous catheters, including totally implanted vascular access devices. There are mechanisms that nurses use to manage care when a totally implanted vascular access device is appropriately accessed but does not produce a blood return, and there is evidence regarding which of these mechanisms are likely to prove successful.

Local Problem: To implement a novel evidence-based protocol for appropriately accessed totally implanted vascular access devices without blood return in an ambulatory outpatient oncology clinic within a community hospital setting.

Interventions: This Institutional Review Board approved 14-week project began in September 2018. Totally implanted vascular access device and alteplase instillation competencies were completed and audited to ensure current knowledge of oncology registered nurses. Electronic health record reports of documentation of the standardized totally implanted vascular access device protocol, alteplase use, and delay of chemotherapy >24hrs were monitored. A system usability scale questionnaire was also administered to unit registered nurses. The system usability scale measures post outcome for satisfaction and sustainability. Satisfaction and sustainability are defined as scoring as acceptable above 70, marginal below 69-50, and not acceptable below 50.

Results: Eighty-five percent (N=28/33) of registered nurses completed both competencies. There were two instances of alteplase use during the study period due to lack of blood return with one documented use of the standardized protocol, both without delay of greater than 24hrs. Fifty-eight percent (N=19/33) of registered nurses completed the system usability scale with 79% (n=15/19) judging it to be acceptable, 16% (n=3/19) as marginal, and 5% (n=1/19) as not acceptable.

Conclusions: A standardized algorithm for totally implanted vascular access devices benefits patients and registered nurses by providing consistent care for malfunctioning totally implanted vascular access devices, and may reduce time to receive scheduled chemotherapy and cost. registered nurses experience less stress and more satisfaction with a standardized protocol and have a clear path when a totally implanted vascular access device is malfunctioning.

Background and Significance

Occlusions in totally implanted vascular access devices (TIVADs) remain a common problem for cancer patients despite advances in their care, technology, and products (Ast & Ast, 2014; Baskin, Pui, Reiss, Wilimas & Metzger, 2009; Cummings-Winfield & Mushani-Kanji, 2008; Goossens, Stas & Moons, 2012; Stammers, Connolly, Brandão, Zupanec, & Gupta, 2017; Waagen & Bliss, 2003). A fully functional TIVAD can be flushed without resistance and have a brisk flowing blood return (Ast & Ast, 2014). Occlusions occur in 14-67% of central venous catheters, including TIVAD (Baskin et al., 2009; Waagen & Bliss, 2003). When a TIVAD is appropriately accessed and still does not produce a blood return, the management of the issue varies across and within institutions. Practices may not be consistent or based on the best evidence (Ast & Ast, 2014; Baskin et al., 2009; Cummings-Winfield & Mushani-Kanji, 2008; Goossens, Stas & Moons, 2012; Muguet, Couraud, Perrot, Claer & Souquet, 2012; Stammers et al., 2017; Waagen & Bliss, 2003). Complications that would ideally be mitigated by best practices may include extended time to receiving scheduled chemotherapy and increased cost. In general, there are mechanisms that nurses use to manage care when a TIVAD is appropriately accessed but does not produce a blood return, and there is evidence in the literature regarding which of these mechanisms are likely to prove successful (Cope, Ezzone, Gerber, Lamprecht & McCorkindale, 2011). However, the unit where this quality improvement (QI) project took place had no standard for management of such care for when a TIVAD is appropriately accessed and does not produce a blood return.

The purpose of this DNP project was to implement an evidence-based protocol for appropriately accessed TIVAD without blood return in an ambulatory outpatient oncology clinic within a community hospital setting. Implementation of a clinical protocol for appropriately

accessed TIVAD would reduce variations in practice and optimize their use (Fernandez-de-Maya & Richart-Martinez, 2013). This would benefit patients and staff nurses by providing consistent care for malfunctioning TIVAD, decreasing time to receiving scheduled chemotherapy, and reducing cost. RNs may experience less stress and more satisfaction with a standardized protocol and a clearly understood path of what to do when a TIVAD is malfunctioning.

Theoretical Framework

The Knowledge to Action cycle was developed by Graham and colleagues and uses knowledge creation in a seven-part action cycle to facilitate the implementation of knowledge translation (Straus, Tetroe & Graham, 2013). It is a map for a continual process using implementation with clinical practice problems (Straus, Tetroe & Graham, 2013). The seven steps include; to identify and assess knowledge needs, adapt knowledge to local context, assess barriers for knowledge use, implement interventions, monitor knowledge use, evaluate outcomes, and sustain knowledge use. The following briefly follows the Knowledge to Action cycle theory for the development of a translation plan used to implement the evidence-based protocol for an ambulatory outpatient oncology clinic for when an appropriately accessed TIVAD does not produce a blood return.

Application of the Knowledge to Action cycle began with an identification of the problem followed by a review and summary of the literature. This revealed a lack in use of evidence-based standardized practice guidelines for guidance and best practice when TIVAD catheter-related occlusion occurs on an outpatient oncology unit at a community hospital (Cope et al., 2011). The evidence suggested implementation of a practice protocol after careful assessment, management, and evaluation. An EBP team was formed. Members included relevant stakeholders such as clinic nurses, clinic champion, nursing education director, member from the

Standards of Practice committee, physician, organizational information technology specialist (IT), pharmacist, and APRN student.

Assessments were conducted through interviews of the outpatient oncology clinic staff RNs at the organization, which identified a lack of standard practice in malfunctioning TIVAD. A concern for several RNs working in the clinic during the interview process, when discussing malfunctioning TIVADs, was that they were unclear on how best to proceed, expressing, "I never know what to do first". Guidance on TIVADs without blood return is provided by the Oncology Nursing Society (ONS) but they stipulate that there are few studies that provide answers for this issue (Cope et al., 2017). Current literature is supported with the opinion that there is lack of evidence for the next systematic step after TIVAD access has been correctly achieved and the effect is no blood return (Ast & Ast, 2014; Baskin et al., 2009; Cummings-Winfield & Mushani-Kanji, 2008; Fernandez-de-Maya & Richart-Martinez, 2013; Goossens, Stas & Moons, 2012; Muguet et al., 2012; Pires & Vasques, 2014; Stammers et al., 2017; Waagen & Bliss, 2003). This was the catalyst for this QI project and the need to adapt knowledge to local context (Straus, Tetroe & Graham, 2013).

For successful organizational implementation, stakeholders must work together with the organization to identify and decrease barriers while increasing enablers. Barriers identified included a lack of clinic process standards for TIVAD without blood return and possible RN hesitancy for change. Enablers were identified as TIVAD competencies and in-services to address concerns and educate RNs on the best current practice, clinical training for best implementation strategies, audits to monitor and adjust training as needed, documentation and analyzing data. A focused process implementation plan to achieve consistency of care through a TIVAD protocol may reduce costs and time to receive chemotherapy. EHR documentation

included TIVAD assessment and the use of a TIVAD algorithm placed in the notes section when used.

Knowledge use was monitored with the use of EHR data and weekly audits during implementation. With the help of IT, the APRN student and RNs documented and tracked chart audits weekly, and obtained a final alteplase total usage report from IT. The process and outcomes were monitored and revised as necessary. Sustaining knowledge use is complex and difficult but an important task. If determined to be effective this DNP project could be replicated in other oncology clinics.

Findings will be presented as a poster presentation at a regional EBP conference in March 2019, at the Maryland Nurses Association, 4th Annual 2019 Nursing Evidence-Based Practice and Research Conference. An article for a professional journal is being considered. This is an important step for evidence (good or poor) to be documented and added to limited research for knowledge of impact of an evidence-based protocol on outcomes and consistency of care in cancer patients experiencing a malfunctioning TIVAD.

Literature Review

The need to implement a practice change for appropriately accessed TIVAD without blood return was identified by an ambulatory outpatient oncology clinic at a local community hospital and is the focus of this literature review. The studies reviewed have important recommendations to offer in clarifying content needed when considering a standardization algorithm for occluded TIVADs (See Appendix F). The discussion begins with examining and determining the cause of occlusion when managing TIVAD occlusions, followed by a discussion of the safety with using a thrombolytic in occluded TIVADs. The discussion is then followed by exploring the pertinence of standardizing practice with algorithm implementation for TIVAD

occlusions while possibly improving outcomes such as reducing time to receiving scheduled chemotherapy, costs, and greater consistency of care.

Relevance of Determining the Cause of TIVAD Occlusions

The Oncology Nursing Society recommends annual competencies for RNs in TIVAD maintenance and care providing proper adherence of practices (Cope et al., 2011). When RNs appropriately access TIVADs that flush but do not produce blood return, the need to investigate the partial occlusion further will occur. Determining of the cause of the occlusion, whether it is mechanical or thrombotic, will reveal proper management of care procedures. Symptoms of pain, redness, tenderness, warmth, swelling or fever may indicate systemic issues and would be triaged separately. This QI project specifically speaks to partial occlusions defined as easy to inject or flush but difficult to aspirate or unable to obtain blood return.

A review conducted by Ast & Ast (2014) describes numerous non-thrombotic complication possibilities that may occur in central vascular access devices (CVAD). Of the 32 citations referenced the authors for this review directly analyzed 30 of the studies. Types of studies reviewed included case reports, textbook chapters, reviews, guidelines, descriptive studies, and expert opinion. Non-thrombotic occlusions may include mechanical, drug or mineral precipitate, and lipid residue. Mechanical occlusion can occur externally or internally. External mechanical occlusions will be the RNs first thought when there is a lack of flow. Assessing for kinks or clamping in external catheters will complete this task. Non-thrombotic internal mechanical occlusions can occur for several reasons. These include catheter tip migration, kinks or malposition of the catheter, pinch of syndrome, and catheter fracture. Drug or mineral precipitate can lead to an occlusion and may be greatly minimized with proper and adequate flushing practices after infusions. Occlusion due to lipid residue should be considered with

parenteral nutrition, which can leave a waxy residue. The outcome of this expert opinion review article concludes that up to 25% of CVADs experience occlusions and if identified early and accurately complications of care can be minimized.

A literature review conducted by Baskin et al. (2009) summarizes occlusions and catheter related thrombosis in central venous catheters (CVC). Articles included from 1965 - January 2009 are long term CVCs such as subcutaneously tunneled catheters and implanted ports. There are 101 citations referenced by the authors of this review. Types of studies reviewed include randomized control trials, randomized placebo-controlled studies, meta-analyses, multiple center international trial, controlled trials, cohort studies, case reports, prospective studies, single descriptive studies, reviews, and expert opinion.

Findings indicated occlusion and catheter related thrombosis (CRT) are the most common complications in CVCs. The cause of the occlusion will determine the appropriate treatment. Discussion of types of CVC occlusion includes CRT, mechanical, and thrombotic catheter obstruction. Pain, tenderness, swelling edema, erythema, and warmth are symptoms of CRT and may lead to complications such as infections, pulmonary embolism, post- thrombotic syndrome, and persistent vascular compromise. This happens in up to 28% of adults and needs to be evaluated. Obvious mechanical obstruction should be ruled out by checking catheter patency; re-accessing and the repositioning the TIVAD (huber) needle. Treatment of thrombotic catheter obstruction may begin with thrombolytic therapy such as alteplase, a common and standard drug widely used in the oncology setting. If alteplase is not successful in producing patency, a linogram (contrast venogram or “dye study”) should be conducted. The reviewers provide a treatment algorithm for the management of a CVC obstruction. It is important for RNs to obtain the knowledge and skills to properly assess and diagnose thrombotic occlusions (McKnight,

2004). The occlusion may be due to venous thrombosis, which may present as pain or edema in neck or upper extremities and will need guidance of the oncology NP or physician for further evaluation with ultrasound (Ast & Ast, 2014; Baskin et al., 2009).

Safety Using Thrombolytics in Occluded TIVADs

The use of alteplase, which degrades fibrin buildup, is an effective and common treatment for thrombotic occlusions and is the only FDA approved thrombotic agent for TIVADs (Cope et al., 2011; McKnight, 2004). Alteplase is used as standard practice for occluded TIVAD. Several investigators concluded thrombolytics are safe to use prior to linogram and are part of standard practice in the oncology setting for occluded TIVAD (Baskin et al., 2009; Stammers et al., 2017; Waagen & Bliss, 2003). Thrombolytics are recommended for use before linogram in two studies (Cummings-Winfield & Mushani-Kanji, 2008; Muguet et al., 2012).

Cummings-Winfield & Mushani-Kanji (2008) conducted a literature review of central venous access devices (CVADs) to develop standardized guidelines for thrombolytic use to clear thrombotic occlusions in Canadian cancer treatment centers. Literature included publications from 1997-2007. The authors referenced 39 citations. Types of studies reviewed include randomized control trials, double blind randomized studies, double blind placebo-controlled control trial, descriptive studies, qualitative studies, prospective studies, reviews, textbook chapters, guidelines, and expert opinion. CVADs include implanted ports, non-implanted tunneled and non-tunneled catheters, and peripherally inserted central catheters (PICC). This review concluded that the use of the thrombolytic, alteplase is recommended as it is approved in Canada and the United States for restoring CVAD patency. The use of a standardized algorithm in the management of thrombotic CVAD occlusions was recommended and the reviewers provided a treatment algorithm for the management of a CVC obstruction.

Waagen & Bliss (2003) conducted a literature review to develop an algorithm for managing dysfunctional VAD, design a program to educate staff in interventional radiology (IR) about the algorithm, and assess if an algorithm is feasible in the clinical site. There were 39 citations referenced by the authors of this review. Types of studies reviewed include randomized control trial, double blind randomized trial, double - blind randomized trial, cohort studies, case reports, descriptive studies, reviews, textbook chapters, guidelines, and expert opinion. The setting for this educational inquiry and program was a 588 bed Midwest hospital with an IR department, inpatient oncology and nephrology services, outpatient oncology and several dialysis centers. Discussion occurred in this review of the importance of RNs ability to recognize, assess, and handle specific catheter dysfunction. It was suggested that conducting as much treatment for dysfunctional VADs in patient care areas as possible before an evaluation by IR may be more cost effective and time efficient for the patient.

Sharma, Ree, & Ree (2008) evaluated the effectiveness and safety of using alteplase in either 2 or 4 mg dose in occluded ports. This was a prospective non-blinded study at the Interventional Radiology Department of Henry Ford Hospital in Detroit, Michigan. The study was conducted from November 2002 to February 2005 using 50 occluded chest ports. Each of the 50 occlusions was conducted in patients at least 18 years old and patency was restored in 100% of cases (95% Cl 92.8% to 100%). Seventy-two percent obtained patency with 2mg dose of alteplase (36/50) and 28% obtained patency with 4mg dose of alteplase (14/50). No adverse effects were observed. Researchers of this study indicated that alteplase has been determined to be a safe first step in restoring blood return in TIVADs.

Stammers et al. (2017) conducted a single-institution retrospective chart review to determine if a chest x-ray is needed prior to administering a thrombolytic such as alteplase in

vascular access occlusion (VAD). This study was conducted at The Hospital for Sick Children in Canada between 2010 and 2011. Three hundred-thirty patients under 18 months of age and with a newly diagnosed cancer were identified. VADs that experienced occlusion were tunneled external central venous lines at 41.5% (16/39), PICCs at 37.0% (27/73), and ports at 19.4% (42/216); (P=0.001). VAD occlusions in 8.1% (9/111) were evaluated with a chest x- ray. Specialists determined that alteplase administration likely would not have caused harm to the patient if administered prior to chest x-ray.

Muguet, Couraud, Perrot, Claer & Souquet (2012) conducted a single-institution retrospective cohort study in a Geneva University Hospital implementing a protocol for unblocking implanted venous access ports (IVADS). Twelve patients were observed over the course of one year. The protocol used a decision tree showing RNs how to proceed through an IVAD obstruction. Steps include needle exchange; if there is no result, then placement of a second needle and flushing with normal saline; if still no result then use of urokinase and a two-needle system. Urokinase is older than alteplase and was the only FDA approved thrombolytic before 1998. Success of 92% (n=11/12) was observed in unblocking IVAD with failure due to mechanical obstruction (a bent catheter).

Standardizing Practice for TIVAD Occlusions

Standardizing practice with protocol implementation increases RN knowledge and skill of appropriate TIVAD maintenance and can lead to improved outcomes for patients and job satisfaction for RNs (Mathers, 2011; Pires & Vasques, 2014). Pires & Vasques (2014) conducted a descriptive study in patients with cancer in Internal Medicine (IM) and Emergency Department (ED) at the University Hospital of Brasilia. The study was conducted from September to October 2012. Their interest was to evaluate staff RNs knowledge of TIVAD using interviews. Twenty-

eight RNs participated, 10 from IM and 18 from ED. The outcome revealed that, of the RNs that were interviewed, their knowledge of TIVADs had much room for improvement. The study concluded that the development and utilization of education and standardization was imperative at this institution. Utilizing evidence with the use of manuals and protocols to standardize clinical skills may ensure quality of clinical practices and holds the added benefit of providing guidance, confidence, and greater safety in actions taken by RNs.

Goossens, Stas, & Moons (2012) conducted a cross sectional retrospective descriptive study in Belgium that looked at utilizing a specialized team of advanced practice registered nurses (APRN) to troubleshoot TIVAD related problems in patients with cancer. The study took place from November 1, 2005 to October 30, 2010. Malfunction was defined as injection or aspiration difficulty. Requests of 3950 TIVAD related problems were analyzed and the institution's Leuven malfunction management protocol was used. All catheter-related problems occurred in a total of 7248 with 5454 being TIVAD related and 3950 concerned TIVAD malfunction. Outcomes looked at were to observe and assess types and number of TIVAD malfunction. Researchers of this study concluded that using an APRN team effectively treated TIVAD malfunctions and allowed RNs to have more time with less stress to care for patients.

The implementation of an evidence-based protocol for appropriately accessed TIVADs without blood return as a practice change, after careful assessment, management, and evaluation utilizing an APRN as part of a multidisciplinary team may help to reduce time to receiving scheduled chemotherapy, costs, and improve consistency of care (Mathers, 2011; McKnight, 2004; Pires & Vasques, 2014).

Implementation Plan

The sample included the RNs working on the outpatient oncology unit (n = 33) and the oncology patients who are experiencing TIVAD occlusion after being appropriately accessed by oncology RNs from October 2018 to December 2018 (n = 2). The setting of this QI project of an evidence-based protocol for appropriately accessed TIVAD without blood return occurred in an ambulatory outpatient oncology clinic at a mid-Atlantic community hospital. The QI approach helped gather evidence for the utilization of a TIVAD protocol. When patients experience a malfunctioning TIVAD time to receive their much-needed chemotherapy may be reduced. Costs may be reduced with a standardized TIVAD competency and protocol implementation. RNs may experience less stress and more satisfaction with a standardized protocol due to having a clearly understood path of what to do when a TIVAD malfunctions.

Implementation readiness of this QI project began in Summer 2018. This included organizational approvals from the University Institutional Review Board (IRB) and the organization's Nursing Research and Evidence-Based Practice Council (NREBPC) in July and August 2018, respectively. After these approvals were obtained the implementation timeline took place over a 14-week period.

At week 1, approval of this QI project was pending from the organizational NREBPC. The APRN student met and spoke with the clinical site rep (CSR_1). They discussed a tentative plan and timeline for staff introduction to and implementation of the QI project and agreed that the charge nurse and three RNs, identified by the CSR, would lead the TIVAD and alteplase competencies (See Appendix A & B). These two procedures are standard practice for all oncology RNs and would act as an annual refresher as well as offer an opportunity to fine tune individual practices if needed.

Organizational approval from the Clinical Review Committee at the University IRB with the determination as Non Human Subjects Research (NHSR) was officially granted on 23 July 2018. During the third week of implementation (04 October 2018), the APRN student met and spoke with the first CSR (CSR_1). The CSR_1 explained to the DNP student that her role at the organization had been retired and the charge nurse would be taking over the QI project duties moving forward. The APRN student was introduced to the charge nurse and newly appointed the second CSR (CSR_2). In weeks 4 and 5, the multidisciplinary QI Project team met with RNs and completed competencies in TIVAD access and alteplase instillation. During week 6 of the QI project the DNP student and appointed CSR_2 met with the staff RNs during the afternoon huddle to continue completion of TIVAD and alteplase competencies with plans to begin introduction and implementation of the TIVAD algorithm the following week.

At week 7 approximately 50% (n=16/34) of RNs had completed the two competencies. The APRN student, CSR_2, and staff RNs met during the afternoon huddle. The TIVAD algorithm was introduced and reviewed (See Appendix C & D). Questions and concerns were addressed and answered, including “how long are specific alteplase dwell times” (30 minutes and 90 min for 2mg alteplase per manufacturer recommendation). It was also discovered that revision of the algorithm was needed at the end point if blood return is not obtained. Who the appropriate contact is and what that meant for this organization was placed at the end point of the algorithm. This end point change from “consult with APRN/IR for US or evaluation of TIVAD” to “ consult with attending Oncologist for Radiology in ACP for dye study” occurred. All algorithm/checklists were updated. CSR_2 was instrumental in continuing encouragement of staff RNs to complete competencies and reminding RNs to refer to the algorithm, which was placed in

every resource folder at each of the 15 pods in the clinic. This resource folder serves as a quick and handy reference for each pod in the clinic.

By week 8, 68% (n=23/34) of RNs had completed both competencies. It was reported that one TIVAD had not produced blood return during the week. Alteplase was used but the standardized algorithm was not utilized or documented as such in the Electronic health record (EHR). During week 8, CSR_2 revealed that she had several competing duties to accomplish and had asked the current clinical educator for the inpatient Oncology unit for assistance and step in as the third CSR (CSR_3) for this QI project. Together, CSR_3 and CSR_2 were very helpful and gracious in the completion of this QI project.

At week 9, 71% (n=24/34) of RNs had completed both competencies. The DNP student checked in with CSR_2, met with CSR_3, and spoke with each RN to discuss any possible questions or concerns of the week. One RN inquired where and how to document use of the TIVAD checklist/algorithm. The APRN student explained that if a TIVAD malfunctions and the checklist/algorithm is used, that it should be documented in the "notes" section of the central line access portion of the EHR when documenting.

By week 10, 85% (n=28/33) of RNs had completed both competencies. One TIVAD had not produced blood return during the week. Alteplase was used and was documented in the "notes" section of the EHR. Weeks 11 and 12 the APRN student met with CSR_2, CSR_3, and each RN.

During weeks 13-14 the DNP student administered the system usability scale (SUS) questionnaire to RNs (See Appendix E). The SUS questionnaire measured, post outcome, RN satisfaction and sustainability (Brooke, 1986) of this QI project. The SUS questionnaire has a reliability coefficient alpha of 0.91 (Lewis & Sauro, 2009). EHR reports were requested and

obtained from IT. These revealed weekly alteplase use during the implementation period (weeks 6 -14) and any measurement of delayed chemotherapy treatment of more than 24 hours for those patients. Chart audits conducted by the APRN student assessed appropriate use and documentation of standardized TIVAD checklist/algorithm.

Results

TIVAD and alteplase instillation competencies were completed and audited to ensure proficiency of oncology RNs. Eighty-five percent (n=28/33) of RNs completed both competencies. Electronic health record reports of documentation of the standardized TIVAD protocol, alteplase use, and delay of chemotherapy >24hrs were monitored. There were two instances of alteplase use during the implementation period due to lack of blood return with one documented use of the standardized protocol, both without delay of chemotherapy treatment of >24hrs.

The SUS was available to all oncology RNs during week fourteen. The SUS is a 10-item questionnaire, likert scale, created by John Brooke in 1986. It has proved to be a valuable evaluation tool, being robust and reliable. It correlates well with other subjective measures of usability. SUS has been made freely available for use in usability assessment, and has been used for a variety of research projects and industrial evaluations; the only prerequisite for its use is that any published report should acknowledge the source of the measure (Brooke, 1986).

The SUS measures the ease-of-use of a newly implemented system, in this case, the implemented TIVAD algorithm. SUS measures post outcome for satisfaction and sustainability of a new system and defines scoring as acceptable above 70, marginal below 69-50, and not acceptable below 50. Nineteen RNs completed the SUS, 58% (n=19/33). The majority of RNs, 79% (n=15/19) scored the TIVAD algorithm as acceptable, three of the RNs or 16% (n=3/19)

applied a score of marginal for a usable system, and there was a score of not acceptable in 5% (n=1/19). Results of the SUS are summarized in Table 1 and Table 2.

Unforeseen immediate staff changes presented a barrier for this QI project. A relationship had been built over a year between the original CSR_1 and APRN student, planning and orchestrating implementation. Organizational decisions resulting in the sudden unavailability of CSR_1 created instant stress and a less clear understanding for the new CSR_2. According to Straus, Tetroe & Graham (2013), potential shared decision making (SDM) barriers include a lack of expectation of the health care process and the perception that performance following the use of SDM will not lead to an improved organizational process. The subsequent CSRs (CSR_2 & CSR_3) took the rapid changes and increase of responsibilities in stride and the APRN student understood that it could not have been easy.

The organization itself identified the problem to be solved and requested an APRN student in need of a scholarly QI project, due to lack of funding and time. This created a "win-win" situation from the beginning, two parties coming to the table willing to participate. The unanticipated turn-over in CSRs required briefing new CSRs and facilitating their learning on the project topic, which delayed project implementation by several weeks. However, cases of lack of blood return necessitating use of the TIVAD algorithm and alteplase are occasional events, so an additional few weeks of implementation may not have resulted in more instances of algorithm and/or alteplase use. This DNP project could be tailored for other oncology clinics.

Discussion

The purpose of this DNP project was to implement an evidence-based standardized algorithm for appropriately accessed TIVAD without blood return. While it is not an emergent situation, it is necessary for TIVADs to have a blood return before patients receive treatment and

can cause delay of several hours. According to Goossens (2012), TIVADs that are not working induce stress in patients as well as RNs. In interviews conducted prior to implementation, unit RNs echoed this sentiment when they shared that they did not have a clear decision path in this situation. Adherence to a TIVAD algorithm benefits patients and RNs by providing consistent care for malfunctioning TIVADs. Evidence-based standardization promotes confidence and certainty of what will happen when the situation of partial occlusion occurs (Pires & Vasques, 2014).

Educational competencies before implementation certified that unit RNs were experts at accessing TIVADs and, when necessary, instilling alteplase according to manufacturer and institutional policies. The high rate of completion of the competencies, 85%, displayed this expertise. The SUS was determined to be a simple and effective tool and most RNs determined that the algorithm was acceptable for use in clinical practice.

A major reason this QI project came to be was to build upon evidence of an accepted practice. The intention was to standardize practice, not to introduce new practice. It is a beginning, so that standard practice may one day be more than expert opinion. The gathering and organizing of existing research studies that substantiate practice supported the development of the standardized algorithm used in this project. Adherence to the algorithm guarantees certainty of the process and saves time without duplication of practices. RNs on the unit determined that the TIVAD algorithm was overall useful and acceptable. The algorithm was placed in the resource binder at every bay of the unit for easy access and availability.

This project did not accrue additional costs during implementation. Determination of cost effectiveness was not definitively established in the 14-week period. If duplication of practices and time to treatment are decreased it would stand to reason that cost savings would occur long

term but due to small sample size and the short duration of the project this was not definitively determined.

The significant limitation of the project was sudden staffing changes that resulted in several unanticipated adjustments. The momentum and enthusiasm of the project seemed diluted once the initial CSR left the organization. The cultural setting was not optimal because of sudden changes in leadership and tension within the unit and organization due to these changes. These barriers were somewhat mitigated during implementation by a few leaders who supported and encouraged a culture of EBP on the unit; however, use of the algorithm may not be sustainable without long-term support. Lack of buy in from uninterested team members created an opportunity for the DNP student to use diplomacy and articulation skills at every encounter through positive and frequent communication.

Another limitation of the quality improvement methodology was the nine-month lag time between initial introductions until implementation of the project. The DNP student understood necessary prerequisites prior to implementation but shortening this time may be helpful in sustaining organizational interest for future DNP projects. Implementation of a DNP project may be most successful when the organization itself identifies the problem or need. This was done in this case but, as suggested, the lag time and other factors, such as the staff changes and turnover in leadership previously discussed, diminished interest and buy in. If the DNP student had a relationship with the unit on which the project was implemented, that might have proved helpful.

A significant strength of this QI project includes a devised algorithm that is based on evidence and matches up with the most recent published TIVAD standards from ONS (2017). Due to few and non-robust studies, the national organizational recommendations of practice for TIVAD without blood return by ONS (2017) are based on expert opinion. This QI project was an

attempt to gather and build on the evidence. More robust studies must be undertaken for accepted practice to become EBP.

Conclusion

Overall, this project proved useful for RNs of the unit and the patients that experienced TIVAD occlusion. Standardization allowed all parties to know the path that will occur and the ability to judge, from least to most, the amount of time it may take until treatment. The algorithm also would be a useful tool for novice RNs who are uncertain of what to do when the situation happens. Providing education regarding TIVAD care to RNs during organizational orientation would contribute to dissemination of the project.

Without ongoing support on the unit this project may not be sustainable. However, sustainability and dissemination within the organization would occur if the unit spread their knowledge of and use of the algorithm. Units such as the Inpatient Oncology unit, Emergency Department, Medical-Surgical unit, or any unit that may encounter patients with TIVADs would benefit from the algorithm as well as any provider that inserts or removes TIVADs such as the Interventional Radiology unit. These units could be used as sites for possible future QI projects that utilize the algorithm to help build on the evidence. Next steps for implementation should include continued use of the TIVAD algorithm and broadening its use to other units at the organization, ensuring standardization of practice of TIVAD care.

References

Ast, D., & Ast, T. (2014). Nonthrombotic complications related to central vascular access devices. *Journal Of Infusion Nursing, 37*(5), 349-358. doi:10.1097/NAN.0000000000000063

Baskin, J., Pui, C., Reiss, U., Wilimas, J., Metzger, M., Ribeiro, R., & Howard, S. (2009). Management of occlusion and thrombosis associated with long-term indwelling central venous catheters. *The Lancet*, 374(9684), 159-169. doi:10.1016/S0140-6736(09)60220-8

Brooke, J. (1986). System usability scale © Digital Equipment Corporation. Redhatch Consulting Ltd., 12 Beaconsfield Way, Earley, Reading RG6 2UX, United Kingdom

Cope, D., Elledge, C., Mackey, H., Moran, A., Rogers, M., Schulmeister, L., Smith, L., Stovall, M. (2017). *Access device standards of practice for oncology nursing.* Camp-Sorrell, D., Mately, L. (Eds.), Pittsburgh, PA: Oncology Nursing Society.

Cope, D., Ezzone, S., Gerber, D., Lamprecht, M., McCorkindale, D., Moran, A., Walker, J., Winkelman, L. (2011). Vascular access devices. In Camp-Sorrell, D. (Eds.), *Access device guidelines: Recommendations for nursing practice and education* (pp. 5-52). Pittsburgh, PA: Oncology Nursing Society.

Cummings-Winfield, C., & Mushani-Kanji, T. (2008). Restoring patency to central venous access devices. *Clinical Journal Of Oncology Nursing*, *12*(6), 925-934. doi:10.1188/08.CJON.925-934

Fernandez-de-Maya J., Richart-Martinez M. (2013). Variability in management of implantable ports in oncology outpatients. *European Journal of Oncology Nursing*, 17(6) , 835-840.

Ford, J. & Ford, L. (2002). Conversations and the authoring of change. In D. Holman & R. Thorpe (Eds), *Management and language: The manager as a practical author* (pp. 141-156). New York: Sage Publishing.

Ford, J., Ford, L., & McNamara, R. (2002). Resistance and the background conversations of change. *Journal of Organizational Change Management, 15*(2), 105-121, doi: 10.1105/0953481022991

Goossens, G., Stas, M., & Moons, P. (2012). Management of functional complications of totally implantable venous access devices by an advanced practice nursing team: 5 Years of clinical experience. *European Journal Of Oncology Nursing*, *16*465-471. doi:10.1016/j.ejon.2011.11.006

Gorski, L. (2017). *Fast facts for nurses about home infusion therapy: The expert's best practice guide in a nutshell*. Retrieved from https://ebookcentral.proquest.com

Gorski, L., Hadaway, L., Hagle, M., McGoldrick, M., Orr, M., Doellman, D. (2016). Infusion therapy standards of practice. *Journal of Infusion Nursing,* 39(1S)

Infusion Nurses Society (2011). *Policies and procedures for infusion nursing* (4th ed.). Infusion Nurses Society.

Mathers, D. (2011). Evidence-based practice: Improving outcomes for patients with a central venous access device. *Journal Of The Association For Vascular Access*, *16*64,70-67,72. doi:10.2309/java.16-2-3

McKnight, S. (2004). Nurse's guide to understanding and treating thrombotic occlusion of central venous access devices. *MEDSURG Nursing*, *13*(6), 377-382.

Melnyk, B., Fineout-Overholt, E. (2012). Evidenced-based practice in nursing & healthcare: A guide to best practice (2nd ed). New York: Lippincott, Williams & Wilkins. Chapter 8.

Muguet, S., Couraud, S., Perrot, E., Claer, I., & Souquet, P. (2012). Clearing obstructed totally implantable central venous access ports: an efficient protocol using a second needle. *Supportive Care In Cancer*, *20*(11), 2859-2864. doi:10.1007/s00520-012-1412-0

Newhouse, R., Dearholt, S., Poe, S., Pugh, L., White, K. (2007). *Johns Hopkins nursing evidenced-based practice model and guidelines*. Indianapolis: Sigma Theta Tau International.

Pires, N., Vasques, C. (2014). Nurses' knowledge regarding the handling of the totally-implanted venous access device. *Texto & Contexto - Enfermagem*, *23*(2), 443-450. https://dx.doi.org/10.1590/0104-07072014000830013

Plohal, A., & Schiller, K. (2017). Efficacy of reducing alteplase dose to restore patency in nonhemodialysis central vascular access devices. *Journal Of Infusion Nursing*, *40*(2), 112-115. doi:10.1097/NAN.0000000000000209

Sauro, J. (2011). Measuring usability with the system usability scale (sus). *Measuring U*. Retrieved from https://measuringu.com/sus/

Sharma, R., Ree, C., & Ree, A. (2008). Efficacy and safety of a single 2 mg dose or 4 mg double dose of alteplase for 50 occluded chest ports using a unique instillation technique. *The International Journal Of Angiology: Official Publication Of The International College Of Angiology, Inc*, *17*(3), 125-128.

Stammers, D., Connolly, B., Brandão, L., Zupanec, S., & Gupta, S. (2017). Evaluation of the need for chest X-rays in the management of asymptomatic, intraluminal vascular access device occlusion in childhood cancer. *Pediatric Blood & Cancer*, *64*(7), doi:10.1002/pbc.26378

Straus, S., Tetroe, J., & Graham, I. (2013). Knowledge Translation in Health Care: Moving from Evidence to Practice. (2nd ed.). Hoboken, NJ :Wiley-Blackwell.

Waagen, G., & Bliss, D. (2003). Development of evidence-based protocols for evaluation and management of dysfunctional vascular access devices in interventional radiology, *Journal Of Vascular Nursing, 21*50-62. doi:10.1016/S1062-0303(03)00032-3

Table 1

System Usability Scale Results (SUS) (n=19)

Usability Adjective	Score Range	Count (n)	%
Acceptable	Above 70	15	79
Marginal	Below 70	3	16
Not Acceptable	Below 50	1	5

Table 2
SUS Individual Scores of RNs (n=19)

Completed SUS	SUS Score	Usability Adjective Acceptable	Usability Adjective Marginal	Usability Adjective Not Acceptable	Detailed SUS Adjective
1	100	X			Best imaginable
2	95	X			Best imaginable
3	95	X			Best imaginable
4	92.5	X			Best imaginable
5	87.5	X			Excellent
6	87.5	X			Excellent
7	87.5	X			Excellent
8	87.5	X			Excellent
9	87.5	X			Excellent
10	85	X			Excellent
11	85	X			Excellent
12	80	X			Good
13	80	X			Good
14	77.5	X			Good
15	72.5	X			Good
16	67.5		X		High marginal
17	67.5		X		High marginal
18	67.5		X		High marginal
19	40			X	Not acceptable

Average = 81
Median = 85

Appendix A:
Implanted Port Competency for Totally Implanted Vascular Access Device (TIVAD)

A. Accessing the implanted port

1. Explains procedure to patient
2. Washes hands and obtains necessary equipment
3. Chooses appropriate size and length noncoring needle for therapy planned
4. Applies gloves
5. Removes dressing if appropriate
6. Palpates port and locates center of septum to be accessed
7. Observes site for edema, erythema, tenderness, condition of the catheter tunnel, or swelling of ipsilateral chest or neck veins or extremity
8. Discards used gloves and reapplies new gloves; applies topical anesthetic cream if ordered
9. Cleanses the area over the septum; administers topical anesthetic, if ordered
10. Grasps the edges of the portal body firmly through the skin to stabilize, pushing the noncoring needle firmly through the skin and diaphragm, stopping when the bottom of the reservoir is reached
11. Flushes saline into port and checks for blood return
12. Applies dressing per institutional policy and planned length of infusion
13. Attaches IV tubing directly to catheter hub if continuous infusion
14. Attaches injection cap if intermittent infusion is planned
15. If continuous infusion is planned, changes noncoring needle at least once every seven days and PRN

B. Flushing an implanted port

1. Explains procedure to patient
2. Washes hands and assembles necessary equipment
3. If port is not accessed, accesses per above procedure
4. Flushes catheter with 10–20 ml normal saline for valved catheters and 5 ml 100 units/ml heparin lock flush for open-ended catheters
5. If port does not need to be used, deaccess per procedure below
6. Accesses and flushes port every four to eight weeks when not in use

C. Deaccessing an implanted port

1. Explains procedure to patient
2. Washes hands and assembles necessary equipment
3. Applies gloves and removes dressing
4. Discards used gloves and reapplies new gloves
5. Stabilizing port through skin with one hand, grasps noncoring needle wings or hub with the other hand and administers flush
6. While instilling the final 1 ml of flushing solution, simultaneously pulls the needle from the port septum, pushing down on the port edges to prevent tugging the port upward
7. Applies pressure over the needle exit site, then applies adhesive bandage if needed

D. Blood drawing from an implanted port

1. Explains procedure to patient

2. Washes hands and assembles necessary equipment

3. Accesses port per above procedure if not accessed

F. Skill

4. Removes at least 5 ml of blood and discards

5. Removes necessary blood for testing using additional syringes or Vacutainer® (Becton, Dickinson and Co.) system

6. Flushes catheter per above procedure and either continues infusion, recaps, or deaccess per above procedure

G. Documentation/patient education

1. Documents all procedures, assessments, and patient response

2. Teaches patient and/or significant others implanted port care and observation

Cope, D., Ezzone, S., Gerber, D., Lamprecht, M., McCorkindale, D., Moran, A., Walker, J., Winkelman, L. (2011). Vascular access devices. In Camp-Sorrell, D. (Eds.), *Access device guidelines: Recommendations for nursing practice and education* (pp. 154-155). Pittsburgh, PA: Oncology Nursing Society.

Appendix B:

Central Venous Access Devices: Declotting with Alteplase

Name: _____ Start Date: _____
Preceptor: _____ Completion Date: _____

COMPETENCY OR SKILL	SELF ASSESS			VERIFICATION			
	1	2	3			Sat/Unsat S/U	
Using the same 10-ml syringe, administered the appropriate dose of solution from the reconstituted vial into the occluded catheter. **If resistance was met, did not forcibly push the solution into the catheter but instead used one of the "One Syringe" or "Three – Way Stopcock" method:**						S / U	
One Syringe Method a. Used the single 10 ml- syringe of alteplase solution attached to the hub of the catheter's dysfunctional lumen. b. After unclamping the catheter, holding the syringe in vertical position with the plunger end up, gently pulled back on the syringe plunger until it reached the 8 or 9 ml mark and hold it to create negative pressure in the catheter. c. While holding syringe in a vertical position and keeping the plunger pulled back, ensuring that the alteplase solution is at the syringe tip, nearest to the catheter hub. d. *Slowly* released the plunger and the negative pressure on the syringe. Repeated as necessary to instill the dose of alteplase solution. Leaving syringe in place. Securing appropriately. Labeling the syringe (name of medication, initial, and time of instillation/start						S / U	

Three –Way Stopcock Method a. Used two 10ml syringe and a three-way stopcock. Attached syringe containing the alteplase solution to the horizontal hub of the stopcock and attached an empty 10ml syringe to the vertical hub. b. Unclamping the catheter, turned the stopcock off to the alteplase syringe and open to the empty syringe, and gently aspirated the empty syringe until the plunger reached the 8- to 9-ml mark. c. While holding the plunger on the empty syringe to create negative pressure, turned the stopcock open to the syringe containing the alteplase solution and allowed it to be drawn into the catheter. d. Repeated as necessary to instill the complete dose. e. Left the syringe in place. Secured it appropriately. Labeled the syringe (name of medication, initial, and time of instillation/start).						S / U	
Waited 30 minutes, and then assessed catheter function by attempting to withdraw blood. If the catheter was functional, then aspirated 4- to 5-ml of blood in patients weighing 10kg or more, or 3ml in patients weighing less than 10 kg, to remove the alteplase and residual clot.						S / U	
If catheter function was not restored after 30 minutes, then relocked the catheter and assessed again in 90 minute (120 minutes after the first instillation). If the catheter was functional, followed the same irrigation process described in the step immediately preceding this one. If catheter had not been restored, repeated the dose of alteplase following the same steps described previously. If the catheter remained occluded, contacted the practitioner.						S / U	
Completing the Procedure							
Flushed the catheter with solution according to institution protocol. Apply new cap.						S / U	
Discarded supplies, removed gloves, and performed hand hygiene.						S / U	
Documented the procedure in the patient's record.						S / U	

Preceptor's Signature: _____

Cope, D., Ezzone, S., Gerber, D., Lamprecht, M., McCorkindale, D., Moran, A., Walker, J., Winkelman, L. (2011). Vascular access devices. In Camp-Sorrell, D. (Eds.), *Access device guidelines: Recommendations for nursing practice and education* (pp. 154-155). Pittsburgh, PA: Oncology Nursing Society.

Gorski, L., Hadaway, L., Hagle, M., McGoldrick, M., Orr, M., Doellman, D. (2016). Infusion therapy standards of practice. *Journal of Infusion Nursing,* 39(1S)

Sharma, R., Ree, C., & Ree, A. (2008). Efficacy and safety of a single 2 mg dose or 4 mg double dose of alteplase for 50 occluded chest ports using a unique instillation technique. *The International Journal Of Angiology: Official Publication Of The International College Of Angiology, Inc*, *17*(3), 125-128.

Appendix C:

Standard Organizational Practice VS Evidence-Based Algorithm

- All Totally Implanted Venous Access Devices (TIVAD) will be appropriately accessed using INS/ONS guidelines.
- Occluded or malfunctioning TIVAD is defined here as: able to flush in but not able to aspirate/produce blood return.

Standard Organizational Practice

Possible troubleshooting of a malfunctioning TIVAD may involve one or more of the following interventions, in no particular or systematic order:

- Instilling alteplase (a thrombolytic) according to INS/ONS guidelines
- Ordering a linogram (dye study) from Interventional Radiology
- Taking the port (Huber) needle out and re-accessing with a new one
- Flushing several times with normal saline,
- Repositioning the patient
- Deep breathing
- Pumping arms up and down

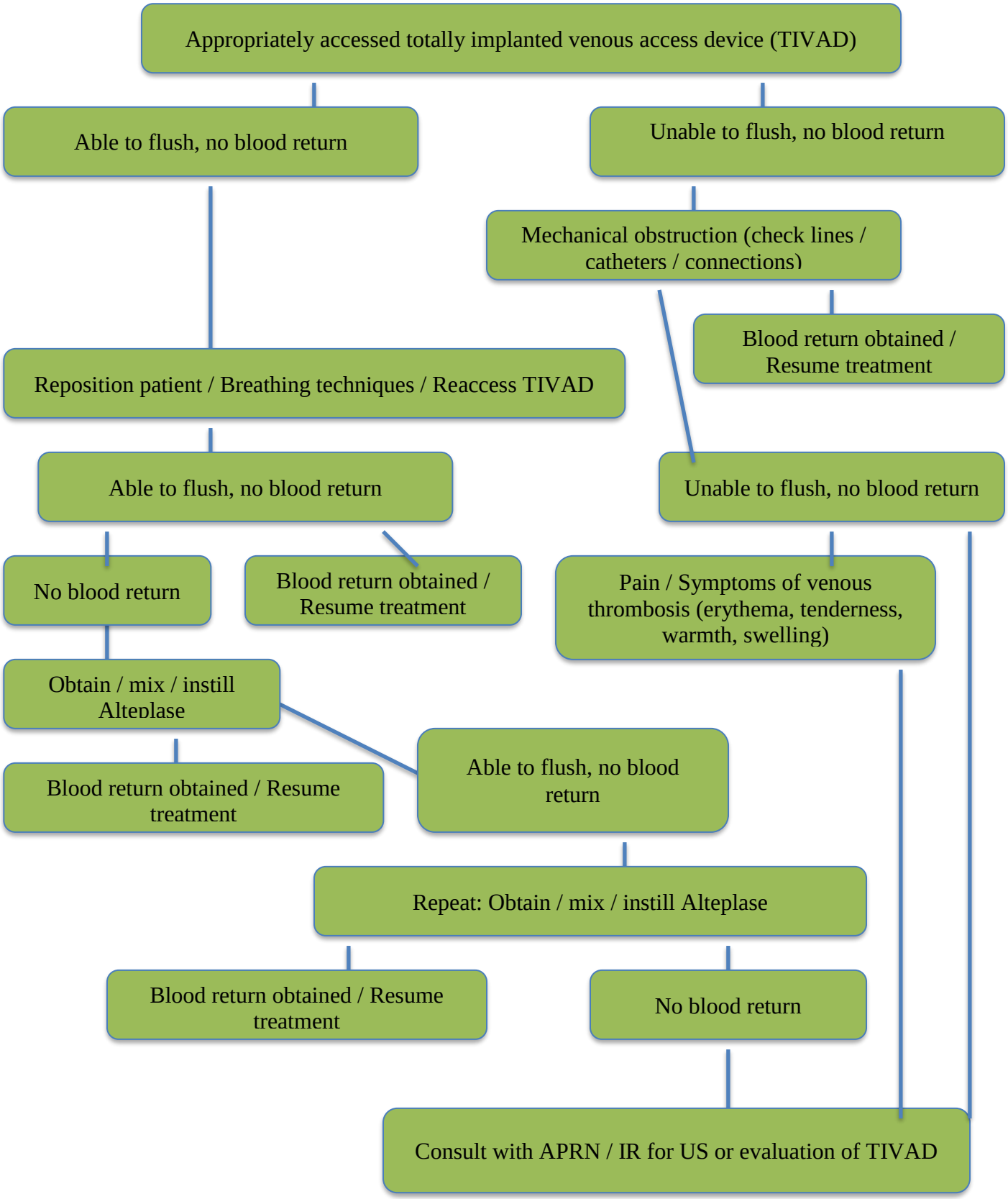
When asked, RNs at the organization agreed to not knowing what to do first or what specific steps to take when presented with a malfunctioning TIVAD.

Current standards are based on expert opinion and accepted practice, showing a need for established evidence (Cope et al., 2017).

Implemented Evidence-Based Algorithm

- The first step to follow for a malfunctioning TIVAD (defined as able to flush in but not able to produce blood return) is to reposition the patient / ask patient to take several deep breaths / deaccess the huber needle and reaccess a second time (Baskin et al., 2009).
- If TIVAD does not flush and there is no blood return the RN will check all lines / catheters / connections for possible mechanical obstruction (Gorski et al., 2016; Waagen, & Bliss, 2003).
- If there are symptoms of pain or venous thrombosis in extremity, shoulder, neck, and chest (erythema, tenderness, warmth, swelling) the RN will consult with the clinic NP / IR for TIVAD evaluation and ultrasound (Gorski et al., 2016).
- If TIVAD continues to malfunction the RN will obtain / mix / instill alteplase per INS/ONS guidelines as described in Appendix B (Baskin et al., 2009; Cope et al., 2011; Gorski et al., 2016). This step can be repeated one time (Cope et al., 2017).
- If TIVAD continues to malfunction the RN will consult with the clinic NP / IR for TIVAD evaluation and ultrasound (Waagen, & Bliss, 2003).
- If blood return is obtained at anytime during this process the RN may resume with chemotherapy/immunotherapy treatment (Baskin et al., 2009).

Appendix D: TIVAD Algorithm



Appendix E:

System Usability Scale © Digital Equipment Corporation, 1986.

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system					

John Brooke, Redhatch Consulting Ltd., 12 Beaconsfield Way, Earley, READING RG6 2UX, United Kingdom
SUS has proved to be a valuable evaluation tool, being robust and reliable. It correlates well with other subjectives measures of usability (eg., the general usability subscale of the SUMI inventory developed in the MUSiC project (Kirakowski, personal communication)). SUS has been made freely available for use in usability assessment, and has been used for a variety of research projects and industrial evaluations; the only prerequisite for its use is that any published report should acknowledge the source of the measure.

Appendix F: Evidence Rating and Grading Table

Author(s), year	Study objective/ intervention or exposures compared	Design	Sample (*n*)	Outcomes studied (how measured)	Results	Melnyk Level of *Evidence* Rating (1-7)	Newhouse Quality of Evidence (A,B,C)
1) Ast, D., & Ast, T. (2014).	To describe various nonthrombotic CVAD complications as well as identification and appropriate interventions used to manage these events.	Expert opinion, informational literature review of topic.	N/A	Outcomes observed that while safe treatment of nonthrombotic occlusions, using agents, has been studied and documented for years, their use in clinical practice is not widespread.	Most agents used for treating nonthrombotic occlusions require special preparation and compounding techniques, add cost, and complicate treatment.	7	B Good quality, Expertise appears to be credible.
2) Baskin, J., Pui, C., Reiss, U., Wilimas, J., Metzger, M., Ribeiro, R., & Howard, S. (2009).	To summarize the literature concerning central venous catheters (CVC) and catheter-related thrombosis (CRT).	Systematic review of descriptive & qualitative studies	N/A	Knowledge that thrombotic central venous catheter occlusions can cause catheter related thrombosis (CRT). CRT can lead to serious complications and prevention is key yet effective prophylactic	Due to lack of prospective studies, controversy continues regarding optimal management of catheter related thrombosis. The etiology	5	A High quality, Clear aim and objective.

				measures have not been established.	of a catheter occlusion determines the appropriate treatment.		
3) Cummings-Winfield, C., & Mushani-Kanji, T. (2008).	An evidence-based review of the literature on institutional and published protocols for thrombolytic treatment of occluded central venous access devices (CVAD) and CVAD-related complications.	Systematic review of descriptive & qualitative studies	N/A	Observed that common complications can lead to premature removal and replacement of central venous access devices (CVAD), which add to cost of device, patient chair and treatment time.	Proper assessment, use, and maintenance of CVADs prevent treatment delays and potentially life-threatening complications. Restoring patency, when appropriate, represents a cost-effective alternative and improves patient quality of life. Standard procedures should be implemented consistently and evaluated	5	B Good quality, Formal quality improvement.

					regularly.		
4) Fernandez-de-Maya, J., Richart-Martinez, M. (2013).	To describe the variability of clinical practice in the manipulation and care of vascular access ports in Spain and to establish if and how much the practices resemble central venous access recommended guidelines.	Descriptive, between January and April 2010	256 hospitals that have day hospitals for adult oncology patients with vascular access ports.	Questionnaires gathered information on technique of needle insertion, blood sample extraction, needle withdrawal, and procedure for the unblocking of a blocked implanted port. Descriptive analysis using SPSS was used.	There is much variation in management of implantable ports; techniques used for insertion, withdrawal of the needle, blood sampling, and unblocking procedures.	6	B Good quality, Expertise appears to be credible.
5) Goossens, G., Stas, M., & Moons, P. (2012).	To determine the number, type, and distribution of requests for malfunction, supplementary investigations, and thrombolytic treatments in the care of totally implanted venous access devices to an Advanced Practice Nursing team.	Descriptive, retrospective study	3950 total requests for malfunctioning totally implanted venous access devices, 2019 patients were analyzed. Male (n=852) Female (n=1167) Purposive sampling.	Device characteristics, catheter-related problems, type and distribution of functional problems, results of chest x-rays and linograms, treatment options, possible removal or exchange (all summarized and aggregate when useful).	Utilizing an Advanced Practice Nursing team specializing in preventing and troubleshooting, malfunctions of totally implanted venous access devices can be managed effectively managed,	6	A High quality, Expertise is clearly evident, thought leader in the field.

					allowing RNs more time and less stress in the care of their patients.		
6) Muguet, S., Couraud, S., Perrot, E., Claer, I., Souquet, P. (2012).	To assess the efficacy (rate of successful unblocking) and tolerance (local and/or general complications) of an original unblocking protocol for implanted venous access ports.	Retrospective, single-institution cohort study	12 patients, 11 men and 1 woman aged 46-72 years old.	Frequencies are expressed as percentages and absolute values. Due to low effective of protocol failure, no other statistical tests were performed.	The unblocking protocol, decision tree, was successful in 11 of the 12 included pts, 92% success rate. 1. Needle exchange. 2. Placement of a second needle and reservoir flushing with normal saline. 3. Use of urokinase in the two-needle system.	4	C Low quality, Conclusions cannot be drawn.
7) Pires, N., Vasques, C. (2014).	To evaluate nurses' knowledge regarding the handling of totally implanted vascular access	Cross-sectional study, with a descriptive character and a qualitative	28 nurses, 10 worked in Internal Medicine (IM) and 18 worked in the Emergency Room (ER).	Two stage study. 1) Interviewing nurses' knowledge of TIVAD management. 2) Conducting integrative review	Nurses' knowledge of TIVAD management included when to use it, the purpose of use,	6	B Good quality, Provides reasonably consistent recommendations based on

	devices (TIVAD).	approach.		for clarification of identified doubts in TIVAD management.	appropriate access, maintenance and handling were inadequate and in need standardized theoretical-practical training.		fairly comprehensive literature review.
8) Stammers, D., Connolly, B., Brandão, L., Zupanec, S., & Gupta, S. (2017).	To define the utility of obtaining CXRs prior to administering tPA in the setting of VAD occlusion.	Retrospective, single-institution cohort study	Pediatric patients (less than 18 years) n=300	Chi-square or Student's t-tests, used logistical regression to compare pt and VAD characteristics and management.	Patients with ports were at lowest risk of occlusion. Routine CXRs in asymptomatic VAD occlusion can safely be omitted prior to the administration of tPA.	4	A High quality, Developed in the last 5 years.
9) Mathers, D. (2011)	To improve nurses' knowledge and skill related to flushing CVADs,	Single descriptive evidence-based practice	Nurses, N=50.	Pre and post implementation data via audits on actual CVAD flushing technique	Significant overall improvement in nurses' skill related to	6	C Low quality, insufficient sample size.

	specifically catheter patency.	change project in a 436 bed regional health care system.		(observed/recorded) and education questionnaires.	proper CVAD flushing technique.		
10) Plohal, A., & Schiller, K. (2017).	To discuss practice project using reduced dosing of alteplase in restoring patency to non-Hemodynamic (HD) CVADs	Single qualitative evidence-based practice project.	Doses of alteplase, N=1147 (0.5mg/2mL=1071, 1mg/2mL= 68).	Cost analysis.	Total cost savings of $86,291.66. Increase in patient wait times due to pharmacy sending lower dose/mixed medication instead of RNs pulling single dose from unit.	6	B Good quality, sufficient sample size.
11) Sharma, R., Ree, C., & Ree, A. (2008).	To evaluate effectiveness/safety of 2mg or double dose 4mg alteplase for restoring function in occluded chest ports.	A prospective, open label, non-blinded study, single institution.	Chest ports, N=50.	The success rate was estimated, along with its 95%CI, assuming an exact binomial distribution.	1 or 2 doses (2mg per dose) of alteplase are highly effective and safe in restoring function of occluded chest ports.	6	B Good quality.

Hierarchy of Evidence

Level of the Evidence	Type of the Evidence
I (1)	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT
III (3)	Evidence obtained from well-designed controlled trials without randomization
IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative studies
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt, E. (2014). *Evidence-based practice in nursing & healthcare: A guide to best practice* (3rd ed.). New York: Lippincott, Williams & Wilkins.

Rating Scale for Quality of Evidence

A: High – consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature

B: Good – reasonably consistent results; sufficient sample, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C: Low/major flaw – Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

Newhouse, R.P. (2006). Examining the support for evidence-based nursing practice. *Journal of Nursing Administration, 36*(7-8), 337-40.

Appendix G:

MAP-IT

DNP Project Name: Evidence-Based Protocol for Malfunctioning Totally Implanted Venous Access Devices (TIVADs)

DNP Project Purpose Statement: The purpose of this DNP project is to implement an evidence-based protocol for appropriately accessed totally implanted vascular access devices (TIVAD) without blood return in an ambulatory outpatient oncology clinic within a community hospital setting. This will help gather much needed evidence for the utilization of a TIVAD protocol. Time to receive much needed chemotherapy regimen, with patient experiencing malfunctioning TIVAD, may be reduced. Costs may be reduced with standardized TIVAD competency and protocol implementation. RNs may experience less stress, more satisfaction with standardized protocol; have a clearly understood path of what to do when a TIVAD is malfunctioning.

Short-Term SMART Objective: By August 30, 2018 we will obtain 75% of registered nurses (RNs), currently working at the outpatient oncology clinic, successfully completing clinic TIVAD competencies 1 month prior to protocol implementation of an evidence-based protocol for appropriately accessed totally implanted vascular access devices (TIVAD) without blood return.
Short-Term SMART Objective: By August 30, 2018 will obtain 50% of RNs, currently working at the outpatient oncology clinic, will be familiar with and able to follow the TIVAD protocol within 1 month of implementation of an evidence-based protocol for appropriately accessed totally implanted vascular access devices (TIVAD) without blood return.
Short-Term SMART Objective: By October 30, 2018 the evidence-based protocol is utilized in 60% of appropriately accessed TIVAD by RNs, currently working at the outpatient oncology clinic, within 1 month of implementation.
Short-Term SMART Objective: Ongoing but completed by October 30, 2018 will revisit questions and concerns of champions, RNs, and stakeholders on use of the TIVAD protocol and revise.
Short-Term SMART Objective: By October 30, 2018 will obtain 75% of RNs, currently working at the outpatient oncology clinic; will be utilizing the TIVAD protocol successfully.

Long-Term SMART Objective: By May 01, 2019 we will have achieved an approval for and implementation of an organizational, standardized TIVAD protocol.
Annual TIVAD competencies may be continued as part of RN job description.
The long-term goal of the DNP project may result in successful implementation of an evidence-based protocol for malfunctioning TIVAD.

Population/Context: The population focused on to complete this DNP project consists of patients receiving oncology care at an ambulatory outpatient oncology clinic in a community hospital with TIVADs. Patients with cancer experiencing a malfunctioning TIVAD, after appropriate access, oncology RNs will perform the implemented TIVAD protocol.

Similar to the MAP-IT approach of continual, rapid cycles for evaluating and improving the Knowledge to Action is a map to aid in the continual process of identifying through implementing in clinical practice problems (Straus, Tetroe, & Graham, 2013). The seven steps for Knowledge to Action include; to identify and assess knowledge needs, adapt knowledge to local context, assess barriers for knowledge use, implement interventions, monitor knowledge use, evaluate outcomes, and sustain knowledge use.

Mobilize: *WHO will help facilitate the changes in structures and processes (practices)?*
Fundamental to infusing chemotherapy, all venous access lines (TIVADs, any central line, peripheral iv) must produce a brisk blood return before chemotherapy treatment may begin, each time, and every time. The Director of Ambulatory Medical Oncology noticed the RNs in her clinic, who are extremely educated, knowledgeable, and capable of taking care of a patient with an occluded TIVAD (able to flush in but not able to produce blood return), but each had a different method and reason on solving this. Some of the troubleshooting involved instilling alteplase (a thrombolytic), ordering a linogram (dye study) from Interventional Radiology, taking the port (Huber) needle out and re-accessing with a new one, flushing several times with normal saline, repositioning the patient, deep breathing, pumping patient arms up and down. When asked about this, the RNs agreed to not knowing what to do first and what specific steps to take when presented with a malfunctioning TIVAD. The Director identified this as an opportunity for growth and enlisted an APRN/DNP student from the University of Maryland, School of Nursing to help facilitate in solving this problem. The implementation of an evidence-based protocol for appropriately accessed TIVADs without blood return. A literature search was conducted to assess the scope of the problem. The organization identified a lack of standard practice in malfunctioning TIVADs. This is the catalyst for this quality improvement inquiry and the need to adapt knowledge to local context (Straus, Tetroe & Graham, 2013). A core team was enlisted in the mobilization of identifying, assessing, and adapting knowledge.
List of core team members include the Director of Ambulatory Medical Oncology, 3-4 oncology RN clinic champions (identified and asked by the clinic director), University of Maryland, School of Nursing DNP Faculty and Mentor, and an APRN/DNP student from the University of Maryland, School of Nursing.
Others will be mobilized after a protocol is planned and has been approved. These additional important evidence based practice (EBP) team members include up to 6-10 individuals. Members of the DNP QI Project team will include relevant stakeholders consisting of oncology charge nurse, oncology nurse educator, clinic staff nurse, nurse practitioner, physician, and pharmacist. Important stakeholders to be updated but not necessarily needed at monthly meetings include member from the Standards of Practice committee, organizational information technology specialist (IT) and Interventional Radiology. All team members are integral as individuals and will help facilitate the changes in structures and practices needed for implementation.

Assess: *WHAT structures and processes (practices) need to change and WHY? What metrics, structure, process, and outcome measures will be used to measure progress?*
The Director and DNP student met on three occasions to conduct chart reviews, examine TIVAD malfunction, note alteplase use, and inspect electronic health record (EHR) documentation. Months researched were January 2017 - December 2017.

- Chart reviews revealed that documentation is incomplete on several occasions. Annual TIVAD competencies are not current practice at this organization. This practice may be beneficial in reminding RNs of proper and necessary TIVAD procedures and documentation responsibilities for their own protection as well as appropriate patient care.
- Examination of TIVAD malfunction included observing current practices of oncology RNs and informal interviewing of their personal clinical practice.
- Alteplase use was studied by noting which patients had single episodes of alteplase use (indicating TIVAD malfunction) and which patients had multiple episodes of alteplase use. If multiple episodes were noted, were they for consecutive visits or months apart? Were there any similarities in patients needing multiple alteplase in a short span of time? Patients with metastatic cancer or a certain type of cancer? How long had the TIVAD been placed?
- Current EHR documentation includes TIVAD assessment utilizing a drop down menu for TIVAD care. Additional adaptation tools may be required for EHR. This includes the implemented TIVAD protocol as a drop down menu in the EHR, modifying the one currently in place.

Monthly audits and chart reviews will reveal several measures. These consist of how often are TIVADs malfunctioning, are RNs documenting use of and utilizing the TIVAD protocol when appropriate, is there a reduction of malfunction?

Knowledge use will be monitored with the use of EHR data and measurement assessments to include monthly/bimonthly audits. With the help of IT, the APN, RNs, and champions will document and track chart audits every month, obtain monthly reports from IT, share and discuss with RNs, the multidisciplinary team, and with stakeholders at already established monthly/bimonthly staff meetings. The process and outcomes will be evaluated and revised as necessary (several rapid map-it cycles). Sustaining knowledge use is complex and difficult but an important task and if determined to be effective this DNP project could be replicated in other oncology clinics.

Plan: *HOW will these changes be made (strategies and tactics)? WHEN will these changes be made?*

Summer 2018 Plan includes organizational approvals from Anne Arundel Medical Center (AAMC) Nurse Research Council presentation and University of Maryland, Baltimore (UMB) Institutional Review Board (IRB).

TIVAD competencies and in-services to address concerns and educate RNs on the best current practice; clinical training for best implementation strategies; documentation and analyzing data. EHR documentation includes TIVAD assessment; additional adaptation tools may be required. This includes the implemented TIVAD protocol as a drop down menu in the EHR.

- In-service training for RNs on appropriate TIVAD access and competency will occur 1 month prior to implementation, September 2018. Champions will be instrumental in this endeavor.
- Annual TIVAD competencies for RNs will be appraised 1 month prior to implementation (August 2018) and continue each year.
- Evidence-based practice standard TIVAD protocol for malfunctioning TIVAD will be reviewed (August 2018). Questions answered.
- The Director, IT representative, and appropriate organizational administrators will authorize, input, and revise additional documentation for TIVAD in EHR to include standardized protocol to be implemented (September 2018).
- Authorization for oncology RNs to proceed with care stated in the implemented TIVAD protocol. The Director and oncology attendings to draft standing order for authorization of alteplase with appropriate protocol performance (September 2018).
- Implementation of TIVAD protocol should ensure when an oncology RN contacts IR for a malfunctioning TIVAD or an attending oncologist with a concern, it is assured that the RN has assessed and completed all steps in the TIVAD protocol, November 2018 (please see Appendix B).

Please note: *The Implement and Track portions of the MAP-IT worksheet will be completed during the NDNP 811 DNP Project Proposal course with MAP components complimentary or synergistic with the Logic Model.*

Implement: *WHAT strategies and tactics were used? WHEN were the desired changes made?*
Step 1: Perform small tests of change
Step 2: Full-scale implementation
Track: *WHAT structures and processes (practices) were changed based on the metrics we used to measure progress (including frequency of assessment)? HOW did these changes affect outcomes? WHAT do we need to do differently to make greater progress toward improving outcomes?*

Date: _____ Re-Assessment Date 1: _____ Re-Assessment Date 2:_____, etc.

Plan Developed by (List all contributors): Cristina Mullenix, BSN, RN; Lynn Graze, RN, MSN, OCN; Gina Rowe, PhD, DNP, MPH, FNP-BC, PHCNS-BC, CNE

Reference: Guidry, M., Vischi, T., Han, R., & Passons, O. MAP-IT: a guide to using healthy people 2020 in your community. U.S. Department of Health and Human Services. The Office of Disease Prevention and Health Promotion, Washington, D.C. https://www.healthypeople.gov/2020/tools-and-resources/Program-Planning

Appendix H:

Project Proposal Summary

Evidence-Based Protocol for Malfunctioning Totally Implanted Venous Access Devices (TIVADs)

Fundamental to infusing chemotherapy, all venous access lines (TIVADs, any central line, peripheral iv) must produce a brisk blood return before chemotherapy treatment may begin, each time, and every time. Occlusions in totally implanted vascular access devices (TIVAD) remain a common problem for cancer patients despite advances in their care, technology, and products (Ast & Ast, 2014; Baskin, Pui, Reiss, Wilimas & Metzger, 2009; Cummings-Winfield & Mushani-Kanji, 2008; Goossens, Stas & Moons, 2012; Stammers, Connolly, Brandão, Zupanec, & Gupta, 2017; Waagen & Bliss, 2003). Occlusions occur in 14-67% of central venous catheters, including TIVAD (Baskin, Pui, Reiss, Wilimas & Metzger, 2009; Waagen & Bliss, 2003).

A literature search was conducted to assess the scope of the problem. The organization identified a lack of standard practice in malfunctioning TIVADs. This is the catalyst for this quality improvement inquiry and the need to adapt knowledge to local context (Straus, Tetroe & Graham, 2013). In general, there are mechanisms that nurses use to manage care when a TIVAD is appropriately accessed but does not produce a blood return, and there is evidence in the literature regarding which of these mechanisms are likely to prove successful. However, the unit where this quality improvement project will take place has no standard for management of such care for when a TIVAD is appropriately accessed and does not produce a blood return. The question proposed is: In cancer patients experiencing a malfunctioning TIVAD, in comparison to the practices currently in place, what is the impact of an evidence-based protocol on the outcomes of time to receiving scheduled chemotherapy, costs, and consistency of care?

The purpose of this DNP project is to implement an evidence-based protocol for appropriately accessed TIVADs without blood return in an ambulatory outpatient oncology clinic within a community hospital setting. Implementation of a clinical protocol for appropriately accessed TIVAD will reduce variations in practice and optimize their use (Fernandez-de-Maya & Richart-Martinez, 2013). This will benefit patients and staff nurses by decreasing time to receiving scheduled chemotherapy, providing consistent care for malfunctioning TIVAD, and reducing cost. RNs may experience less stress, more satisfaction with standardized protocol, and have a clearly understood path of what to do when a TIVAD is malfunctioning.

The short-term goals of the DNP project include 75% of registered nurses (RNs) successfully completing clinic TIVAD competencies one month prior to protocol implementation; 50% of RNs will be able to follow the TIVAD protocol within 1 month before implementation; the evidence-based protocol is utilized in 60% of appropriately accessed TIVAD by RNs within 1 month of implementation; revisit questions and concerns of champions, RNs, and stakeholders on use of the TIVAD protocol. The long-term goal of the DNP project may result in successful implementation of evidence-based protocol for malfunctioning TIVAD October 2018 and 75% of RNs may utilize the protocol successfully.

Planning for implementation readiness of the QI project begins Summer 2018. This will include organizational approvals from Anne Arundel Medical Center (AAMC) Nurse Research Council and University of Maryland, Baltimore (UMB) Institutional Review Board (IRB).

After these approvals have been obtained the timeline of this QI project of an evidence-based protocol for appropriately accessed TIVAD without blood return will take place over a 14-week period, tentatively from 15 August 2018 to 30 November 2018.

Week 1: Multi disciplinary (multi-d) meeting of the DNP QI Project team: clinic director, Lynn Graze; APRN/DNP student, Cristina Mullenix; oncology charge nurse, Peggy; oncology nurse educator, Stephanie Smith; clinic staff nurse, Carol Brumstead; nurse practitioner; physician; and pharmacist. Updates provided to a member from the Standards of Practice committee, organizational information technology specialist (IT) and Interventional Radiology (IR). All team members are integral as individuals and will help facilitate the changes in structures and practices needed for implementation.

Weeks 2-5: In-service training for RNs on appropriate TIVAD access and competency. Annual TIVAD competencies for RNs will be appraised and will continue each year, proper TIVAD needle access and alteplase instillation. The oncology charge nurse (Peggy), oncology nurse educator (Stephanie Smith), clinic staff nurse (Carol Brumstead), and Clinic Director (Lynn Graze) will conduct competencies, in-service education, and training described (see Appendices A-D). Data collection will begin during this portion of the QI project.

Weeks 6-13 project implementation will occur, “go live!”. Data collection will continue during this time of the QI project.

Week 14 “wrap up”. Gaps in education, processes, questions, and solutions to be discussed and improved upon during meetings with RNs and multi-d team that conducted during this period, RNs will complete system usability scale (SUS).

Data collection includes TIVAD competencies (Appendix A), thrombolytic (alteplase) instillation competencies (Appendix C), EHR chart audits for monthly alpeplase use, proper use and documentation of TIVAD protocol (Appendix B), measurement of delayed chemotherapy treatment of more than 24 hours, and the SUS questionnaire (Appendix D).

Competencies of TIVAD and alteplase instillation will be conducted and documented in weeks two through five. Annual competencies are not current practice at this organization. The addition of this practice will be beneficial in revisiting proper and necessary TIVAD procedures for RNs. Documentation responsibilities are valuable for their own protection as well as appropriate patient care. Proper thrombolytic (alteplase) instillation competency and documentation will ensure that RNs are appropriately trained for use. Competencies will be conducted and documented. The oncology charge nurse (Peggy), oncology nurse educator (Stephanie Smith), and/or clinic staff nurse (Carol Brumstead) will conduct and document completed competencies in an electronic folder.

Current EHR documentation includes TIVAD assessment utilizing a drop down menu for TIVAD care. Additional adaptation tools may be required for EHR. This includes the implemented TIVAD protocol as a drop down menu in the EHR, modifying the one currently in place. Monthly audits and chart reviews will reveal several measures. These consist of how often are TIVADs malfunctioning, are RNs documenting use of and utilizing the TIVAD protocol when appropriate, is there a reduction of malfunction or treatment delay of more than 24 hours?

Knowledge use will be monitored with the use of EHR data and measurement assessments to include monthly/bimonthly audits. With the help of IT, the APN, RNs, and champions will document and track chart audits, obtain reports from IT, which will be shared and discussed with RNs, the multidisciplinary team, and with stakeholders at already established monthly staff meetings. This will occur after implementation of TIVAD protocol, weeks 10 and 14. The SUS will be administered to all oncology RNs weeks fourteen and fifteen. The SUS is a

10-item questionnaire, likert scale, created by John Brooke in 1986 is a reliable tool that measures usability.

TIVAD and alteplase instillation competencies will be measured with tracking audits making sure all oncology RNs have obtained and are current, percentage of total RNs (n=33). Descriptive analysis with SPSS will be used for study as well as measuring the mean, standard deviation, frequency, and percentage of completion. EHR reports from IT will include monthly alteplase use, proper use and documentation of TIVAD protocol, measurement of delayed chemotherapy treatment of more than 24 hours will be requested and pulled. Descriptive analysis with SPSS will be used for study in addition to mean, standard deviation, and frequency. The SUS conducted by RNs, administered and collected by the DNP project lead, will be measured using the mean, standard deviation, frequency, and percentage of usability Brooke, 1986).

Confidentiality and data security will be maintained through password protected computers and a locked file cabinet when necessary, minimizing risk. This QI project will be submitted for organizational approval from Anne Arundel Medical Center (AAMC) Nurse Research Council and University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) for a Non Human Subjects Research (NHSR) determination.