Effect of Heparin on Preventing Central Venous Catheter Occlusions in Adult Patients

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Abstract

Invasive intravenous catheters, commonly known as central venous catheters (CVCs), infuse life-saving medications and products to patients but require maintenance flushing solutions to preserve their functionality. The most commonly used maintenance flushing solutions are heparin and normal saline, but there is limited evidence-based research supporting the superiority of one flushing solution for occlusion prevention (Goossens, 2015). The problem is with over 5 million CVCs inserted yearly in the U.S. up to 35% fail because of occlusions. The retrospective three-month chart review of adult intensive care patient’s electronic health records (EHRs), conducted at a Midwest medical center, explored the effectiveness of flushing 6 milliliters of heparin concentrated with 10 units per milliliter every eight hours on CVC occlusion rates over the indwelling duration of the CVC. Iowa’s Model of Evidence-Based Practice to Promote Quality Care theory aligned with the study findings for integration of policy change and development of CVC flushing standardization in clinical practice. A Kolmogorov-Smirnov test, found no significant difference (p < 0.05) in (N = 47) heparinized flushing and CVC occlusion rates using a 95% confidence interval. The study concluded heparin is an effective flushing solution in preventing CVC occlusions in adult ICU patients. Incidental findings include 5 EHRs lacking documentation for CVC removal. Future study recommendations include comparing the effectiveness of heparin to normal saline flushes on occlusion prevention in short and long-term CVC use, and developing a quality improvement project addressing CVC occlusion and removal rationale documentation.

Keywords: central venous catheter, occlusion, heparin, normal saline
Central Venous Catheter Maintenance with Flushing Solutions

Caring for intensive care unit patients often requires maintaining central venous catheters (CVCs), an invasive intravenous catheter used to infuse life-saving medications and products. To maintain a CVCs functionality, routine flushing is required (Goossens, 2015). The primary CVC flushing solutions utilized in practice today include heparin and normal saline, but heparin is twice as expensive as normal saline and has the potential for significant bleeding complications (López-Briz et al., 2014; Sona et al., 2012).

With a failure rate around 35% of the 5 million CVCs inserted each year within the United States, a call to action in determining a cost-effective, yet safe flushing method for financial sustainability and conservation of scarce healthcare resources is needed (Kornbau et al., 2015; The Joint Commission, 2012). Evidence is lacking on which flushing solution is the most effective in preventing CVC occlusions which leads to variations in practice techniques and high failure rates. Therefore further research on this topic is necessary.

The purpose of this study determined how flushing central venous catheters with 6 milliliters of heparin concentrated with 10 units per milliliter every eight hours affects occlusion rates in adult intensive care unit (ICU) patients. The findings of the study add to the current body of knowledge through utilization of evidence-based research which support current practices within institutions, improves outcome consistency, reduces or complications, and conserves overall healthcare resources. The results apply to ICU settings and outpatient centers such as infusion centers, cancer treatment centers, and hemodialysis centers to deliver safe and cost-effective care.

Background
CVCs are a type of intravenous access devices inserted into large blood vessels by a physician or specially-trained professional. CVCs are indicated in acutely ill patients requiring long-term infusions, medications or products that can damage smaller vessels, or monitoring of hemodynamic status (Zhong et al., 2017). In addition, CVCs are life-saving tools, but do not come without risks. Potential complications from the insertion of CVCs include serious bleeding, collapsed lung, pulmonary embolism, and heart arrhythmias (Kornbau et al., 2015). Complications related to the maintenance of CVCs are bloodstream infections, catheter occlusions, accidental removal, and delays in medical treatment (Parás-Bravo et al., 2016). To prevent these complications and maintain the patency, either a continuous or intermittent flushing solution is used to clear the catheter of medications, blood, or microorganisms (Goossens, 2015).

The two most commonly used flushing solutions for CVC flushing maintenance are heparin, a blood thinning medication, or normal saline, a sodium chloride and water solution. Heparin was first implemented by the Cleveland Clinic in 1972 as an intermittent flushing solution to eliminate the need for intravenous infusions run by equipment that inhibited patient mobility (Stern, Pittman, Doershuk, & Matthews, 1972). Heparin is thought to be beneficial in breaking down existing blood clots or preventing blood clot formation within the first day of insertion, but has important safety considerations (Zhong et al., 2017). According to López-Briz et al. (2014), heparin can increase the risk for systemic bleeding, may cause a condition called heparin-induced thrombocytopenia (HIT) that significantly reduces platelet levels, can interact with other medications, and may worsen liver or kidney function. In addition, heparin costs on average over twice the amount of normal saline (Sona et al., 2012). Considering the potential
dangers and costs of heparin compared to normal saline, studying the effectiveness and safety of heparin is warranted to ensure patient safety and conserve healthcare resources.

Scope and Significance of CVC Occlusions

With over 35% of inserted CVCs becoming occluded (Kornbau et al., 2015), the scope of CVC occlusions impacts patients, nurses, physicians, and institutions alike. In 2009, there were close to 20,000 cases of catheter line-associated blood stream infections, which can be caused from an occlusion, and can cost the patient an additional $15,000 to repair or replace (The Joint Commission, 2012). Insurance companies are now refusing to reimburse hospitals for an entire patient’s hospitalization costs if they suffer a catheter-associated blood line infection (Moehring et al., 2013). These staggering statistics demonstrate the magnitude of preventing CVC occlusions and the application for nurses maintaining the function of the line, physicians ordering effective CVC flushing solutions, and institutions creating evidence-based protocols to guide maintenance and prevent CVC complications.

Although standardizing the flushing solution for CVCs seems like a small piece of the puzzle in improving healthcare outcomes, it supports the national goals of Healthy People 2020. One of Healthy People 2020 goals in long term reduction of overall healthcare spending, is to ensure patients do not experience delays in care resulting in life-threatening complications, and conserves hospital resources that are being used to troubleshoot or replace CVCs (Kornbau et al., 2015; U.S. Department of Health and Human Services, 2018). Implementing small preventive measures locally through evidence-guided protocols contributes to keeping national and global healthcare affordable in the climate of overspending and overusing scarce resources.

The Institute of Medicine (2010) emphasizes the need for continuous healthcare improvement through policies and practices grounded in evidence and increased collaborative
practices among interdisciplinary team members in research and policy formation. In addition, the Quality and Safety Education for Nurses Institute [QSEN] (n.d.) identifies evidence-based practice as one of the main competencies for nurses because it empowers them to understand the reasoning behind their interventions and increases patient safety and outcomes (Melnyk, Gallagher-Ford, Long, & Fineout-Overholt, 2014). Including nurses and interdisciplinary team members in policy formation and research studies such as a standardized CVC care protocol, allows for multiple viewpoint considerations, creates open dialogue between professions, and engages healthcare workers to be active participants in improving care. If nurses are encouraged to engage in local policy development, nurses will be more likely to participate at the state, national, and global level as well. For this research study, incorporating nurses in policy development is beneficial to creating a protocol that is uniquely tailored to the institution’s capabilities, engages nurses to practice according to evidence versus tradition, and promotes a feeling of ownership and responsibility to carry out the protocol correctly.

**Research Purpose**

The purpose of this study was to determine the effectiveness of heparinized flushing, a common standardized practice in many institutional policies, how flushing central venous catheters with 6 milliliters of heparin every eight hours in adult intensive care unit patients affects central venous catheter occlusion rates over the indwelling duration of the catheter.

According to Macias, Loveless, Jackson, and Suresh (2017), when studies provide understandable evidence with similarly supporting studies, it promotes consistent, high quality patient care. To provide a higher quality of care, there needs to be a consensus regarding the standardized approach to caring for CVCs. The study supports advancing the current knowledge of the most effective flushing solution, including the concentration and frequency of the flush in
preventing CVC occlusions in adult hospitalized patients based on evidence-based research. Evidence-based standardized CVC care with an effective flushing mechanism is necessary for consistent and safe health care delivery.

The research question based on the Population, Intervention, Comparison, Outcome and Time abbreviated as PICOT is: (P) for adult intensive care unit patients, (I) how does heparinized flushing of the central venous catheter with 6 milliliters of heparin every eight hours, (O) effect central venous catheter occlusion rates (T) over the indwelling duration of the catheter?

**Review of Literature**

**Introduction**

The databases utilized in the review of literature included CINAHL Complete, MEDLINE, DynaMed Plus, and PubMed from years 2000 to 2018. The keywords searched were central venous catheter, CVC, CVAD, heparin, normal saline, sodium chloride, flush, occlusion, maintenance, versus, and patency in varying combinations together and separately. For all databases, inclusion criteria included full text articles, articles published from 2000 and beyond, and articles that studied CVCs. Due to the limited amount of available literature, studies with children were included in the search criteria. Research articles that were excluded were articles not available in full text, articles published before year 2000, and articles that studied other types of intravenous devices other than CVCs. CINAHL Complete generated 67 articles, PubMed generated 160 articles, and MEDLINE generated 124 articles. Articles excluded from further consideration were those that compared flushing solutions other than heparin and normal saline and those studying flushing solutions for purposes other than intermittent flushing and maintaining the patency of CVCs. Literature was also found through secondary sources. In addition, recommendations for CVC maintenance from the Infusion Nurses Society, Centers for
Disease Control and Prevention, The Joint Commission, and the American Society of Clinical Oncology were reviewed and included.

Although studies compare heparin to normal saline for the prevention of CVC occlusions, no studies have found statistically significant results for recommending one solution over the other. Due to the differences in researched flush concentrations, frequencies, type of catheter, and conceptual definitions, researchers are unable to draw a conclusion on the efficacy of heparin versus normal saline in preventing CVC occlusions. In addition, there is a lack of literature available on adult, hospitalized patients with CVCs, which is the target population of this study.

**Current Recommendations and Practice**

When developing flushing policies, institutions gather recommendations from national organizations and accrediting bodies who perform and continuously review evidence-based research. The Infusion Nurses Society recommends flushing CVCs with either heparin concentrated 10 units per milliliter or normal saline to prevent occlusion (Gorski, 2017). However, no guidelines for a specific flushing solution, frequency, or amount of flush are provided based on lack of supporting evidence. The CDC recommend not using prophylactic anticoagulation, such as heparin, for the prevention of catheter-line infections, however the CDC does not specifically provide recommendations for the prevention of CVC occlusions, intermittent flushing, the flushing solution, or frequency in maintaining CVCs (O’Grady et al., 2011). The Joint Commission (2009) recommends flushing CVCs with normal saline every eight hours while not in use and before and after medication administration. Heparin concentrated 10 units per milliliter may be used only when ordered by a physician, flushing each port with 6 milliliters, every eight hours, after medication administration, and followed by a
normal saline flush (The Joint Commission, 2009). The American Society of Clinical Oncology recommends flushing CVCs with normal saline over heparin in patients with cancer based on the lack of evidence that heparin is superior (Schiffer et al., 2013). For cancer patients, neither the National Comprehensive Cancer Network, International Society of Thrombosis and Haemostasis Scientific and Standardization Committee, American College of Chest Physicians, European Society for Medical Oncology, nor International Initiative on Thrombosis and Cancer recommend using anticoagulant flushing solutions for prevention of CVC occlusions (Gross & Gordon, 2017). Depending on where institutions look for recommendations, inconsistent guidelines in conjunction with limited significant studies explain current variations in policy development and flushing methods.

To demonstrate the wide variations of current practice, Sona et al. (2012) conducted a national survey among critical care nurses in the United States and found over 70% of the 632 participants currently use normal saline for intermittent CVC flushing to prevent occlusion. Within that survey, the researchers found a wide variation of flushing solutions, concentrations, and volumes used, ranging from 10 to 1000 units per milliliter for heparin and 10 to 20 milliliters of normal saline. In addition, the frequency of flushing ranged from every eight hours, once daily, or only after accessing the catheter (Sona et al., 2012).

**Heparin versus Normal Saline Flushing**

Findings thus far suggest that neither heparin nor normal saline are superior over each other in preventing CVC occlusions. A systematic review of ten randomized-controlled trials of 7875 adults with central venous catheters found no significant differences between heparin in concentrations between 10 to 5000 units per milliliter and normal saline on occlusion rates in any of the studies (Trow, 2018). In a randomized-controlled trial of 341 intensive care adult patients
with a CVC, heparin and normal saline were used as intermittent flushing solutions every eight hours with no significant differences in catheter line occlusion rates (Schallom, Prentice, Sona, Micek, & Skrupky, 2012). A similar, double-blinded randomized controlled trial of 84 adult intensive care patients comparing intermittent flushing with heparin and normal saline found no statistical differences among the two solutions and recommended using normal saline based on cost and safety considerations (Heidari Gorji et al., 2015). A smaller randomized-controlled pilot study of only 30 participants also found no significant difference among occlusion rates or rate of repair using heparin versus normal saline in bone marrow transplant patients (Klein, Jepsen, Patterson, Reich, & Mason, 2018). Finally, a quasi-experimental retrospective study examined the rate of repairing CVC occlusions in 300 adult intensive care patients and found no occlusion rate difference between the heparin or normal saline groups, suggesting the use of normal saline over heparin for improved patient safety (Cates, Johnson, & Cooney, 2017). These studies were among the few available studying comparable variables in adult ICU patients with CVCs.

Additional studies analyzing different study population demographics and types of catheters such as children and peripheral intravenous catheters found similar results to the studies discussed above. Heparin was associated with slightly lower occlusion rates in children with CVCs, although results were not statistically significant (de Neef, Heijboer, van Woensel, & de Haan, 2002). In a study comparing flushing 3 milliliters of heparin concentrated 100 units per milliliter and 10 milliliters of normal saline in peripherally inserted central catheters, there were fewer occlusions in the heparin group, but again not statistically significant to recommend the use over normal saline (Bowers, Speroni, Jones, & Atherton, 2008). Findings thus far comparing
heparin to normal saline have failed to prove superiority of one over the other, therefore many recommendations prefer normal saline based the lower cost and safety profile benefits.

**Gaps of Knowledge**

One study found heparin superior to normal saline in preventing CVC occlusions, however, the concentration utilized was 5000 units per milliliter, a dose much higher than other studies, limiting comparability due to variable measurement inconsistencies (Rabe et al., 2002). To confirm these differences, a meta-analysis performed by Goossens (2015) found that heparin concentrations varied from “2.5 U/ml to 100 U/ml,” an amount too variable for clinical significance (pp. 6). In another meta-analysis by López-Briz et al. (2014), the heparin concentrations within the studies varied by up to 4500 U/ml. Studying heparin at higher doses is likely to produce fewer occlusions based on the anticoagulant properties of the drug. To make a statistically significant conclusion for clinical practice, the same or similar concentrations of flushes needs to be studied.

Other gaps in current literature include the differences between study objectives, methods, and conceptual definitions. For example, one study failed to discuss flushing frequency methods and based their outcomes on total CVC occlusion rates over a 21-day period (Heidari Gorji et al., 2015). Another study compared heparin versus normal saline effectiveness based on the retrospective rate of repairing CVC occlusions (Cates et al., 2017). Although one study found normal saline as effective as heparin in maintaining the patency of peripheral intravenous catheters, CVCs are not an equally comparable type of catheter to apply study results for flushing maintenance (Choudhary, Patidar, & Bindu, 2015).

Conceptual definitions of how studies defined a catheter occlusion were noted. Schallom et al. (2012) defined occlusion if nurses were unable to instill the flushing solution after several
attempts. Rabe et al. (2002) on the other hand described a catheter as occluded if there was an inability to withdraw blood prior to flushing.

Although the inconsistencies among study methodologies create inconclusive support for one flushing solution over another, it can be beneficial. If institutions cannot afford to change current practices by implementing heparin flushes, or vice versa, do not have enough support to discontinue heparin flushes, the current evidence does not indicate patients are at risk for immediate harm or require an immediate change in practice. However, because heparin has significant associated bleeding risks, it is beneficial for institutions considering standardizing flushing practices using normal saline over heparin for CVC occlusion prevention. This is an example of the benefits of nurses reviewing evidence-based research to propose policy changes when potential patient danger exists or more efficient methods can be developed.

Consequences of CVC Occlusion

The consequences of CVC occlusions impact patients, nurses, physicians, institutions, and healthcare as a whole. For patients, the most dangerous consequences include delays in patient care, increased risk for infection, deep vein thrombosis, invasive procedures to repair occlusions, and even patient death (Kornbau et al., 2015). Potential consequences from using heparinized flushes include risks of bleeding, heparin-induced thrombocytopenia at a rate of up to 30% in heparin-flushed CVCs, drug interactions with potential anaphylactic shock, increased healthcare costs, and worsening of underlying medical conditions from prolonged bleeding times (Heidari Gorji et al., 2015; López-Briz et al., 2014). If an occlusion prevents a medication or blood product from being administered promptly, an unstable patient could potentially die. In the event an occlusion cannot be repaired, the patient may need an entirely new CVC which
increases the risk for infection, adds an additional cost to the patient and institution, and requires the hospital to utilize resources that could have otherwise been saved.

Resulting consequences from inconclusive research to demonstrate the efficacy of heparin flushes over normal saline are variations in practice protocols which can confuse caregivers who work in multiple healthcare settings, reliance on physician preferences versus evidence-based research, and inconsistent patient outcomes (Mathers, 2011). Consequences of CVC occlusions are immediate, impacting the affected patient and local institution, and long-term and widespread if they continue to occur to create nationwide financial burdens as resources are cumulatively depleted. If a standardized approach to maintaining CVCs is not established through clearly researched evidence, responsibility is left into the hands of institutions to determine what is the most safe and cost-effective strategy, risking inconsistent patient outcomes.

Proposed Solutions

One proposed solution is a chart review in an institution that utilizes heparinized flushing and compare the rate of CVC occlusions to institutions that utilize normal saline to determine if a change in practice would be beneficial. The chart review will analyze the type of flushing solution administered, the frequency of flushing administration, rate of occlusion, and rationale for CVC failure. After reviewing the results of the study, evidence-based research, and determining the significance in comparison to protocols that implement normal saline, the results will be presented in a collaborative manner to the medical director of the ICU and the Nursing Evidence-Based Practice and Research Council to validate current practice or assist in developing practice improvement strategies. Collaboration is defined as working together and
working as a team for one sole purpose. Evidence-based practice is defined as using statistically significant research to support implementing an intervention in the clinical setting.

**Theoretical Framework**

The underlying literature review framework is based upon the Iowa Model of Evidence-Based Practice to Promote Quality Care (Titler et al., 2001). This model, created in 1994 by Titler and colleagues for the University of Iowa Hospitals and Clinics, encourages nurses to implement evidence-based research into practice (Titler et al., 2001). In 2001, the model name and primary focus were revised to emphasize evidence-based practice, rather than just research, and identified financial sustainability as a priority when implementing practice changes (Titler et al., 2001). The main concepts from this model integrate evidence-based research into practice, identifying current clinical problems that prompt improvement, and collaborating between interdisciplinary team members to improve the efficiency of healthcare delivery (Titler et al., 2001). The Iowa Model for Evidence-Based Practice supports forming a team, after a known problem is identified, to identify a solution that is effective across the entire interdisciplinary team (Keele, 2011). The Iowa Model also provides a step-by-step process of how to implement evidence-based practice to ensure it is successful and not negatively impacting an organization (Keele, 2011).

Evidence-based practice is defined by Titler et al. (2001) as “the conscientious and judicious use of current best evidence to guide health care decisions” (pp. 502). Evidence-based practice relates to the core purpose of the research study because there is a current lack of evidence to promote a nationwide change in practice. Because there is an identified problem, the first required step of the underlying framework, utilizing the Iowa Model guides integrating the study results into clinical practice for policy change and development of CVC flushing
standardization. According to Schiffer et al. (2013), policy change requires interdisciplinary collaboration to successfully carry out evidence-based practice. The underlying framework will support collaborative efforts during the research process and institutional implementation to promote quality and safe healthcare.

**Summary of Literature Review**

The review of literature highlighted current recommendations and practice methods for flushing CVCs. The current available literature on heparin and normal saline for the prevention of CVC occlusions were discussed addressing the limited support for one flushing solution over the other (Cates et al., 2017; Heidari Gorji et al., 2015; Schallom et al., 2012). Due to minimal available studies using comparable variables, studies with varying methodology including children and peripheral intravenous devices were reviewed (Bowers et al., 2008; deNeef et al., 2002). To demonstrate the need for further research, the gaps in knowledge were discussed noting differences among flushing concentrations, frequencies, catheters, and conceptual definitions (Cates et al., 2017; Choudhary et al., 2015; Goossens, 2015; Heidari Gorji et al., 2015; López-Briz et al., 2014; Rabe et al., 2002; Schallom et al., 2015). Consequences because of occlusions were discussed showing the overall impact and financial burden on patients, nurses, local and nationwide institutions (Heidari Gorji et al., 2015; Kornbau et al., 2015; López-Briz et al., 2014; Mathers, 2011). Finally, the proposed solution for the chart review using the Iowa Model of Evidence-Based Practice by Titler et al. (2001) demonstrates how evidence-based practice and collaboration will guide changing the current method of CVC flushing. After a thorough review of the current literature, it is evident that further research is necessary conclude whether heparin is a safe and effective flushing solution in preventing CVC occlusions and improve the quality and safety of healthcare.
Methodology

Design

This study is an exploratory retrospective chart review examining data collected in the past and obtained from medical records at Rapid City Regional Hospital. The researcher lacks complete control of the variables under study because these variables occurred in the past or attribute variables lack manipulation. The researcher cannot control operational definitions of variables or the reliability or completeness with which the data is collected. The researcher recognizes retrospective data represents an important source of information because many research questions can only be answered using data collected in the past (Portney & Watkins, 2015).

Statistical Bias

This medical record retrospective review identifies patients admitted to the intensive care with a CVC line inserted within the facility. To avoid statistical bias, the retrospective data collection started with patients who met the inclusion criteria starting November 1, 2018 through January 30, 2019. There were no exceptions for those included or excluded in the study based on the outlined study criteria.

Study Procedures, Collection Tool, & Statistical Analysis

The co-investigator (CI) reviewed charts in a private room in the hospital and had access to the medical records based on facility protocol. The CI was provided the medical record numbers and access to the electronic records of the patients admitted to the intensive care unit with a central venous line catheter inserted while at the facility. Utilizing the master list (Appendix G), the researcher assigned each medical record number meeting the study criteria a research code based on the consecutive order the medical record was reviewed. This avoided
duplication of data and allowed for organizing the data for analysis. The researcher recorded data from the medical record review within the Data Collection Tool (Appendix H). Data obtained from the retrospective chart review was categorized within an Excel spreadsheet, organized, and statistically analyzed using the Statistical Package for the Social Sciences (SPSS) software. The findings generated information pertaining to the research question and potentially added to the body of knowledge of CVC treatment for the designated population.

**Study Duration**

The timeline for the study began upon IRB approval (Appendix D) and examined all patient charts that met the inclusion criteria over a 3-month period starting September 1, 2018 through November 30, 2018, or until 60 patients are identified. The co-investigator expected to identify with the chart review, a potential study population of 60 patients with a central venous line, and heparin flush. As a pilot graduate student project, it was unknown the number of central venous line patients who are treated with heparin that will be needed to provide the appropriate sample numbers needed for data collection and analysis.

**Study Participants Inclusion and Exclusion Criteria**

The CI expected to identify with the data collection a potential study population of 60 subjects. However, it was unknown because the researcher did not have access to the number of patients admitted over time, and the number of patients who met the inclusion criteria. The study population and characteristics included patients older than 18 years of age admitted to the intensive care unit at Rapid City Regional Hospital with a central venous catheter. The sample inclusion criteria for the data collection over a 3-month period included patients between the ages of 18 and 99 years of age, patients admitted to the adult intensive care unit, patients who have a documented central venous catheter inserted within the facility, and no allergy to Heparin.
(Schallom et al., 2012). Sample exclusion criteria included patients younger than 18 years of age, or older than 99 years of age, patients not admitted to the adult intensive care unit, patients who do not have a documented central venous catheter inserted within the facility; i.e. peripheral, or arterial, etc. catheter, and an allergy to Heparin (Schallom et al., 2012). There were no exclusions for race, ethnicity, gender, education, or socioeconomic status.

**Data and Safety Monitoring Plan**

To uphold confidentiality and patient privacy standards, a CITI certification has been completed by the CI (Appendix B). By following the procedures documented below, protection of confidentiality included: 1) the co-investigator had a password-protected file on a personal computer that only the researcher has access to for the research study data, 2) the co-investigator computed the data from the study and placed this within protected files on a personal computer; only the researchers had access to these files, 3) the researchers reported only aggregate data, and 4) any hard copy of research data was stored in the locked locker of the research investigator. Only the investigators had information of the master list of the study participants. The researcher’s removed all identifying information of the study participants; assigned research codes kept the patient’s medical record number and information from the study confidential. The researcher’s data collection occurred at a professional site (Rapid City Regional Hospital) in a designated private office identified by Angela Mills. To provide patient confidentiality, the researcher utilized a participation number instead of medical record numbers. The data analyst’s list of medical records meeting the inclusion/exclusion criteria was securely locked in the researcher’s locker on the unit.
Record Keeping and Data Disposition

The CI presented the findings of the study to the Rapid City Regional Hospital Director of Intensive Care Unit and Nursing Evidence-Based Practice and Research Council. The CI, in a paper and Prezi graduate nursing presentation at Clarkson College, shared the data results, also. Any data collected in writing was shredded per Rapid City Regional Hospital protocol. Disposal of the study data occurred within the designated timeframe, and by the institutional shredding methods in addition to permanent deletion of computerized files.

Results

The retrospective chart review was conducted on adult patients meeting the inclusion criteria in the intensive care unit at Rapid City Regional Hospital, totaling 52 patients. The study found that of the 52 patients, 47 CVCs were removed per provider’s orders without occlusion documentation. However, five patient’s lacked documentation of the reason for removal. The average length of CVC dwelling time was three days, with the maximum length, nine days, and the minimum, one day. Using a Kolmogorov-Smirnov test, there was no significant difference (p < 0.05) in heparin flushing of CVC lines on the rate of occlusion. A confidence interval of 95% was used.

Legal and Ethical Considerations

The potential legal and ethical risks include breach of confidentiality from patients causing mistrust, legal ramifications, and loss of confidence in care. There was also the risk that medical record documentation was lacking or did not meet the standard of care. The potential existed that a health care provider’s performance in relation to the study findings could be reflectively scrutinized if the results demonstrated the provider did not follow the standardized hospital flushing policy, resulting in catheter occlusions or patient harm. The overall study risk
was classified as minimal risk to the subjects as it did not involve any physical or psychological test and did not change the care of the patient with a central venous line catheter during their intensive care stay because the study occurred after their hospitalization was completed.

The researchers took the following steps of protection against these legal and ethical risks: 1) each researcher completed the CITI certification (Appendix B), 2) researchers kept all information confidential by entering data into password encrypted computer files, assigned study participant’s a research code using a master list, and removed all identifying information, 3) upon completion of the data collection, analysis, and study completion, collected data information was the property of Clarkson College and disposed within the designated time and by the institutional shredding methods, burning, and file deletion by the researchers, and 4) the researcher received IRB approval from both Clarkson College and Rapid City Regional Hospital before the study commenced (Appendices E and F). Researchers followed the recommended retention periods of the Clarkson College IRB and Rapid City Regional Hospital IRB. The data was reported in aggregate format protecting the identity of the subjects and the health care provider. The researchers were nonjudgmental of health care provider documentation, treatment plans, and handled the collected health care data with respect.

**Discussion**

The results of the study demonstrated the use of heparinized flushes for CVCs is an effective method for prevention occlusion. However, this study did not support heparin as the safest or most cost-effective flushing solution available for preventing CVC occlusions. Considering in this study the average dwelling duration of CVCs was three days, the study findings did support heparin was effective in preventing CVC occlusions short-term. It is
unknown whether there is a significance difference in the rate of occlusions long-term using heparinized flushes.

The implications for further research include comparing heparin to other effective flushing solutions, such as normal saline, in both the short and long-term use for CVC occlusion prevention. There is also room for practice improvement in educating health care providers documenting the reason for removal of the CVC in order to gather accurate data on current occlusion rates.

**Conclusion**

The study found no significant differences difference between heparinized flushing and CVC occlusions, concluding heparin is an effective flushing solution to maintaining CVC patency. Currently, no studies provided a clear clinical recommendation for using heparin or normal saline to prevent CVC occlusions as discussed within the review of literature. This retrospective data collection validates the effectiveness of current heparinized flushing protocols in preventing CVC occlusions at Rapid City Regional Hospital. Performing this study promotes evidence-based practice, prioritizes patient safety, and promotes quality and efficient care that have both local and global impacts on policy development and healthcare sustainability.
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References


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Appendix A: Citi Certifications

This is to certify that:

Kassandra

Has completed the following Citi Program course:

Group 2: Biomedical Studies not classified as Clinical Trials Involving Drugs
Devices (UNO HPER)
Group 2: Biomedical Studies not classified as Clinical Trials Involving Drugs
Devices (UNO HPER)
1 - Basic

Under requirements set by:

University of Nebraska Medical Center

Verify at: www.citiprogram.org/verify/?w8211a747-3ab9-4c9d-b9f9-ccd2df66d6-2634287
**EFFECTS OF HEPARIN ON CATHETER OCCLUSIONS**

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**COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)**

**COMPLETION REPORT - PART 1 OF 2**

**COURSEWORK REQUIREMENTS**

*NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.*

- **Name:** Kasandra Wheeler (ID: 7028690)  
- **Institution Affiliation:** University of Nebraska Medical Center (UNMC/UNO) (ID: 417)  
- **Institution Email:** wheeler.kasandra@clarksoncollege.edu  
- **Institution Unit:** SICU  
- **Phone:** 6057552260

- **Curriculum Group:** Group 2: Biomedical Studies not classified as Clinical Trials Involving Drugs or Devices (UNO HPER)  
- **Course Learner Group:** Same as Curriculum Group  
- **Stage:** Stage 1 - Basic Course  
- **Description:** This course is designed for individuals involved in the conduct (i.e., listed on the IRB application) of biomedical studies that are not considered clinical trials. Examples may include research involving exercise science (UNO HPER), human biological material (HBM) research or banking, medical records and nutrition. This course is comprised of the institutionally required modules for Biomedical Human Subjects Research.

- **Record ID:** 26342879  
- **Completion Date:** 27-Feb-2018  
- **Expiration Date:** 26-Feb-2021  
- **Minimum Passing:** 75  
- **Reported Score:** 90

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### REQUIRED AND ELECTIVE MODULES ONLY

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<td>Records-Based Research (ID: 6)</td>
<td>27-Feb-2018</td>
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<td>Genetic Research in Human Populations (ID: 6)</td>
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<td>Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)</td>
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<td>Research Involving Children (ID: 9)</td>
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<td>Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)</td>
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For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?ucd9386b7-cc51-48e8-823f-261f66b795b-26342879](http://www.citiprogram.org/verify/?ucd9386b7-cc51-48e8-823f-261f66b795b-26342879)
Appendix B: Letter Requesting Site Approval

Angela Mills, ICU Nursing Director
Rapid City Regional Health
353 Fairmont Blvd
Rapid City, SD 57701
Re: Effectiveness of Heparin Flushing for Central Venous Catheter Occlusion Prevention

Dear Angela Mills,

I am a graduate nursing student at Clarkson College, finishing my master’s degree in family nurse practitioner. My graduate research project involves a chart review studying the occlusion rate of central venous catheters using heparinized flushing solutions in adult intensive care unit patients. The need to address this potential problem is important because central venous catheters cost up to $15,000 to replace or repair if occluded and occlusions can complicate patient care resulting in delayed medical care, infection, and even patient death. Currently, Rapid City Regional Hospital intensive care unit protocols endorse using heparin as the primary flushing solution to prevent occlusion. After completing a thorough review of literature, there is no evidence that supports the superiority of heparin over normal saline to prevent central venous catheter occlusions. I feel the analyzing the current rate of central venous occlusions using the current heparin flushing protocol can improve the current quality of current central venous catheter flushing protocols, reduce the risk of patient harm, and improve financial sustainability in the future.

This project will need approval by the Clarkson College Internal Review Board (IRB), which holds students to high ethical standards. My advisor, Dr. Jane Langemeier, is working with me throughout this endeavor to ensure quality and accuracy. My project involves a retrospective chart review of central venous occlusion rates in the intensive care unit to determine the average rate of catheter failures related to occlusions.

I am hopeful you will consider my request and grant me approval to facilitate this research project at Rapid City Regional Hospital intensive care units. I am looking to review 60 patient charts. The project will not report any patient-specific identifiers respecting the anonymity of electronic medical records. I will need a written approval from you for presentation to the Clarkson College Institutional Review Board [IRB]. I would be happy to visit with you further about this study anytime. Following conclusion of the project, I will share the results with you, the Clarkson College Graduate and Undergraduate faculty and staff along with my fellow students in the future.

Sincerely,

Kasandra P. Wheeler
919 Summerfield Dr.
Rapid City, SD 57703
605-553-4383/wheeler.kasandra@clarksoncollege.edu
Jane Langemeier, Ph.D., R.N.
Clarkson College
101 South 42nd Street
Omaha, NE 68131
Office Phone: 402-552-3193/langemeierjane@clarksoncollege.edu
Appendix C: Rapid City Regional Site Approval

Regional Health

October 1, 2018

Kassandra Wheeler
919 Summerfield Dr.
Rapid City, SD 57703

Dear Kasandra,

You have my approval to facilitate your research project at Rapid City Regional Hospital in the Adult Intensive Care Units and the review of 60 patient charts.

I look forward to reviewing the results of your research.

Sincerely,

Angela Mills
Director Adult Intensive Care Unit
Rapid City Regional Hospital
353 Fairmont Boulevard
Rapid City, SD 57701
December 3, 2018

Principal Investigator: Jane Langemeier, Ph.D., M.S.N., R.N.
Co-Investigator: Kasandra Wheeler, R.N., B.S.N.
Clarkson College

Dear Dr. Langemeier:

Clarkson College’s Institutional Review Board office has received and reviewed your application for exempt review of the quality improvement, evidence-based practice research study “Effect of Heparin on Preventing Central Venous Catheter Occlusions in Adult Patients.” The Clarkson College IRB office assigned #2018.11.04 to the exempted application.

Please add the words “This project has been exempted from full-board review by the Clarkson College Institutional Review Board as IRB #2018.11.04” (as applicable).

Best wishes on the successful completion of this study. If for some unforeseen reason the project extends beyond one year, you will need to complete additional paperwork to the IRB office.

Please feel free to contact us if you have any questions regarding the process or need any other assistance from Clarkson College’s IRB office in the future.

Sincerely,

Patricia Brennan, Ph.D.
IRB Chair
Clarkson College
Appendix E: Rapid City Regional Hospital IRB Approval

Regional Health


Designated IRB of Record: Regional Health Institutional Review Board (RH IRB) FWA # 00003696

Name of Institution Relying on the IRB of Record: (Institution) IRB Registration #: 000036909

The Officials signing below agree the RH IRB is the IRB of Record for review and continuing oversight of its human subject research described below. This agreement is limited to the following specific protocol(s):

Name of Research Project: Effects of Heparin on Central Venous Catheter Occlusions
Name of Principal Investigator (PI): Jane Langemeier, PhD, MSN, RN
Name of Student/Resident if not the PI: Kasandra Wheeler, RN
Sponsor or Funding Agency: N/A
Award Number, if any: N/A

RH IRB shall cooperate with the institution's reasonable requests to perform audits of the RH IRB operations (i.e. meeting minutes, protocols, ICF's, etc.) pertaining to this protocol or permit the institution to conduct such audits, provided that such audits will be at institution's expense. The institution will coordinate with the RH IRB to minimize disruption to the RH IRB's operations as a result of any such audit, and such audits will be performed during the RH IRB's normal working hours.

The review performed by the RH IRB will meet the human subject protection requirements of Office of Human Research Protection (OHRP). The RH IRB will report unanticipated adverse events involving participants to the institution's IRB. Relevant minutes of RH IRB meetings will be made available to the institution's signatory official upon request. The institution remains responsible for ensuring compliance with the terms of its own FWA. This document must be kept on file by both parties and provided to OHRP/Food and Drug Administration (FDA) upon request.

University IRB

By: Clarkson College
Print Full Name: Tony Damwood
Title: President

Date: 10/7/18

Rapid City Regional Hospital, Inc.

By: Nancy Klunder
Print Full Name: Nancy Klunder
Title: VP of CR

Date: 1/15/19

Version: 9/2016
Appendix F: Master List Documentation Form

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Appendix G: Data Collection Tool

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