# FACTORS ASSOCIATED WITH PHARMACEUTICAL VENOUS THROMBOEMBOLISM PROPHYLAXIS IN HOSPITALIZED SURGICAL PATIENTS

by

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#### **ABSTRACT**

Despite evidence that venous thromboembolism (VTE) is one of the most preventable causes of death, pharmaceutical prophylaxis is underused. It is unclear why such evidence-based risk assessment and treatment is often omitted or delayed. One unexamined factor is nursing's role in the administration of prophylaxis, and the nursing work environment. This study applied a theoretical framework of situational awareness, recognized by high reliability organizations (HROs) as a critical component in daily operations, to an important problem: VTE prophylaxis. This retrospective cohort study, utilizing data from the Michigan Surgical Quality Collaborative (MSQC), the electronic medical record, and the staffing system, aimed to examine environmental factors associated with 1) the administration of pharmaceutical VTE prophylaxis, 2) VTE occurrences, and 3) other postoperative occurrences. The sample included patients from a single institution in the MSQC database who were hospitalized for at least 24 hours and remained on the same unit (N=1,370). Correlations and logistic regressions were used to analyze the data. Nearly one-third of patients experienced an error. Significant predictors included VTE risk score, the difference between actual and budgeted RN hours per patient day (RN HPPD), census, workload, education, and unit type, all in expected directions. As the gap in RN HPPD decreased, patients were 12.4% more likely to receive prophylaxis. Patients were less likely to receive prophylaxis as nursing workload increased. The more baccalaureate-prepared nurses on the unit, the more likely patients

received prophylaxis; a 1% increase corresponded to a 4% decrease in patients not receiving necessary prophylaxis. Patients admitted to surgical units were four times more likely to receive the prophylaxis. Patients who received prophylaxis were less likely to have a VTE occurrence. This is the first study to examine the environmental factors of situational awareness and patient outcomes. Situational awareness is recognized as a contributing factor in HROs to manage and reduce risk. Future work is needed to extend this research and contribute to an understanding of how the nursing work environment impacts patient outcomes in a high reliability organization. The findings from this study have potential to extend our understanding of the complex work in nursing.

## **CHAPTER I**

# **INTRODUCTION**

#### **Statement of the Problem**

The need for hospitalized surgical patients to receive appropriate venous thromboembolism (VTE) prophylaxis is widely recognized, yet this critical therapy is often omitted or delayed (Joint Commission, 2010; Joint Commission, 2015). The estimated annual incidence of VTE occurrences is approximately 900,000, and almost two-thirds of these cases are associated with recent hospitalization (Geerts, 2008). Hospitalized patients with a high-risk of VTE may develop a deep vein thrombosis (DVT) and die from pulmonary embolism (PE) even before it is diagnosed (Joint Commission, 2015). The majority of fatal VTE-related events occur as sudden or abrupt death, which emphasizes the importance of prevention as the most critical action step in combatting this complication (Geerts, 2008).

Despite the evidence that VTE is one of the most preventable causes of death, effective strategies to reduce related morbidity and mortality, such as pharmaceutical and mechanical interventions, are often underused (Hacking, Hellewell, & Sadler, 2005; Joint Commission, 2010). A recent analysis, which evaluated prophylaxis rates in 17,084 surgery patients, found that more than one-third of patients at risk for VTE (38%) did not receive prophylaxis (Cohen, et al., 2008). Simply put, while the risk factors for the development of VTE, such as surgery, are broadly acknowledged, appropriate

preemptive actions are not always implemented (Kwan, Daniels, Ryan, & Fields, 2015; McCaffrey & Blum, 2009).

Several regulatory agencies have made recommendations related to proper VTE prophylaxis. The Agency for Healthcare Research and Quality (AHRQ) defined VTE prophylaxis as the "number one patient safety practice" for hospitalized patients (Shojania, 2001). The National Quality Forum (NQF) (2006) recommends routine evaluation of hospitalized patients and appropriate prophylaxis for patients at risk for VTE. Furthermore, the Joint Commission and the Centers for Medicare & Medicaid Services (CMS) require hospitals to submit attestation of compliance with VTE prophylaxis as a Core Measure and subsequently fines hospitals that demonstrate poor performance (Joint Commission, 2015).

Evidenced-based guidelines and individualized risk assessment tools, have been published and implemented; still, no single strategy or set of strategies has markedly improved the delivery of patient-specific VTE prophylaxis (Caprini, 2005; Douketis et al., 2012; Gharaibeh, Albsoul-Younes, & Younes, 2015; Krell et al., 2015). One example of such tools is the Caprini risk assessment. Further defined later, the Caprini risk assessment uses several elements of the patient assessment to calculate risk and recommended treatment (Caprini, 2005). Nonetheless, a recent study (Krell et al., 2015) found that patients received similar postoperative prophylaxis regardless of VTE risk. Proper use of VTE prophylaxis requires a multidisciplinary collaborative approach to assess, develop, initiate and implement tailored interventions (Hacking, Hellewell, & Sadler, 2005; Joint Commission, 2010). Nurses, although well positioned to administer interventions, are reliant on concerted functions of a multidisciplinary team, including

institutional policies, VTE risk assessment, physician orders, and pharmaceutical support, within the larger care delivery system to prevent and diagnose VTE.

Possible explanations for the disparity between recommended and administered prophylaxis can be explored in the context of situational awareness. Organizations with a strong safety record recognize the concept of situational awareness as a critical component in daily operations (Frankel, Leonard, & Denham, 2006; Weick & Sutcliffe, 2001). These high reliability organizations (HROs) (e.g., air traffic control, aviation, and nuclear power) are successful at operating in high risk conditions with few accidents (Frankel, Leonard, & Denham, 2006; Weick & Sutcliffe, 2001). In 2000, the Institute of Medicine (IOM) urged healthcare organizations to implement strategies adapted from HROs, yet a limited number of studies have attempted to measure and improve the critical component of situational awareness in healthcare environments (Fore & Sculli, 2013; Salmon & Stanton, 2013). Likewise, the academic literature has paid little attention to the use of situational awareness theory and principles in the design of healthcare systems (Riley, Endsley, Bolstad, & Cuevas, 2006).

Since the measurement of situational awareness can be elusive and problematic, stakeholders within healthcare organizations have not been keenly interested in using situational awareness as a key criterion for healthcare delivery and redesign (Salmon & Stanton, 2013). Despite these issues, situational awareness is a promising concept that has much to offer safety-related research in the delivery of clinical care (Salmon & Stanton, 2013). The body of literature on the topic has steadily expanded since the initial IOM recommendation (Figure 1), and the number of nursing studies that reference situational, or situation, awareness also continues to increase (Fore & Sculli, 2013).

Although the concept of situational awareness has primarily been studied within HROs, it is relevant to compare the operational environment of HROs to that of frontline nursing, which, like other safety-sensitive disciplines, includes multiple goals to be pursued simultaneously, multiple tasks competing for attention, performance under high stress, and negative, even catastrophic, consequences associated with poor performance.

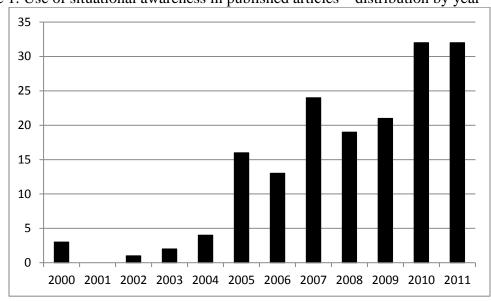


Figure 1. Use of situational awareness in published articles – distribution by year

Defined by Endsley (1995) as "the perception of the elements in the environment in a volume of time and space, the comprehension of their meaning and the projection of their status in the near future" (p. 36), situational awareness is a multidimensional concept that describes how individuals, teams, or systems interact to develop and maintain awareness (Endsley, 1995; Salas, Prince, Baker & Shrethra, 1995; Stanton et al., 2006). According to the literature, 'loss of situational awareness' or 'poor situational awareness' is a frequent cause of error in real time tasks and has been linked to poor performance (Carretta, Perry, & Ree, 1995; Endsley, 1995; Endsley & Robertson, 2000;

Durso, Truitt, Hackworth, & Crutchfield, 1997; Gugerty, 1997). Multiple studies from aircraft control, aircraft maintenance, aviation, and driving suggest relationships between situational awareness and human error, poor performance, and poor outcomes (Carretta et al., 1995; Durso et al., 1997; Endsley & Robertson, 2000; Gugerty, 1997). The concept of situational awareness can be used to examine complex factors of individual, team, and system components that impact the administration of VTE prophylaxis in hospitalized surgical patients. In this study, we explore venous thromboembolism (VTE) prophylaxis using a model of situational awareness in dynamic decision making (Endsley, 1995).

# **Research Questions & Aims**

We adapt a model of situational awareness to identify contextual factors associated with the administration of pharmaceutical VTE prophylaxis. This study utilizes secondary analysis of data from the Michigan Surgical Quality Collaborative (MSQC), patient-level data from the institution's electronic medical record, and unit-specific nursing data from an internal staffing database. The overall aim of this study is to improve the understanding of contextual factors, from the perspective of situational awareness, and the effect on the administration of VTE prophylaxis. Specific aims are addressed below.

**Aim 1**) Identify factors in a situational awareness model applied to VTE that are significantly associated with the administration of pharmaceutical VTE prophylaxis for:

- 1a) All patients
- 1b) Patients with a VTE risk assessment score of 0-2
- 1c) Patients with a VTE risk assessment score of 3 or greater

**Aim 2**) Examine factors in a situational awareness model applied to VTE that are significantly associated with:

- 2a) VTE
- 2b) DVT
- 2c) PE

**Aim 3**) Examine system factors and individual factors associated with other postoperative occurrences (i.e., Surgical Site Infection (SSI), Urinary Tract Infection (UTI), Return to the Emergency Department (ED), Readmission, and All-Cause Morbidity)

# **Significance of the Study**

The administration of pharmaceutical VTE prophylaxis is a critical nursing task that can have profound consequences for patients if not performed accurately, yet it is often completed in demanding environments that require an exceptional ability to multitask. Appropriate VTE prophylaxis for hospitalized surgical patients is frequently omitted or delayed, despite wide recognition of its importance. Possible explanations for this can be explored in the context of situational awareness. Specifically, in this study, we explore how the patient-specific VTE risk assessment score, system factors representing stress and workload (i.e., hours per patient day, census, workload, complexity), and unit-level individual factors (i.e., education and unit type) relate to the administration of pharmaceutical VTE prophylaxis, as well as patient outcomes.

No studies have utilized secondary data sources to examine key aspects of VTE prophylaxis administration and postoperative VTE occurrences using a model of situational awareness in dynamic decision-making. An analysis of this type is relevant, because the development and maintenance of situational awareness in the operational

environment is critical to decision-making in nursing practice, but has heretofore not been openly discussed and explored.

Nurses represent the largest component of the health care team and perform critical tasks like patient assessment and surveillance (Institute of Medicine, 2004). What they do or fail to do is directly related to patient outcomes (Doran, 2011). High levels of situational awareness are a vital precursor in the delivery of appropriate and effective nursing care to hospitalized patients (Fore & Sculli, 2013). For example, as nurses become aware of disjointed bits of clinical information, accurately combine relevant data elements to understand the true condition of the patient at that moment, and look ahead to gain a picture of the patient's projected future state, the groundwork for solid decision making exists. A natural corollary to this is that, as nurses move through the subconscious process of developing situational awareness (perception, comprehension and projection), failures in that process can lead to inaccurate or substandard clinical decisions. Vigilance and monitoring, also critical to decision making, require that attention, knowledge, and responsiveness (elements of situational awareness) are clearly identified, defined, and supported by the nurse (Institute of Medicine, 2004; Fore & Sculli, 2013). Like the operational environments of HROs, situational awareness in nursing practice is often threatened by mental load, task load, time pressure, distractions, fatigue, and the presence of automation (Wise et al., 2010; Fore & Sculli, 2013). For those who play the largest role in assessing, evaluating, and monitoring patients at the frontline, failure to identify and manage factors leading to poor situational awareness can result in errors (Sculli & Sine, 2011). Furthermore, it has been established that errors in the administration of VTE can lead to catastrophic outcomes for patients (Geerts, 2008;

Joint Commission, 2015). As nurses develop situational awareness and decide on treatment plans, this process can be derailed by multiple environmental and non-environmental factors. Understanding these factors offers insight into how best to manage nursing processes and the clinical environment to support optimal decision making. Exploring VTE prophylaxis administration with secondary data, using a model of situational awareness in decision making, is an indispensable and novel approach to examining this process.

## **CHAPTER II**

#### **REVIEW OF LITERATURE**

# **Venous Thromboembolism Prophylaxis**

Venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), is a leading cause of morbidity and mortality in hospitalized patients (Kahn et al., 2013). Numerous randomized, controlled trials show that using pharmaceutical VTE prophylaxis in hospitalized patients at risk for VTE is safe, effective, and cost efficient (Kahn et al., 2013). Despite this evidence, effective strategies to reduce morbidity and mortality associated with VTE, which require a multidisciplinary approach to assess, develop, and implement individualized interventions, are often underused or utilized inappropriately (Hacking, Hellewell, & Sadler, 2005; Joint Commission, 2010, Kahn et al., 2013). Studies suggest that, even when VTE prophylaxis is an automated part of all admission and transfer order sets, resulting in prescribers ordering prophylaxis for a majority of patients, nurses believe that it is ordered for patients not in need of therapy; therefore, they may not administer it (Elder et al., 2014).

Since nurses have such a prominent role in postoperative decision-making related to the administration of VTE prophylaxis, a physician order for VTE prophylaxis does not ensure consistent administration (Elder et al., 2014; Grier, 2014; Krell et al., 2015). Team-based multidisciplinary clinical decision-making, though often elusive in healthcare, is likely a better method for successful implementation of patient safety

initiatives related to VTE prophylaxis than a single intervention alone (Berenholtz & Pronovost, 2003).

According to guidelines, patients at risk for VTE occurrences should receive VTE prophylaxis using pharmaceutical or mechanical strategies, or both (Elpern, et al., 2013; Grier, 2014). Patients with orders for only mechanical prophylaxis, in the form of intermittent sequential compression devices (SCDs), may be receiving inadequate treatment due to the frequent misapplication of the therapy, such as when devices are not applied correctly, or not reapplied when only brief removal was intended (Elpern, et al., 2013; Grier, 2014). More specifically, mechanical prophylaxis was misapplied in 49% of observations and was entirely absent in 15% of cases (Elpern et al., 2013).

Because daily checklists to improve mechanical VTE prophylaxis are not likely to prevent misapplication of devices (Elpern et al., 2013), it is prudent to focus on pharmaceutical prophylaxis as a standard of care for hospitalized surgical patients (Elpern, et al., 2013; Grier, 2014). Unfortunately, the administration of pharmaceutical prophylaxis is also substandard. In a recent study of hospitalized patients, Pleet and Colleagues (2014) found that fewer than 40% of patients had an adequate pharmacological order for VTE prophylaxis within 24 hours of hospital admission. Furthermore, even when adequate VTE prophylaxis was ordered, only 30% of patients received >80% of the prescribed dose (Pleet, Vaughn, Morris, Moss, & Cheifetz, 2014).

The purpose of this review is to identify variables that impact the administration of pharmaceutical VTE prophylaxis in hospitalized adult patients after surgery. PubMed and CINAHL were searched using the following: "venous thromboembolism" AND "Prophylaxis" AND "Nursing" AND Publication Date 2013 – Present [August 22, 2015].

The chosen date range ensured inclusion and review of pertinent articles published after the 2013 comprehensive Cochrane Review on this topic (Kahn et al., 2013). Studies outside of the hospital setting, involving only mechanical prophylaxis, or conducted with pediatric patients, were excluded. The initial search yielded 35 studies in PubMed and 8 in CINAHL. After review (to identify variables that impact administration of VTE prophylaxis), application of the exclusion criteria (i.e., outpatient, mechanical prophylaxis only, or pediatric patients), and removal of duplicates, 11 articles were fully reviewed, including the aforementioned Cochrane Review found during initial search efforts (Table 1).

Table 1. Variables that impact the administration of pharmaceutical VTE prophylaxis: a review of the literature

Study	Туре	Conclusion(s)	Main Concepts that Impact VTE Administration
Adams, A. (2015)	Concept Analysis	Defining attributes of proactivity in VTE prevention include: personal initiative, taking charge, and feedback-seeking behavior; Antecedents are: autonomy, leadership, knowledge, education, training, responsibility, accountability, role-based self-efficacy, ethics, and duty of care.	Goals & Objectives
Baillie, C.A., Guevara, J.P., Boston, R.C.,	Quasi-Experimental	Implementation of a multifaceted intervention resulted in an immediate and sustained decrease in the proportion of missed	Communication
Hecht, T.E. (2015)		and refused doses of pharmacological thromboprophylaxis.  The main components of this intervention were: (1) a three-	Feedback
		step algorithm developed to standardize nurses' response to patient refusal of pharmacological thromboprophylaxis, (2) the integration of daily assessment of VTE prophylaxis into a multidisciplinary rounds checklist on the three medical units studied, and (3) provision of regular audit and feedback of unit performance.	Standardization
Elder, S., Hobson, D.B., Rand, C.S.,	Mixed Methods	Nurses on units with low administration rates often believe they have the skills to determine which patients require	Preconceptions
Streiff, M.B., Haut, E.R., Efird, L.E., Shermock, K.M. (2014)		pharmacological venous thromboembolism prophylaxis. They are also more likely to believe that ordered doses are discretionary and to offer the medication to patients as optional.	State of the Environment
Gaston, S. & White, S. (2013)	Mixed Methods	Feedback revealed a general lack of knowledge of VTE and risk assessment recommendations for all adult admissions to hospital. Some participants reported being surprised at the statistics of VTE in people admitted to hospital or recently discharged. Some of the medical ward nursing staff assumed that VTE risk assessment was an area of concern only for surgical ward admissions and therefore not part of their role.	Knowledge / Education

Gharaibeh, L., Albsoul-Younes, A., Younes, N. (2015)	Observational, cross- sectional study	Reminders of VTE risk assessment are important, because VTE may be missed or overlooked in acutely ill patients owing to the presence of more urgent medical conditions. Even when the VTE risk is assessed, when it is not estimated correctly, it places the patient at risk of VTE, because VTE risk assessment depends on careful detection of risk factors and meticulous investigation of the patient's medical history so as not to miss any risk factor.	Reminders
Grier, M.A. (2014)	Article	The ability to communicate accurate information regarding the purpose of VTE prophylaxis to patients provides rationale for nurses to build knowledge of pathophysiology and prevention methods. The key to both successful implementation of nursing interventions and patient adherence to recommendations is adequate education. Patients and their families are far more likely to adhere to prescribed therapy if they understand the rationale for it.	Communication  Knowledge / Education
Kahn, S.R., Morrison, D.R., Cohen, J.M., Emed, J., Tagalakis, V, Roussin, A, & Geerts, W. (2013)	Cochrane Review	Education and alerts were associated with increases in the prescription of appropriate prophylaxis, and multifaceted interventions were associated with increases in the prescription of any prophylaxis and appropriate prophylaxis. Multifaceted interventions had the largest effect. It was also shown that multifaceted interventions that included an alert may be more effective at improving rates of prophylaxis than those without an alert.	Feedback  Knowledge / Education  Reminders
Kwan, S., Daniels, M., Ryan, L., & Fields, W. (2015)	Quality Improvement	The reason for nursing noncompliance with VTE prophylaxis was found to be multifaceted. First, the processes had not been adequately understood or adopted by the staff. Second, management expectations of nursing staff were not consistent. Third, there was no standardized method to identify process failures. The result was lack of improvement on performance.	Feedback  Knowledge / Education  Preconceptions  Standardization

Pleet, J.L., Vaughn, B.P., Morris, J.A., Moss, A.C., & Cheifetz, A.S. (2014)	Retrospective Review	Although, in most cases, the reason for not giving prophylaxis was not recorded by the nurse, the most common documented rationale was patient ambulation and patient refusal.	Preconceptions
Seki, J.T, Vather, T., Atenafu, E.G., Kukreti, V, & Krzyanowska, M.K. (2014)	Cross-Sectional	Development of guidelines and institutional policies coupled with educational in-services for physicians, nurses, and pharmacists, as well as engagement of the Cancer Quality Committee resulted in a significant VTE prophylaxis uptake rate.	Standardization
Vervacke, A., Lorent, S., & Motte, S. (2014)	Retrospective Review: Interrupted Time Series Study	Results suggest a large uncertainty in identifying patients requiring VTE prophylaxis in the clinical setting. Pharmacist-driven multi-targeted interventions were implemented and included efforts to communicate the rationale underlying the	Clinical Reminders  Communication
		guidelines, to involve clinical pharmacists going to the wards after each complete evaluation, and to provide medical staff and nurses with feedback and explicit practical recommendations, which were made available at the time of each anticoagulant prescription via an intranet application, pocket-cards and posters.	Education / Knowledge Standardization

Although a 2013 Cochrane Review (Kahn et al.) showed that multifaceted interventions were the most effective at improving rates of prophylaxis, the main concepts that impact VTE administration can be separated into several factors: 1) system interventions, 2) individual factors, and 3) the state of the environment. System factors included standardization, communication, and clinical reminders. Individual factors included goals / objectives, preconceptions, and knowledge / education. The third variable that impacts administration of VTE prophylaxis in hospitalized patients is the state of the environment; an example of this may be regular auditing or discussion of compliance rates.

# **System Interventions**

A number of task and system factors, including system capability, stress and workload, complexity, and automation, are postulated to influence decision making (Endsley, 1995). Errors of omission may be related to under-prescribing by physicians and inconsistent administration by the nursing staff (Pleet et al., 2013). It is unclear if risk factors are given an equal level of attention by nurses and physicians (Elder et al., 2014); this is likely related to the fact that risk assessments and the subsequent ordering of prophylaxis via standardized order sets are physician-centered tasks (Kahn et al., 2013). Standardized multidisciplinary interventions have been found to improve prophylaxis administration (Vervacke, Lorent, & Motte, 2014; Baille, Guevara, Boston, & Hecht, 2015). In the context of situational awareness, these interventions would support system capabilities and automation. Other interventions aimed at standardization include algorithms to regiment nurses' responses to patient refusal of pharmaceutical prophylaxis, and daily assessment of VTE prophylaxis during multidisciplinary rounds (Baillie et al., 2015). Standard processes, immediate correction of process failures

(feedback), and staff engagement are essential in improving administration rates (Kwan et al., 2015; Seki et al., 2014). In one study, pharmacist-driven interventions, including a multidisciplinary approach, educational tools, and visual displays of prophylaxis guidelines (i.e., posters, pocket guides, reminders) increased the proportion of patients receiving prophylaxis (Vervacke, Lorent, & Motte, 2014).

A standardized, multi-disciplinary approach is dependent on communication. Not only must the team exchange information verbally, but information exchange must also include the patient. The need to communicate accurate information regarding the purpose of VTE prophylaxis to patients provides a rationale for nurses to build knowledge of pathophysiology and prevention methods (Grier, 2014). Patients and their families are far more likely to adhere to prescribed therapy if they understand the rationale for it (Grier, 2014). A standardized, system approach to VTE education is warranted.

System capabilities that support nurses' cognitive workload have also been successful at improving prophylaxis administration rates. A 2015 study on hospital guidelines suggests the need for system interventions related to VTE risk assessment (Gharaibeh et al., 2015); however, despite a policy mandating a VTE risk assessment for each patient, a paper-based risk assessment was present in only 47.2% of assessed files, leaving many high-risk patients without proper VTE prophylaxis (Gharaibeh et al., 2015). The 2013 Cochrane Review showed that multifaceted interventions including an alert or clinical reminder may be more effective at improving rates of prophylaxis than those without the reminder (Kahn et al., 2013).

#### **Individual Factors**

Individual goals, objectives, preconceptions, knowledge, and education impact clinical decision-making and administration of VTE prophylaxis. A recent concept analysis published by Adams (2015) identified proactivity, which is comprised of personal initiative, taking charge, and feedback-seeking behavior, as a main contributor in VTE prevention. Since nurses have a pivotal role in VTE prevention, they must take charge to ensure patients receive the best possible clinical care (Adams, 2015). Increased vigilance by clinical personnel is also warranted (Adams, 2015; Elpern, Killeen, Patel, & Senecal, 2013).

Similarly, preconceptions play a role in the administration of VTE prophylaxis.

Studies suggest that the most common documented rationales for non-administration were patient refusal, accounting for nearly half of omitted doses, and omission by the nurse due to patient ambulation (Elder et al., 2014; Pleet et al., 2014). Additionally, during observations, Elder et al. (2014) found that some nurses presented pharmacological prophylaxis as an optional treatment, and the management of patient and nurse expectations are often unclear (Kwan et al., 2015). As mentioned above, system fixes and standardized guidelines are put in place to overcome barriers that originate in erroneous individual beliefs.

The key to successful implementation of any intervention comes from adequate identification and education of those responsible for assessing for and administrating VTE prophylaxis, not simply from systems-based initiatives (Grier, 2014). Nurses caring for patients at risk for VTE must be intimately familiar with the pathophysiology of VTE in order to prevent this complex hematologic process. Further, knowledge of

pharmacologic prevention methods and mechanical prophylaxis is essential to preventing VTE (Grier, 2014; Kwan et al., 2015).

Gaston & White (2014) discovered a general lack of knowledge of VTE and risk assessment among nurses. For example, nurses acknowledge that they use their clinical decision-making skills to determine when to omit unnecessary doses of prescribed VTE prophylaxis (Elder et al., 2014). Several studies suggest that nurse education improves VTE prophylaxis compliance (Gaston & White, 2013; Kahn et al., 2013; Seki, Vather, Atenafu, Kukreti, & Krzyzanowska, 2013; Vervacke, Lorent, & Motte, 2014). Educational sessions added to existing policy changes resulted in achievement of a 96.7% rate of VTE prophylaxis maintained for ten weeks (Seki, Vather, Atenafu, Kukreti, & Krzyzanowska, 2013). However, in another study, educational outreach, while deemed resource intensive, had no measureable impact on clinical practice (Duff, Walker, Omari, Middleton, & McInnes, 2013). These varied findings may support the recommendation of a multi-faceted approach that includes stronger system actions supported by education and training.

Evidence suggests that further education is needed (Elder et al., 2014; Seki et al., 2014). A multidisciplinary approach to patient care, including standardization and improvement of communication among providers, could optimize patient outcomes by increasing the appropriate ordering of VTE prophylaxis and compliance with administration standards (Elder et al., 2014; Vervacke, Lorent, & Motte, 2014).

#### State of the Environment

When considering the state of the environment, Elder et al. (2014) found that higher patient-to-nurse ratios were a contributing factor in omitting doses of VTE prophylaxis, even though, in a recent survey, nurses had denied that nursing workload

was a major reason for omission. Also of interest, although most nurses (83%) responded 'agree' or 'strongly agree' that they have adequate clinical judgment and experience to determine if administration is necessary, nurses on 'low performing' units were more likely to say that VTE prophylaxis is prescribed for patients who do not need it (Elder et al., 2014). Nurses on these 'low performing' units are also more likely to believe that pharmacological VTE prophylaxis is ordered even when not required (Elder et al., 2014). As mentioned above, combining initiatives can be fruitful: for example, in conjunction with other interventions, regular auditing and feedback on unit performance improved administration rates (Baillie et al., 2015; Kahn et al., 2013; Kwan et al., 2015; Seki et al., 2014). Concurrent review of process measures (e.g., using Core Measures), immediate feedback, and correction of process failures also improved compliance with VTE prophylaxis (Kwan et al., 2015).

# **Discussion**

Findings highlight a need for a better understanding of why rates of VTE prophylaxis remain relatively low (Pendergraft et al., 2013). Studies focusing on areas in need of attention are necessary to better understand why current guidelines for VTE prophylaxis prescription and administration are not followed (Duff et al., 2013; Elper et al., 2013; Pleet et al., 2014). Several studies suggest the importance of nurse education on the administration of VTE prophylaxis protocols. However, despite nurse knowledge of what to do, VTE prophylaxis is not always provided when needed. From a human factors perspective, education and training is but one part of an overall solution to this problem. More research is needed to understand why such interventions do not have a more pronounced effect on prescription and administration of VTE prophylaxis (Kahn et al., 2013).

Based on these findings, it is advisable to explore the association of system factors, individual factors, and the state of the environment related to pharmaceutical VTE prophylaxis in hospitalized surgical patients. Further research to examine VTE in hospitalized surgical patients, using a situational awareness context, may be accomplished with retrospective review of patient and unit-level data. Examination of this single condition, VTE in hospitalized surgical patients, in the context of situational awareness is also likely to improve understanding of barriers and successful interventions.

## **Theoretical Framework**

Endsley's (1995) model of situational awareness in dynamic decision-making (Figure 2) provides the theoretical framework for this study. Endley's model presents situational awareness in the state of the environment as a predominant concern leading to decision-making and explores the relationship between situational awareness and multiple system and individual factors. According to this model, a person's perception of the relevant elements in the environment, as determined from the system or direct senses, forms the foundation for the development of situational awareness in which comprehension and projection follow.

 System Capability
 Interface Design
 Stress & Workload Complexity
 Automation Task/System Factors Feedback SITUATION AWARENESS Perception Projection Of Future Status Comprehension State Of The Of Elements Of Current In Current Situation Situation Actions Level 1 Level 2 **Individual Factors** Information Processing Mechanisms · Goals & Objectives • Preconceptions (Expectations) Long Term Memory Stores Automaticity Abilities
 Experience
 Training

Figure 2. Model of situational awareness in dynamic decision making

Action selection and performance are shown as a separate stage that proceeds directly from situational awareness. Several major factors are presented to explain the process. Individuals vary in their ability to acquire situational awareness, given the same data input. Endsley (1995) explains that this is a function of an individual's information-processing mechanisms and is influenced by innate ability, experience, and training. Individuals may also have preconceptions and objectives that can act to filter and interpret the environment. System design, in terms of the degree to which the system provides the needed information, is also likely to be a contributing factor. Other features of the environment may include workload, stress, and complexity.

A previously published concept analysis (Fore & Sculli, 2013) identified the three defining attributes of situational awareness in nursing: 1) perception, 2) comprehension, and 3) projection. Although related to other terms in nursing (e.g., vigilance, cognitive task analysis, critical thinking, decision-making, clinical judgment), situational awareness, which may be a consolidation of the related terms, has made an impact on healthcare professionals (Singh et al. 2006). Vigilance, an antecedent to situational awareness, is necessary to achieve perception. Cognitive task analysis or critical thinking may be synonymous with comprehension. Other terms, such as decision making and clinical judgment, may relate to situational awareness, yet situational awareness is a precursor to decision-making and clinical judgment. Models similar to that of Endsley's (1995) do exist (Fore & Sculli, 2013). For example, Tanner (2006) presents a model of clinical judgement in nursing, in which the phenomenon is described as 'interpret – respond – reflect'. Wickens and colleagues (2004) describe the marvel as 'encoding – processing – responding'. No single term in the nursing literature is equivalent to the

term situational awareness as used in high reliability organizations (Fore & Sculli, 2013). However, defining and naming the phenomenon, as high reliability organizations have, is critical to moving forward (Fore & Sculli, 2013).

Similar to our literature review of the main concepts that impact VTE prophylaxis administration, the model of situational awareness can be described using three categories, all of which impact decision making and performance of action: 1) situational awareness in the state of the environment, 2) system factors, and 3) individual factors. The similarities in the categories suggests that the model of situational awareness is a good fit to explore factors that impact VTE prophylaxis in hospitalized surgical patients.

#### Situational Awareness in the State of the Environment

**Perception.** The first step in achieving situational awareness is to perceive the status, attributes, or elements in the environment (Endsley, 1995). In the context of this project, VTE risk factors are elements that may be captured during the admission assessment process and could be collected from the patient, provider, and/or electronic health record. These elements may catch a nurse's attention; however, at level-one situational awareness, no other processing occurs. System capabilities, such as documentation templates, may assist with this.

Comprehension. Comprehension of the situation is based on a synthesis of disjointed level-one elements (Endsley, 1995). Based on level-one elements, the decision maker forms a holistic picture of the environment – comprehension, or level-two situational awareness (Endsley, 1995). A nurse must comprehend that certain elements, when seen together, mean certain things; for example, an obese, preoperative patient with a history of DVT undergoing a colectomy is likely at a higher risk for VTE. The total

VTE risk assessment score (Caprini, 2005), a critical component for appropriate ordering and administration, may support this element of situational awareness.

**Projection.** Level-three situational awareness is demonstrated by the ability to project future actions (Endsley, 1995). Based on projections for the immediate future, decisions are made (Sculli & Sine 2011). Nurses need to forecast what is likely to happen next and plan accordingly. Using the VTE example, a nurse who perceives the need for VTE prophylaxis in a high risk patient with no orders would contact the physician and obtain an order.

## **System Factors**

System factors are the mutable components of a care delivery system (e.g., interventions) that have a direct impact on the degree or level of situational awareness that an individual or clinical team may possess. If these components are robust, specifically with regard to behaviors, it is probable that higher levels of situational awareness will prevail and improved clinical decision-making and patient outcomes will occur. If improvements in situational awareness and clinical decision-making are to be realized, the stewards of care delivery systems must target specific system elements. System factors may include resources (information and equipment), automation, staffing, and skill mix.

Our conceptual model focuses on stress, workload, and complexity. System capability, interface design, and automation were held constant in this study by selecting a timeframe when the system remained stable. Future work using this model could include testing changes in system capability, interface design, and automation after new software is launched.

#### **Individual Factors**

Individual factors that were testable included unit-level data on nurse education and unit type. Conflicting opinions on the impact of training and expertise related to situational awareness suggest the need for further study of the relationship of provider demographics. The role of experience and educational background related to situational awareness continues to be debated. Endsley (1995) suggests that a novice in an area may only have a vague idea of important system components and sketchy rules for determining the behaviour they should employ with the system. However, Durso and colleagues (1997) found that personal factors, including experience, accounted for virtually no variance in situational awareness. In addition, more recent (re)certification of air traffic controllers was associated with reduced severity of operational errors (Durso et al. 1997). As previously stated, nurses on lower performing units are more likely to believe that pharmacological VTE prophylaxis is often ordered but not required (Elder et al., 2014). Given the variance of these findings, the impact of educational degree and unit type are individual factors worthy of further exploration with respect to nursing practice.

#### **Performance of Actions: Prophylaxis Administration**

Situational awareness is the precursor to decision-making (Endsley, 1995). It is expected that poor performance will occur when situational awareness is incomplete or inaccurate, when the correct action for the situation is not known, or when time or other factors limit a person's ability to carry out the correct actions (Endsley, 1995). Therefore, poor situational awareness is a predictor of human errors, errors of omission, adverse events, and poor outcomes. The primary dependent variable in the operational model is the administration of pharmaceutical VTE prophylaxis.

#### **Patient Outcomes**

Patient-level outcomes will also be explored as secondary outcomes. Patient outcomes related to VTE prophylaxis include DVT and PE; however, other outcomes will also be explored in the context of the larger model. Specifically, we will examine surgical site infection (SSI), urinary tract infection (UTI), return to the emergency department (ED), and all-cause morbidity.

### **Case Studies**

Several cases are presented to further define the concept of situational awareness as it relates to pharmaceutical VTE prophylaxis in nursing. The model case is undoubtedly an instance of high situational awareness (perceptions, comprehensions, and projections match the true state). The borderline case shows an example that contains most attributes of the concept, but not all of them. Lastly, the contrary case is a clear example of low situational awareness (perceptions, comprehensions and projections do not match the true state) (Walker & Avant, 2011). Table 2 shows the attributes of situational awareness, using the cases below, within the context of this study.

Table 2. Situational Awareness Components Related to VTE Prophylaxis

Level 1: Perception	61 year-old
	Female
	Major Surgery
	Obesity
Level 2: Comprehension	Caprini VTE Risk Factor Score = 4
Level 3: Projection	Postoperative VTE prophylaxis orders include:
	Heparin injection 5,000 units three times a day
	Sequential Compression Devices (SCD)s
	Patient Out Time is 1543
Decisions / Actions	First dose of Heparin administered 2243
	Patient continues to receive Heparin as ordered
	SCDs are applied and remain in place when the patient is in bed

**Model.** A 61 year-old female is admitted for a total abdominal hysterectomy and bilateral salpingo-oophorectomy, umbilical herniorrhaphy, and right ureterolysis. The preoperative assessment is significant obesity and a documented Caprini score of 4. The patient tolerates the procedure well. Postoperative VTE prophylaxis orders include Heparin injection 5,000 units three times daily (TID) and mechanical VTE prophylaxis with Sequential Compression Devices (SCDs). The patient leaves the operating room at 1543 and is admitted to a surgical unit. The first dose of Heparin is administered at 2243. The patient continues to receive Heparin as ordered throughout the hospital stay and SCDs are applied and remain in place when the patient is in bed. The 30-day postoperative period was uneventful.

**Borderline.** A 46 year-old female patient is admitted to the hospital from home for a scheduled thyroidectomy and neck dissection. During the preoperative physical, the Caprini risk assessment score (Caprini, 2005) is evaluated as 6 (age 1, minor surgery 1,

COPD 1, malignancy 2, hormone replacement 1). The operation is completed as planned. The patient exits the operating room and is admitted to a medical-surgical unit at 1040. Heparin TID and SCDs are ordered for VTE prophylaxis. SCDs are initially documented as "on" in the post-anesthesia care unit; however, no documentation on the unit is noted. The patient refuses the first dose of Heparin stating she does not want a shot. The nurse is agreeable to patient objection knowing that the patient is ambulating often. On postoperative day one, after further education is provided, Heparin is administered as ordered at 2300, about 37 hours after surgery. The postoperative course is uneventful, and the patient returns to the office for a six-week postoperative appointment with no complaints or complications.

Contrary. A 38 year-old postpartum female presents to the emergency department with several days of epigastric and right upper quadrant abdominal pain that worsens after eating. Ultrasound reveals cholelithiasis with gallbladder wall thickening consistent with acute cholecystitis. Lab work is normal. The patient is taken to the operating room for laparoscopic cholecystectomy to treat acute calculous cholecystitis. Family history is significant for DVT and the Caprini risk score is 8 (minor surgery 1, obesity 1, history of DVT 3, laparoscopic surgery 1, oral contraceptives 1, postpartum 1). No pharmaceutical VTE prophylaxis is ordered. SCDs are ordered but not applied due to patient refusal. The immediate postoperative course is uneventful and the patient is discharged home on postoperative day one. On postoperative day three, the patient calls the surgeon's office complaining of sharp pains and numbness in her right calf. The office staff instructs the patient to follow up with her primary care physician if the pain does not subside. Two days later, on postoperative day five, the patient arrives at the ED

and is admitted with similar complaints. Upon further testing, the patient is diagnosed with "PE and DVT X 2" and is hospitalized for treatment with IV Heparin.

#### **Measurement and Data Collection Considerations**

The epistemology and metaphysics of time and space related to situational awareness raise several challenges. We do not perceive time and space through our senses; we do not see, hear, smell, touch, or taste time and space. We may, however, perceive the changes of elements in time. We perceive spatial distances between elements. We perceive that one element follows another. However, what we perceive, we perceive as present. For example, when we perceive one element occurring after another, B following A for example, we have perceived A; however A is merely an item in our memory (Stanford Encyclopedia, 2009).

Our temporal experience is limited in ways that our spatial experience is not. We can perceive objects in a variety of spatial relations to us: near, far, etc. Our temporal experience may be described as past, present, or future; however, we do not perceive the past as past; we perceive it as the present. Likewise, we do not perceive the future. When we measure the duration of an event or interval of time, it is in our memory; hence, past and future exists only in the mind. It is some feature of our memory of an element that allows us to form a belief about duration (Stanford Encyclopedia, 2009).

According to Endsley (1995), although situational awareness consists of knowledge (empirics) of the state of the environment at any point in time, the knowledge includes temporal aspects of the environment, relating to both the past and the future. In addition, situational awareness is highly spatial. Awareness of spatial and functional relationships among system components is required at all times (Endsley, 1995). The

way in which information is perceived is directed by the contents of both the working and long-term memory. Once perceived, information is stored in working memory where most of our active processing occurs (Endsley, 1995). Our working memory, though limited, is an essential component of time perception.

The gap between what is known and what really is remains. Our comprehension and projection is dependent on our ability to perceive elements within a volume of time and space. The challenge lies in making clinical judgments based on our perceptions, which may not represent the true state of things. In order to achieve level-two situational awareness (comprehension), new information must be combined with existing knowledge to compose a picture of the situation (Endsley, 1995). In addition, projection and subsequent decision-making also occur in the working memory (Endsley, 1995). Unfortunately, attention (often needed for perception) and working memory (used for comprehension and projection) are forced to compete with each other. In other words, if a nurse is assessing a patient, and perceiving elements which may not be within normal limits, the nurse would likely have a difficult time comprehending the concepts and projecting the next steps. Once the nurse begins comprehending or projecting, levels of attention and perception decrease.

Multiple measurement tools have been developed in an attempt to measure situational awareness outside of healthcare (Carretta et al., 1995; Endsley, 1995; O'Brien & O'Hare, 2007; Wright et al., 2004). Likewise, observation and survey instruments have been developed and used in healthcare to measure situational awareness as a component of crew resource management (Frankel et al., 2007; Guise et al., 2008; Malec et al., 2007, Morgan et al., 2011). Semi-structured, open-ended interviews have also been

used to assess situational awareness retrospectively in medicine (Singh et al., 2011). Additionally, the situational awareness global assessment technique (SAGAT), which includes the use of temporary freezes during simulation scenarios to collect situational awareness data, has been suggested as a valid tool (Endsley, 1995; Endsley & Robertson, 2000).

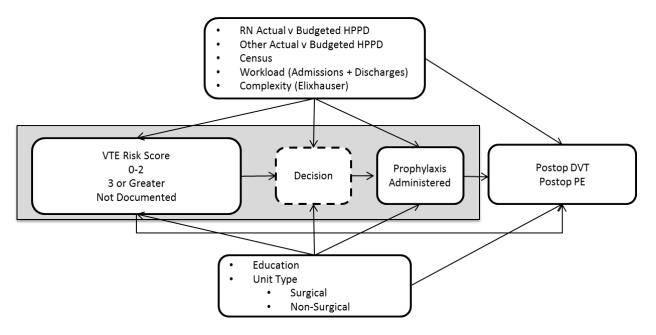
Despite the development of these instruments, measurement concerns persist, because capturing a specific moment in time in the mind's eye in retrospective fashion may not be possible. Furthermore, the theoretical aspect of retrospectively interviewing nurses has been questioned (Fore, 2012). As emphasized above, the perception of elements within a volume of space and time presents challenges for assessing situational awareness retrospectively. Humans tend to validate their decisions after they are made, thereby creating bias when reflecting on the actual awareness of the situation within the volume of space and time in question; in short, knowledge of the outcome can influence judgment of the situation (Caplan, Posner, & Cheney, 1991). Tools like the SAGAT may also pose concerns. High levels of situational awareness in a simulated scenario may not equate to high levels in other scenarios, both simulated and / or real. Additionally, the external pressures of the practice environment can affect situational awareness, meaning that high levels of situational awareness observed in simulated scenarios may not equate to high levels in clinical practice. Situational awareness is a moment time. It is likely inconsistent in practice and dependent on a multitude of variables. For this reason, strategies to support the development of situational awareness require support of the cognitive processes that precede it. In the practice environment, it is more feasible to assess and measure the strategies that support high levels of situational awareness rather

than situational awareness itself. This study uses retroactive review of the medical record, selecting key variables that demonstrate the various elements in the conceptual model of situational awareness in decision-making.

## **Conceptual Model**

The conceptual model (Figure 3) was developed to provide theoretical explanations for the relationship among factors of situational awareness in dynamic decision-making, administration of VTE prophylaxis, and patient outcomes.

Figure 3. Factors Associated with the Administration of Pharmaceutical VTE Prophylaxis



The proposed model, based on Endsley's (1995) theoretical framework of situational awareness in dynamic decision-making, and simplified to limit the relationships that could be feasibly tested in the scope of this study, aims to examine the factor(s) that influence(s) the performance of actions, in this case VTE prophylaxis administration.

#### **CHAPTER III**

#### **METHODS**

The methods presented below were formulated to answer the three aims of this study. This chapter describes the research design, data sources and measures, data management, data analysis, and data security procedures. The study was approved by the University of Michigan Institutional Review Board (IRB) [HUM00094525].

## **Research Design**

This is a retrospective cohort study using data from MSQC as the primary sample to examine the relationship of system factors and individual factors on pharmaceutical VTE prophylaxis in the context of a model inspired by situational awareness in dynamic decision-making. This study utilized secondary data analysis. Additional patient-level data were obtained from the medical record. Unit-specific nursing data were collected from an internal staffing system. Since a critical aspect of the model is unit-level factors, it was necessary to use a multi-level analysis that consisted of patient- and unit-level data. Although patient-level data remained the primary unit of analysis, nursing-specific variables were collected on a unit level and linked by patient unit assignment during the first 24 hours after the patient left the operating room. The additional patient-level and unit-level nurse data were matched using the patient's medical record number, operation date, and unit assignment.

The study included all eligible patients, using MSQC criteria, from the study hospital that were found in the MSQC database from June 1, 2012 to May 31, 2014. These dates were selected because collection of VTE-related information was not started until June 1, 2012. Additionally, since situational awareness is impacted by system design and a substantial system change to the electronic medical record occurred on June 7, 2014, data collection concluded on May 31, 2014. From June 1, 2012 to May 31, 2014, the computer platform remained consistent. Although MSQC is a collaborative of many hospitals, the scope of this study did not extend beyond the institution for which data were available.

#### **Data Sources and Measures**

In this study, the explanatory variables of interest were selected based on Endsley's (1995) model of situational awareness. The literature supports each area of the model as a contributing factor in the administration of pharmaceutical VTE prophylaxis. Each measure, data source, and their roles in the operational model are described below and also shown in Tables 3 and 4, independent and dependent variables, respectively. Data sources included MSQC, electronic medical records, nursing informatics, and ANSOS One-Staff<sup>TM</sup>, the institution's staffing application suite.

Table 3. Description of Independent Variables

Concept	Measure (level)	Data Source	Time Frame	Туре
Comprehension	VTE Risk Factor Score	Medical Record	Closest to operation date, up to 30 days	Continuous and
	(patient)		prior	Categorical
Stress and Workload	RN HPPD (unit)	ANSOS One-Staff <sup>™</sup>	Date of Operation	Continuous
	Other Nurse HPPD (unit)	ANSOS One-Staff <sup>™</sup>	Date of Operation	Continuous
	Census (unit)	ANSOS One-Staff <sup>™</sup>	Date of Operation	Continuous
	Workload (unit)	Health System Data Warehouse	Date of Operation	Continuous
Complexity	Elixhauser (patient)	Health System Data Warehouse		Continuous
Experience and Training	Education (unit)	Nursing Informatics	2014	Continuous
	Unit Type (unit)	Nursing Informatics	2012 - 2014	Categorical

Table 4. Description of Dependent Variables

Concept	Measure (level)	Data Source	Time Frame	Туре
Performance of Actions	Prophylaxis Administered (patient)	MSQC	Within 24 hours from out of [operating] room time	Categorical
Postop VTE Occurrences	DVT	MSQC	30 day postoperative	Categorical
	PE	MSQC	30 day postoperative	Categorical
Other Postoperative Occurrences	SSI	MSQC	30 day postoperative	Categorical
	UTI	MSQC	30 day postoperative	Categorical
	Return to ED	MSQC	30 day postoperative	Categorical
	Readmission	MSQC	30 day postoperative	Categorical
	All-cause Morbidity	MSQC	30 day postoperative	Categorical

### Michigan Surgical Quality Collaborative (MSQC)

The MSQC is a voluntary network of 173 Michigan hospitals, funded by Blue Cross Blue Shield, dedicated to collecting data on surgical patients for the purpose of performance improvement (MSQC, 2014). Each hospital employs a qualified Surgical Clinical Quality Reviewer (SCQR) to prospectively collect data on general, vascular, and hysterectomy surgery patients (MSQC, 2014). A systematic sampling methodology was designed to capture a representative portion of surgical cases. The reviewer manually abstracts or validates these cases via the medical record and enters all required elements in to a secure web-based workstation, which is accessible online through the MSQC private website (MSQC, 2014). As per the MSQC protocol, cases were selected using an established procedure to minimize the possibility of selection bias (Fink et al., 2002; MSQC, 2014). A list of MSQC-eligible procedures, at the time of this study, is presented in Appendix A.

An important strength of MSQC is the reliability of the data it generates. MSQC continuously monitors data and site data collection practices, to assure the reliability of the data through a variety of means, such as reviewer training, inter-rater reliability (IRR) assessments, online case studies, and conference calls (MSQC, 2014). Participating sites are also required to maintain an agreement rate of >= 95% upon formal IRR review (MSQC, 2014). Due to the reliability of the data, MSQC participants can confidently use the online reports, in conjunction with standard reports, to effectively identify opportunities for improving processes to achieve more favorable surgical outcomes (MSQC, 2014).

Several variables from MSQC were vital to this study. The case number was used to identify the sample and the associated medical record number, which was necessary to obtain patient-level variables not already included in the dataset. Additionally, the surgery date, obtained from MSQC, was vital in obtaining all other measures in this study. Outcome measures directly obtained from the MSQC dataset included the primary and secondary outcomes, which were originally obtained from abstracted clinical documentation or follow-up phone calls: prophylaxis administered and 30-day postoperative occurrences. These 30-day postoperative occurrences were deep vein thrombosis (DVT), pulmonary embolism (PE), surgical site infection (SSI), urinary tract infection (UTI), return to the emergency department (ED), readmission, and all-cause morbidity.

Prophylaxis Administered. The primary outcome measure in this study was the administration of pharmaceutical VTE prophylaxis. Administration of pharmaceutical VTE prophylaxis is a variable that is manually abstracted from the medication administration record (MAR) and stored in the MSQC data set. The variable reflects actual administration of pharmaceutical VTE prophylaxis. As defined by MSQC, prophylaxis administration includes the following types of VTE prophylaxis employed up to, and including, the first 24 hours after the "Patient Out of [Operating] Room" time.

Type (i.e., Heparin twice a day, Heparin three times a day or intravenous, low molecular weight Heparin, or Other anticoagulant), date, and time of VTE prophylaxis employed up to, and including, the first 24 hours after the "Patient Out of Room" time is recorded.

Exception and Contraindication are also noted. Exceptions may be appropriate for a variety of reasons including: a) documentation of a contraindication to anticoagulation

such as active bleeding, allergy, or a history of heparin-induced thrombocytopenia, b) patient is an outpatient, or c) patient being discharged before they can receive more than one dose of medication postoperatively; however, patient refusal is not an exception to VTE prophylaxis. Likewise, blood transfusion (intraoperative or immediately postoperative) is not an exception to postoperative VTE prophylaxis. Lastly, it is recorded if the patient does not receive any prophylaxis.

It is important to emphasize the discrete time frame necessary for the administration of postoperative VTE prophylaxis within the MSQC dataset. Only VTE prophylaxis administered up to, and including, the first 24 hours after "patient out of room" time are recorded as administered. If the prophylaxis is administered after the 24 hour timeframe, the variable is recorded as 'no', or not administered. This was imperative in our study and enabled us to look at the other variables surrounding administration of VTE prophylaxis during a specified timeframe.

**Postoperative Occurrences**. Postoperative occurrences, up to 30 days after surgery, were included as secondary outcomes. In addition to VTE occurrences (DVT and PE), other postoperative outcomes collected by MSQC were explored.

DVT is defined as a new blood clot or thrombus within the venous system that developed in a patient postoperatively (MSQC, 2014). The blood clots usually originate in the deep leg veins or the pelvic venous system (MSQC, 2014). To be included as an occurrence, the clot must require therapy and the diagnosis be confirmed by a duplex, venogram, or CT scan, and the patient must be treated with anticoagulation therapy and/or placement of a vena cava filter or clipping of the vena cava (MSQC, 2014). A PE, defined as the identification of a new blood clot in a pulmonary artery causing

obstruction of the blood supply to the lungs, usually originating in the deep leg veins or the pelvis venous system, must also be confirmed by V-Q scan interpreted as high probability of pulmonary embolism or a positive CT spiral exam, TEE, pulmonary arteriogram, 2-D echocardiogram, or CT angiogram (MSQC, 2014).

Additional outcome variables include other postoperative occurrences that are available in the MSQC dataset: Surgical Site Infection (SSI), Urinary Tract Infection (UTI), Return to the Emergency Department (ED), Readmission, and All-Cause Morbidity. Intent of the variables, definitions, variable options, and other notes are included in Appendix B.

#### **Health Service Data Warehouse (HSDW)**

It was necessary to obtain several additional clinical measures from the institution's health system data warehouse (HSDW). The HSDW provides access to organizational data resulting from clinical documentation. MRNs and surgery dates were provided to obtain the following patient-level measures: VTE Risk Factor Score and Elixhauser Comorbidity Index. Additionally, all unit-based admissions and discharges occurring during the study time period were collected from the HSDW.

**Risk Factor Score.** According to Endsley (1995), comprehension of the situation is based on a synthesis of disjointed elements. Comprehension extends beyond simply being aware of the elements that are present to include an understanding of the significance of those elements in light of pertinent goals (Endsley, 1995). Our model utilized the Caprini risk assessment score (Obi et al., 2015; Bahl et al., 2010; Caprini, 2005) to represent comprehension. As in Ensdley's (1995) model, risk factor assessment

is a key piece of effective care, yet risk assessment alone does not guarantee proper orders and administration (Elder et al., 2014; Gharaibeh et al., 2015; Krell et al., 2015).

The Caprini risk assessment score is a valid and reliable tool that is calculated on all surgical patients prior to operation and serves to provide a synthesis of disjointed VTE risk factors (Obi et al., 2015; Bahl et al., 2010). The measure captures the risk assessment closest, and up to 30 days prior, to surgical time. The Caprini risk assessment model was introduced at the study hospital in 2005 to improve compliance with VTE prophylaxis guidelines for medicine and surgery patients using a point-scoring system (Bahl et al., 2010). The scores for individual risk factors are summed to produce a cumulative risk score that defines the patient's risk level and associated prophylaxis regimen (Bahl et al., 2010). The VTE cumulative risk score and risk level was collected for each patient in the study population. Aligned with hospital policy, VTE risk factor was grouped in three categories: those not requiring pharmaceutical VTE prophylaxis (VTE risk factor score 0-2), those requiring pharmaceutical VTE prophylaxis (VTE score 3 or greater), and those who did not have a documented risk factor score.

Patient Severity of Illness. Both the Elixhauser and Charleson co-morbidity indices, which represent complexity of care, were obtained from the HSDW. Although they yielded similar results, Elixhauser was used on the model for risk adjustment due to studies suggesting that the method is superior in similar populations (Lieffers, J,R., Baracos, V.E., Winget, M, & Fassbender, K., 2011). The Elixhauser Comorbidity Index is a method for measuring patient comorbidity based on diagnosis codes found in administrative data (Elixhauser, Steiner, Harris, & Coffey, 1998).

**Workload.** Workload was calculated by adding the number of admissions and discharges on the unit during postoperative day one for each patient. All admissions and discharges were obtained from all units during the study period and patients were matched by unit assignment during the 24-hour postoperative time period.

# Nursing Informatics and ANSOS One-Staff<sup>TM</sup>.

Unit-specific nursing variables were collected through the institution's nursing informatics department and the ANSOS One-Staff<sup>TM</sup> application suite. All staffing data, by unit and date (operation date and postoperative day one), were obtained from ANSOS One-Staff<sup>TM</sup>, an enterprise productivity management system designed to help healthcare staffing management meet budgetary targets and address performance gaps.

Hours per Patient Day (HPPD). As a measure of stress and workload on the unit, HPPD was obtained for each operation date. HPPD is readily available from the productivity reports, which were run for each day and unit for all sample cases.

Registered Nurse (RN) and other nurse HPPD were also calculated to provide proxy measures for stress and workload. In order to normalize the information due to differences on the unit, HPPD was calculated by subtracting the actual HPPD from the budgeted HPPD.

Education and Unit Type. In the conceptual model, training and experience impact the development of situational awareness (Endsley, 1995). With experience, recurrent situational components are noticed and, along with recurrent associations and relationships, form a basis for situational awareness development (Endsley, 1995). Unit-level nurse education was obtained from the institution's nursing informatics department to measure the level of nurse training and experience on each unit. Unit-level education

and training was measured by the percentage of nurses on each unit who had a Bachelor's degree. Unit type has also been associated with VTE prophylaxis administration compliance (Elder et al., 2014) and was therefore included in our model, since it is likely related to knowledge and education and / or the activity on the unit (Kahn et al., 2013; Gaston & White, 2013 Grier, 2014; Vervacke et al., 2014; Kwan et al., 2015). Unit type was categorized as surgical and non-surgical. In this study, surgical units are those units whose primary population is surgical patients. Non-surgical units include units that may host surgical patients; however, other patient types are often present. These units include observation, medical, medical-surgical, and intensive care. Due to the number of units and the rarity of events, it was important to consolidate unit data to allow for statistical power.

### **Data Management Procedures**

Table 5 depicts the relationships of the data sources. The MSQC sample provided case numbers, linked to patient medical record numbers (MRNs), and operation dates as the primary source. MRNs and operation dates were used to collect the additional patient-level data not available from MSQC. Additionally, the MRNs and operation dates were used to find the unit assignments for each patient. Unit assignments, operation dates, and postoperative day-one dates were used to collect nurse staffing and the other related nursing variables. Both the unit the patient went to after surgery and the unit they were discharged from were provided for each patient in the sample. In order to assign a single unit for each patient during the 24-hour postoperative period, chart review was completed whenever the two units differed.

Table 5. Data Sources and Management

Data Source	MRN	Date(s)	Unit Level	Patient Level
MSQC	Х	Х		Х
HSDW	X	X	X	X
Nursing Informatics		Х	X	
and ANSOS One-Staff <sup>™</sup>				

### **Data Analysis**

All data analysis was performed using SPSS Version 20.0. Descriptive statistics were calculated to describe the characteristics of our sample and to check for any violation of assumptions. Frequencies were calculated for all variables, and descriptives were explored for all continuous variables. Prior to testing the larger model, correlation analysis was used to describe the strength and direction of the linear relationships within the model. Pearson correlation coefficients were applied to the study model. Logistic regression was used to assess if variables were predictive, and the relative contribution of each variable. In order to include all available information, missing data was imputed with dummy variables and included in the regression models. Regression coefficients for the missing data were consistently insignificant.

# **Data Protection & Security**

All data were stored in compliance with the Health Insurance Portability and Accountability Act (HIPPA), as well as institutional regulations. Medical record numbers were used to link datasets, and were permanently deleted as soon as the complete data set was constructed.

#### **CHAPTER IV**

#### **RESULTS**

# **Univariate Analysis**

# **Demographics**

The study sample included 1,370 patients who had an eligible procedure between July 1, 2012 and June 30, 2014 and who were in the hospital for at least 24 hours after the operation. The sample was predominantly female (60.9%, n=834) and white (83.9%, n=1150). The majority (75.1%, n=1029) of the operations were scheduled. Nearly 14% (n=187) were urgent and 11.2% (n=154) were emergent (Table 6). Ages ranged from 18 to 97 with a mean age of 55.56. The average length of stay was 5.76 days (Table 7).

Table 6. Demographic Characteristics of Categorical Variables

Characteristic (N=1370)	<u>n</u>	%
Gender		·
Male	536	39.1
Female	834	60.9
Race		
White	1150	83.9
Black	117	8.5
Asian	35	2.6
Other	3	0.2
Unknown	65	4.7
<b>Surgical Priority</b>		
Scheduled	1029	75.1
Urgent	187	13.6
Emergent	154	11.2

Table 7. Demographic Characteristics of Continuous Variables

Characteristic	<u>Range</u>	<u>M</u>	<u>SD</u>
Age (years)	18 – 97	55.56	15.89
Length of Stay (days)	1 – 92	5.76	8.0

#### **Errors of Omission and Commission**

An important finding in this study is the number of errors. Perhaps most alarming is the number of patients who needed pharmaceutical VTE prophylaxis but did not receive it. Also of concern is the number of patients who received pharmaceutical prophylaxis despite a low (0-2) risk score, which per policy requires only ambulation (risk score of 0) or SCDs (risk score one or two). Over 75% (n=1033) of the patients had a total VTE risk factor score of three or greater and therefore required pharmaceutical VTE prophylaxis per hospital protocol. Almost 20% (n=268) had a score of zero to two. Five percent (n=69) did not have a documented risk factor score. In spite of the high percentage of patients requiring pharmaceutical VTE prophylaxis based on risk score alone, only 58.2% (n=798) received pharmaceutical VTE prophylaxis of any kind within the 24-hour postoperative period. This equates to 235 (18.1%) errors of omission. Interestingly, nearly 14% (n=178) of patients who did not need the prophylaxis received it anyway, resulting in 178 errors of commission. Errors of omission and commission are depicted in Table 8.

Table 8: Errors of Omission and Commission

	Prophylaxis Not Needed	Prophylaxis Needed	
Prophylaxis Not Administered	90	235 (18.1%) Errors of Omission	325
Prophylaxis Administered	178 (13.7%) Errors of Commission	798	976
	268	1033	1301

Chi Square, p=.000

#### **Clinical Outcomes**

The majority (94.7%) of patients were followed for the complete 30-day postoperative period. Only 1.3% (n=17) of patients experienced postoperative VTE. Fourteen patients (1.0%) developed a DVT in the 30-day postoperative period and 4 (0.3%) were diagnosed with a PE. Nine percent of patients (n=127) developed a SSI and nearly 4% (n=51) developed a UTI (Table 9). The 30-day readmission rate was 9.8% (n=134), and about 5% (n=74) of the patients returned to the ED within 30 days. The all-cause morbidity rate was 19.3% (n=264) (Table 9).

#### **Model Characteristics**

The actual versus budgeted HPPD varied widely. RN HPPD (actual minus budgeted HPPD) ranged from -5 to 17. The mean difference was 0.67. Other nursing staff HPPD ranged from -3 to 6 with a mean difference of 0.88. Unit census also varied widely by unit type with a range of .70, on the observation unit, to 35 patients, on a surgical unit. The average census was 21.42. Workload (admissions plus discharges) ranged from 0 to 25 with an average of 7.5 over a 24-hour period (Table 10).

Table 9. Dependent Variables

Characteristic	<u>n</u>	%
Prophylaxis Administered (n=1370)		
Yes	1023	74.7
No	347	25.3
30-day Postoperative Occurrence (n=1298)		
Followed for 30 days	1298	94.7
VTE	17	1.3
DVT	14	1.0
PE	4	0.3
SSI	127	9.3
UTI	51	3.7
Return to ED	74	5.4
Readmission	134	9.8
All-Cause Morbidity	264	19.3

The patients were dispersed among 24 units. Just under 44% were admitted to a surgical unit (n=599). Non-surgical units included medical-surgical, observation, medical, and the intensive care unit (56.3%, n=771). The percent of BSN-educated nurses on each unit ranged from 47.37% to 82.81%, with the mean being 62.65% (Table 11).

Table 10. Model Characteristics of Continuous Variables

Characteristic	<u>Range</u>	<u>M</u>	<u>SD</u>
RN Actual v Budgeted HPPD (n=1336)	-5 – 17	.67	2.17
Other Actual v Budgeted HPPD (n=1336)	-3 – 6	.88	0.97
Unit Census (n=1336)	0.70 - 35.0	21.42	8.54
Unit Workload (n=1370)	0 – 25	7.5	6.14
Elixhauser (n=1363)	0 – 21	4.04	3.31
Education (n=1356)	47.37% - 82.81%	62.65%	8.84%

Table 11. Model Characteristics of Categorical Variables

Characteristic (N=1370)	<u>n</u>	%
VTE Score		•
0 – 2	268	19.6
3 or greater	1033	75.4
Not Documented	69	5
Unit Type		
Surgical	599	43.7
Non-Surgical	771	56.3

# **Bivariate Analysis**

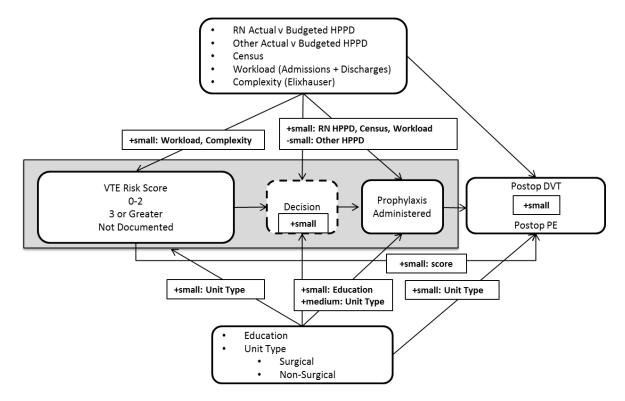
Correlations were conducted between all variables of interest (Table 12) in the study model (Figure 4).

Table 12: Correlation Matrix

Vai	riables	1	2	3	4	5	6	7	8 E	9
		VTE Sc	Prophy	RN	Other	Census	Work	Comple	du	Unit
1.	VTE Score	-								
2.	Prophy Admin	.086**	-							
3.	RN Act v Bud	036	.057*	-						
4.	Other Act v Bud	001	087**	.457**	-					
5.	Unit Census	.031	.261**	294**	264**	-				
6.	Unit Work- load	.065*	.153**	158**	032	.540**	-			
7.	Comple x-ity	.221**	.021	099**	.013	.137**	.080**	-		
8.	Edu- cation	015	.182**	064*	187**	.308**	.034	051	-	
9.	Unit Type	.036	.307**	062*	105**	.600**	.716**	.000	.179**	-

<sup>\*\*</sup>Correlation is significant at the 0.01 level (2-tailed)
\*Correlation is significant at the 0.05 level (2 tailed)

Figure 4: Conceptual Model



Correlations were found between multiple variables. Of interest, RN HPPD had a positive correlation with the administration of prophylaxis [r=.057 (p=.05)] and other nurse HPPD had a small negative correlation [r=-.087 (p=.01)]. Furthermore, nurse education [r=.182 (p=.01)] and unit type [r=.307 (p=.01)] also had positive correlations with prophylaxis administration. Unit census [r=.261 (p=.01)] and workload (admissions plus discharges) [r=.153 (p=.01)] had a positive correlation to the administration of VTE prophylaxis, which is likely due to the time-sensitive nature of the administration of VTE prophylaxis, and the need to complete this task within 24 hours after the patient leaves the operating room. Not surprisingly, patient complexity (Elixhauser) [r=.221 (p=.01) was positively correlated with the VTE risk score. The crude VTE risk score was

correlated to VTE [r=.062 (p=.05) and DVT [r=.090 (p=.01)]. Additionally, DVT and PE were also correlated [r=.129 (p=.01)] (Table 12).

### **Logistic Regression: Administration of VTE Prophylaxis**

**Aim 1**) Identify factors in a situational awareness model applied to VTE that are significantly associated with the administration of pharmaceutical VTE prophylaxis for:

- 1a) All patients
- 1b) Patients with a VTE risk assessment score of 0-2
- 1c) Patients with a VTE risk assessment score of 3 or greater

A logistic regression analysis was conducted to assess if the administration of pharmaceutical VTE prophylaxis for all patients using VTE score, HPPD, census, workload, complexity, education, and unit type as predictors. A test of the full model against a constant was statistically significant, indicating that the predictors reliably distinguished between the administration and omission of the VTE prophylaxis (chi square = 233.537, p < .001 with df = 12).

Table 13 presents the results of logistic regression analysis that examined the extent to which factors in a situational awareness model are significant predictors when applied to VTE and the administration of pharmaceutical VTE prophylaxis for all patients in the sample. Specifically, covariates included: VTE score 0-2 (B=-.652, p=.000), RN HPPD (B=.117, p=.001), census (B=.030, p=.012), workload (B=-.045, p=.020), education (B=.038, p=.000), and surgical unit (b=1.605, p=.000). VTE score not documented, other nurse HPPD, and complexity were not significantly associated with the administration of VTE prophylaxis.

Table 13. Logistic Regression: All Units, Administration of Prophylaxis

	В	SE	Wald	р	Odds		nfidence
					Ratio	Inte	rval
						Lower	Upper
						Bound	Bound
VTE Score Not	588	.319	3.407	.065	.555	.298	1.037
Documented							
VTE Score 0 – 2	652	.167	15.308	.000*	.521	.376	.722
RN HPPD	.117	.035	11.242	.001*	1.124	1.050	1.203
Other HPPD	077	.076	1.016	.313	.926	.798	1.075
Census	.030	.012	6.271	.012*	1.030	1.007	1.055
Workload	045	.019	5.414	.020*	.956	.921	.993
Complexity	.029	.022	1.774	.183	1.029	.986	1.074
Education	.038	.009	18.005	.000*	1.039	1.021	1.057
Surgical Unit	1.605	.241	44.514	.000*	4.980	3.107	7.980

<sup>\*</sup>Significance < 0.05

Similarly, a logistic regression analysis was conducted to predict the administration of pharmaceutical VTE prophylaxis for patients on surgical and non-surgical units using VTE risk score, HPPD, census, workload, complexity, and education as predictors. A test of the two models (i.e., surgical and non-surgical) suggested statistically significant results comparable, indicating that the predictors reliably distinguished between the administration and omission of the VTE prophylaxis (chi square = 19.835, p=.011 with df = 8 and chi square = 73.017, p < .001 with df = 8, respectively).

Tables 14 and 15 depict the results of the logistic regression analyses that examined the extent to which factors in a situational awareness model are significant predictors when applied to VTE and the administration of pharmaceutical VTE prophylaxis for patients with a VTE risk score greater than three and for patients with a VTE risk score zero to two. On surgical units, the primary predictor for VTE prophylaxis was VTE score. Those with a VTE score zero to two or a VTE risk score not documented were less likely to have received VTE prophylaxis (B=-1.197, p=.005 and

B=-1.458, p=.000), as would be reasonably expected. No other variables were significant predictors of prophylaxis administration. Conversely, on non-surgical units, there were several predictors: VTE score zero to two (B=-.410, p=.036), RN HPPD (B=.114, p=.001), other HPPD (B=-.161, p=.035), census (B=.045, p=.000), and workload (-.105, p=.000). VTE score not documented, complexity, and education were not significantly associated with the administration of VTE prophylaxis on non-surgical units.

Table 14. Logistic Regression, Surgical Units, Administration of Prophylaxis

	В	SE	Wald	P	Odds	95% Cor	nfidence
					Ratio	Inte	rval
						Lower	Upper
						Bound	Bound
VTE Score Not	-1.458	.525	7.711	.005*	.233	.083	.651
Documented							
VTE Score 0-2	-1.197	.309	14.957	.000*	.302	.165	.554
RN HPPD	.078	.193	.162	.687	1.081	.740	1.579
Other HPPD	354	.343	1.065	.302	.702	.359	1.374
Census	.002	.047	.002	.964	1.002	.913	1.100
Workload	004	.030	.017	.897	.996	.938	1.057
Complexity	052	.039	1.797	.180	.949	.879	1.025
Education	.020	.019	1.097	.295	1.020	.983	1.058

<sup>\*</sup>Significance < 0.05

Table 15. Logistic Regression, Non-Surgical Units, Administration of Prophylaxis

	В	SE	Wald	Р	Odds Ratio	95% Confidence Interval	
						Lower	Upper
						Bound	Bound
VTE Score Not	.052	.355	.022	.883	1.054	.525	2.113
Documented							
VTE Score 0-2	410	.196	4.392	.036*	.663	.452	.974
RN HPPD	.114	.035	10.608	.001*	1.121	1.047	1.201
Other HPPD	161	.076	4.423	.035*	.852	.733	.989
Census	.045	.011	17.444	.000*	1.046	1.024	1.068
Workload	.045	.025	3.310	.069	1.046	.997	1.098
Complexity	105	.023	19.888	.000*	.901	.860	.943
Education	.011	.007	2.608	.106	1.011	.998	1.025

<sup>\*</sup>Significance < 0.05

Specifically looking at those patients who needed prophylaxis (VTE risk score three or greater), predictors of prophylaxis administration included RN HPPD (B=.112, p=.005), census (B=.050, p=.000), workload (B=-.084, p=.000), and unit type (B=2.173, p=.000) (Table 16). For patients who didn't need prophylaxis, predictors of prophylaxis administration included RN HPPD (B=.163, p=.043) and unit type (B=1.336, p=.002) (Table 17). Patients were more likely to receive prophylaxis on surgical units regardless of whether they needed it (p=.000) (Table 18 and 19).

Table 16. Logistic Regression, VTE Risk Score 3 or Greater

	В	SE	Wald	р	Odds	95% Coi	nfidence
					Ratio	Inte	rval
						Lower	Upper
						Bound	Bound
RN HPPD	.112	.040	7.936	.005*	1.119	1.035	1.210
Other HPPD	117	.087	1.811	.178	.889	.749	1.055
Census	.050	.013	15.296	.000*	1.051	1.025	1.077
Workload	084	.023	13.835	.989	1.000	.952	1.051
Complexity	.000	.025	.000	.000*	.919	.880	.961
Education	.010	.008	1.722	.189	1.010	.995	1.026
Surgical Unit	2.173	.310	49.204	.000*	8.783	4.786	16.118

<sup>\*</sup>Significance < 0.05

Table 17. Logistic Regression, VTE Risk Score 0-2

Table 17. Logistic K	Table 17. Logistic Reglession, VIE RISK Score 0-2											
	В	SE	Wald	р	Odds	95% Confidence						
					Ratio	Interval						
						Lower	Upper					
						Bound	Bound					
RN HPPD	.163	.080	4.103	.043*	1.177	1.005	1.377					
Other HPPD	159	.178	.800	.371	.853	.601	1.209					
Census	.043	.027	2.526	.112	1.044	.990	1.101					
Workload	.072	.045	2.555	.110	1.074	.984	1.173					
Complexity	066	.036	3.429	.064*	.936	.873	1.004					
Education	.015	.012	1.382	.240	1.015	.990	1.040					
Surgical Unit	1.336	.433	9.524	.002*	3.804	1.628	8.889					

<sup>\*</sup>Significance < 0.05

Table 18. Crosstabs, VTE Score 3 or Greater

	Non-Surgical Units	Surgical Units	
Not Administered	202	33	235
(Errors of Omission)	(19.6%)	(3.2%)	255
Administrated	375	423	700
Administered	(36.3%)	(40.1%)	798
	577	456	1033

Chi Square, p=.000

Table 19. Crosstabs, VTE Score 0-2

	Non-Surgical Units	Surgical Units	
Not Administered	68	22	90
Not Administered	(25.4%)	(8.2%)	90
Administered	84	94	170
(Errors of Commission)	(31.3%)	(35.1%)	178
	152	116	268

Chi Square, p=.000

# **Logistic Regression: Postoperative VTE Occurrences**

**Aim 2**) Examine factors in a situational awareness model applied to VTE that are significantly associated with:

- 2a) VTE
- 2b) DVT
- 2c) PE

A logistic regression analysis was conducted to predict the occurrence of postoperative VTE, DVT, and PE using VTE risk score, the administration of VTE prophylaxis, HPPD, census, workload, complexity, education, and unit type. Examining surgery units only, a test of the full model against a constant was not statistically significant, indicating that the predictors did not reliably predict VTE events. Likewise,

when examining DVT and PE events independently, the models did not predict DVT or PE. In contrast, when looking specifically at non-surgical units, the model was statistically significant, suggesting that the predictors did reliably predict VTE events on non-surgical units (chi square = 18.038, p=.021 with df=8).

Table 20 presents the results of logistic regression analysis that examined the extent to which factors in a situational awareness model are significant predictors when applied to the occurrence of VTE events on non-surgical units. Significant covariates included administration of VTE prophylaxis (B=-1.661, p=.036) and RN HPPD (B=.413, p=.006).

Table 20. Logistic Regression, Non-Surgical Units, VTE

	В	SE	Wald	р	Odds Ratio		onfidence terval	
						Lower	Upper	
						Bound	Bound	
VTE Score 3 or Greater	.449	.838	.286	.593	1.566	.303	8.100	
Prophylaxis	-1.661	.794	4.375	.036*	.190	.040	.901	
RN HPPD	.413	.151	7.437	.006*	1.511	1.123	2.034	
Other HPPD	436	.408	1.144	.285	.647	.291	1.437	
Census	.151	.079	3.676	.055	1.163	.997	1.358	
Workload	.140	.101	1.914	.167	1.150	.943	1.402	
Complexity	.042	.079	.280	.597	1.043	.893	1.219	
Education	.039	.039	1.045	.307	1.040	.964	1.122	

<sup>\*</sup>Significance < 0.05

## **Logistic Regression: Other Postoperative Occurrences**

**Aim 3**) Examine system factors and individual factors associated with other postoperative occurrences

Multiple logistic regression analyses were completed to explore factors within a model of situational awareness that may have an impact on post-operative occurrences. Using RN HPPD, other nurse HPPD, census, workload, complexity, education, and unit type as predictors for SSI, UTI, return to ED, readmission, and all-cause morbidity, the model was significant in predicting readmissions (chi square=22.922, p=.002 with df=7) (Table 21), all-cause morbidity (chi square=28.711, p=.000 with df=8) (Table 20), and SSI (chi square=19.942, p=.031 with df=8) (Table 23); however, the sole significant predictor of SSI was complexity (B=.107, p=.000).

Predictors of readmission included census (B=.040, p=.022), complexity (B=.067, p=.010), and education (B=-.019, p=.017). Predictors of all-cause morbidity were RN HPPD (B=.110, p=.006), census (B=.045, p=.001), complexity (B=.168, p=.000), and unit type (B=-.567, p=.012).

Table 21. Logistic Regression, All Units, Readmissions

	В	SE	Wald	р	Odds	95% Cor	nfidence
					Ratio	Inte	rval
						Lower	Upper
						Bound	Bound
RN HPPD	.037	.054	.457	.499	1.037	.933	1.153
Other HPPD	.012	.122	.009	.925	1.012	.796	1.285
Census	.040	.017	5.230	.022*	1.040	1.006	1.076
Workload	.026	.021	1.414	.234	1.026	.984	1.070
Complexity	.067	.026	6.676	.010*	1.069	1.016	1.124
Education	019	.008	5.699	.017*	.981	.966	.997
Surgery Unit	359	.285	1.581	.209	.699	.400	1.222

<sup>\*</sup>Significance < 0.05

Table 22. Logistic Regression, All Units, All-Cause Morbidity

	В	SE	Wald	р	Odds Ratio		nfidence erval
						Lower	Upper
						Bound	Bound
RN HPPD	.110	.040	7.495	.006*	1.116	1.032	1.207
Other HPPD	.101	.095	1.138	.286	1.107	.919	1.333
Census	.045	.014	10.325	.001*	1.046	1.018	1.075
Workload	.027	.017	2.490	.115	1.028	.993	1.063
Complexity	.168	.021	66.576	.000*	1.183	1.136	1.231
Education	.012	.008	2.340	.126	1.013	.997	1.029
Surgery Unit	567	.225	6.349	.012*	.567	.365	.882

<sup>\*</sup>Significance < 0.05

Table 23. Logistic Regression, All Units, SSI

Table 23. Logistic 1	В	SE	Wald	р	Odds	95% Confidence		
					Ratio	Inte	Interval	
						Lower	Upper	
						Bound	Bound	
RN HPPD	.101	.055	3.344	.067	1.106	.993	1.232	
Other HPPD	038	.133	.083	.774	.962	.741	1.249	
Census	.026	.018	2.067	.150	1.027	.990	1.065	
Workload	.026	.022	1.331	.249	1.026	.982	1.071	
Complexity	.107	.026	17.406	.000*	1.113	1.059	1.171	
Education	.005	.011	.242	.623	1.005	.985	1.026	
Surgery Unit	.080	.297	.072	.788	1.083	.606	1.937	

<sup>\*</sup>Significance < 0.05

Also, when examining postoperative occurrences using the same model with unit subsets, the model predicted several post-operative occurrences on non-surgical units, but the same did not hold true when applying the model to surgical units. The variables reliably predicted SSI (chi square=28.512, p=.000 with 6 df), UTI (chi square=20.327, p=.002 with df=6), readmission (chi square=24.216, p=.000 with df=6), and all-cause morbidity on non-surgical units (chi square 101.505, p=.000 with df=6).

Table 24 presents the results of logistic regression analysis that examined the extent to which factors are significant predictors when applied to SSI on non-surgical

units. Like the parent model, complexity was the only significant predictor of SSI (B=.185, p=.000). Additionally, complexity (B=.085, p=.016) was the only significant predictor for readmission on non-surgical units (Table 25). Table 26 presents the results of the model applied to UTI on non-surgical units. Predictors were RN HPPD (B=.172, p=.045), census (B=.103, p=.015), and workload (B=.087, p=.068). Lastly, predictors of all-cause morbidity on non-surgical units included complexity (B=.244, p=.000) and education (B=.029, p=.008) (Table 27).

Table 24. Logistic Regression, Non-Surgical Units, SSI

	В	SE	Wald	р	Odds	95% Cor	nfidence
					Ratio	Inte	rval
						Lower	Upper
						Bound	Bound
RN HPPD	.058	.064	.811	.368	1.059	.934	1.201
Other HPPD	002	.154	.000	.989	.998	.738	1.350
Census	.011	.021	.260	.610	1.011	.970	1.054
Workload	.033	.040	.646	.422	1.033	.954	1.118
Complexity	.185	.038	23.571	.000*	1.203	1.117	1.297
Education	.024	.015	2.539	.111	1.025	.994	1.056

<sup>\*</sup>Significance < 0.05

Table 25. Logistic Regression, Non-Surgical Units, Readmissions

	В	SE	Wald	р	Odds Ratio		nfidence erval	
						Lower	Upper	
						Bound	Bound	
RN HPPD	.043	.060	.501	.479	1.044	.927	1.175	
Other HPPD	036	.138	.070	.791	.964	.736	1.264	
Census	.038	.020	3.662	.056	1.039	.999	1.080	
Workload	.060	.033	3.194	.074	1.062	.994	1.134	
Complexity	.085	.035	5.856	.016*	1.088	1.016	1.166	
Education	014	.010	1.824	.177	.987	.967	1.006	

<sup>\*</sup>Significance < 0.05

Table 26. Logistic Regression, Non-Surgical Units, UTI

	В	SE	Wald	р	Odds	95% Confidence Interval	
					Ratio		
						Lower	Upper
						Bound	Bound
RN HPPD	.172	.086	4.031	.045*	1.188	1.004	1.405
Other HPPD	.261	.249	1.096	.295	1.298	.797	2.114
Census	.103	.042	5.970	.015*	1.109	1.021	1.205
Workload	.087	.047	3.326	.068	1.090	.994	1.197
Complexity	052	.072	.519	.471	.949	.824	1.093
Education	.025	.022	1.399	.237	1.026	.983	1.070

<sup>\*</sup>Significance < 0.05

Table 27. Logistic Regression, Non-Surgical Units, All-Cause Morbidity

	В	SE	Wald	р	Odds Ratio	95% Confidence Interval	
						Lower	Upper
						Bound	Bound
RN HPPD	.086	.044	3.788	.052	1.090	.999	1.189
Other HPPD	.151	.106	2.022	.155	1.162	.945	1.431
Census	.029	.016	3.420	.064	1.030	.998	1.062
Workload	.043	.028	2.315	.128	1.044	.988	1.104
Complexity	.244	.030	65.792	.000*	1.277	1.204	1.354
Education	.029	.011	7.103	.008*	1.030	1.008	1.052

<sup>\*</sup>Significance < 0.05

### **CHAPTER V**

### **DISCUSSION**

The results of these analyses leave little doubt that the factors in the model of situational awareness in dynamic decision-making impact the operational environment in nursing, much as they do in other high reliability organizations. This study demonstrates several unique approaches to examining how multiple factors of situational awareness impact both VTE prophylaxis and the prevalence of adverse postoperative occurrences. It is important to note that this is the first study to utilize secondary data analysis to capture real-time stressors in the nursing clinical environment at the time elements of VTE prophylaxis were, or were not, completed. Secondly, this study not only examined patient census, but also explored 'busyness' or 'churn', described as the number of admissions and discharges on the unit, as a factor impacting the administration of VTE prophylaxis and postoperative occurrences. Stress and high level workload are ubiquitous and inevitable on many nursing units. This study aimed to explore the impact of such strain as it relates to nursing care, specifically administration of VTE prophylaxis.

One of the most worrisome findings was the sheer number of errors that occurred. In a population of 1,370 post-surgical patients, 30% (n=413) experienced an error. More importantly, 22.7% (n=235) of patients who needed prophylaxis did not receive it. This is slightly lower than the rate suggested by Cohen and colleagues (2008), who found that 38.7% of patients at risk for VTE did not receive prophylaxis. As previously mentioned,

studies conducted in HROs frequently identify poor situational awareness as a recurrent cause of human error, sub-standard performance, and poor outcomes (Carretta, Perry, & Ree, 1995; Endsley, 1995; Endsley & Robertson, 2000; Durso, Truitt, Hackworth, & Crutchfield, 1997; Gugerty, 1997). Furthermore, even with the abundance of research that has been done on VTE prophylaxis, several studies indicate a need for additional research to better understand why existing interventions do not have a pronounced effect on improving prophylaxis compliance rates (Duff et al., 2013; Elper et al., 2013; Kahn et al., 2013; Pendergraft et al., 2013; Pleet et al., 2014).

Post hoc chart review of a 10% sample of patients with a VTE score of 3 or greater who did not receive prophylaxis revealed that these patients all had a VTE risk assessment completed during, and documented in, the pre-operative history and physical (H&P); however, the prophylaxis was not ordered. In these cases, the H&P was signed by a Physician Assistant (PA), and the VTE assessment was clearly documented and included recommendations for pharmaceutical VTE prophylaxis if the patient was admitted. At the time of this study, these assessments were not automatically linked to a specific order set. In several cases, prophylaxis was not ordered, since the expected length of stay was less than 24 hours, yet no reassessment or reference to the original VTE score triggered an order for pharmaceutical VTE prophylaxis when the patient's length of stay exceeded 24 hours.

When applying this conceptual model to pharmaceutical VTE prophylaxis, several predictors related to situational awareness were seen. First, although s subset of patients with a VTE risk score of 0-2 still received prophylaxis despite not needing it, they were nearly 50% less likely to receive it than those with a higher score. Second,

several predictors in the original model were significant, as expected. Consistent with the literature, RNs had a significant impact on patients receiving prophylaxes. Elder et al. (2014) found that higher nurse-to-patient ratios were a contributing factor of patients receiving prophylaxis. In our study, as RN HPPD increased, patients were 12.4% more likely to receive prophylaxis. Additionally, more baccalaureate-prepared nurses on the unit made it more likely that patients received prophylaxis. Specifically, a 1% increase in the percentage of baccalaureate nurses corresponded to a 4% decrease in the patient not receiving prophylaxis when indicated. This is similar to other studies suggesting the effectiveness of baccalaureate-prepared nurses on VTE prophylaxis compliance (Gaston & White, 2013; Kahn et al., 2013; Seki, Vather, Atenafu, Kukreti, & Krzyzanowska, 2013; Vervacke, Lorent, & Motte, 2014).

In this study, it was found that patients were less likely to receive prophylaxis as nursing workload increased, which contradicts the findings of other studies that nursing workload was not a major reason for omitting doses of VTE prophylaxis (Elder et al., 2014). Related to workload, and at first glance paradoxical, as census increased the administration of prophylaxis also increased; however, this was likely due to the practice of administering prophylaxis within the first 24 hours after a patient leaves the operating room. The opposing results of census and workload may provide a good example of why using the total number of admissions and discharges to calculate workload is likely a better proxy measure for 'busyness' on the unit than is the census.

Unit type was a significant indicator for receiving pharmaceutical VTE prophylaxis. Patients admitted to surgical units were four times more likely to receive it, whether they needed prophylaxis or not. This is not surprising since studies suggest that

patients receive similar postoperative prophylaxis regardless of VTE risk (Elder et al., 2014; Gharaibeh et al., 2015; Krell et al., 2015). In this study, we found that this held true on surgical units, where about 53% of patients received prophylaxis regardless of their risk score. On non-surgical units, 24.4% of low risk patients received prophylaxis, yet only 14% with a risk score greater than 3 received it.

Since unit type proved to be a major predictor of VTE prophylaxis, in accordance with the literature, sub-analyses were completed. In a 2014 study (Elder et al.), researchers found that nurses on 'low performing' units believed VTE prophylaxis was prescribed for patients who did not need it, and that administration was not required. When examining surgical units alone, less variation was found: the only significant predictors of prophylaxis administration were a VTE score 0-2 or a score not documented. Appropriately, these patients were less likely to receive prophylaxis. This lack of variation suggests that surgical units likely operate similarly across the institution. When exploring non-surgical units, much more variation existed. As expected, patients with a VTE risk score of 0-2 were less likely to receive prophylaxis. Other predictors that negatively impacted the administration of VTE prophylaxis were other nurse HPPD and complexity. Since RN HPPD increased the likelihood of receiving prophylaxis, one can understand how a skill mix including non-RN unit staff, float nurses, travel nurses, and non-licensed personnel can impact task completion. Since patients excluded from receiving VTE prophylaxis were not included in this study, it is surprising that complexity negatively impacted the administration of prophylaxis.

Knowing that risk should determine treatment, we also examined differences between the two risk groups (VTE risk score 0-2 and 3 or greater). Predictors for both

groups included RN HPPD, complexity, and surgical unit. As RN HPPD increased, prophylaxis was more likely to be administered. Additionally, as previously mentioned, patients on surgical units were also more likely to receive prophylaxis. In the context of the full model, complexity had a positive impact on prophylaxis administration.

It was more difficult to apply the model to postoperative occurrences, which are often rare events. The rate of VTE in our population was only 1.3% (n=17). The only significant predictor of VTE events was the important finding that patients who did not receive VTE prophylaxis were more likely to have a VTE event on non-surgical units. This supports the important and well-known approach of providing VTE prophylaxis for those at risk.

Not surprisingly, when the model was applied to postoperative occurrences, complexity, measured by the Elixhauser comorbidity index, proved to be a significant predictor of readmissions, morbidity, and SSI. The census was also a predictor in readmissions and morbidity. Two predictors of particular note include the negative relationship of nurse education on readmissions and of non-surgical units on morbidity. A lower percentage of BSN-prepared nurses on a unit correlated to an increase in readmissions. This could be related to more highly developed critical thinking skills and the prevalence and quality of patient education offered by baccalaureate-prepared nurses. The finding that patients admitted to surgical units are less likely to experience all-cause morbidity supports the idea that surgical patients should be admitted to surgical units postoperatively.

### **Conclusions**

This dissertation examined pharmaceutical venous thromboembolism (VTE) prophylaxis using factors in a model of situational awareness. This was a novel approach: no previous studies have utilized secondary data sources to examine key aspects of a situational awareness model using a single condition to predict the performance of actions (administration of VTE prophylaxis) and postoperative occurrences. As the growing interest in HROs has indicated, the development and maintenance of situational awareness in the operational environment is critical to decision-making, yet its role in nursing practice has not been openly discussed and explored. For instance, existing studies have attempted to measure situational awareness in nursing in a variety of ways; however, since measurement concerns persist, stakeholders have been less interested in using situational awareness as a key criterion for healthcare delivery and redesign. Also, the academic literature has given little attention to the use of situational awareness theory and principles to drive the design of healthcare systems and environments (Riley, Endsley, Bolstad, & Cuevas, 2006; Salmon & Stanton, 2013). Such literature underscores the need to better understand situational awareness as a prominent predictor for safety and effectiveness (Salmon & Stanton, 2013). This dissertation provides important information that examines the potential implications of pharmaceutical VTE prophylaxis and of factors in a model of situational awareness.

### Limitations

The nature of this research poses several limitations. First, despite the proposed usefulness of the model in dynamic decision-making, other factors not measured in this study are likely to have an impact on the administration of VTE prophylaxis in the

operational environment. Nonetheless, the use of secondary data analysis within the existing conceptual framework facilitated the selection and manipulation of important factors that would have otherwise been difficult to study. Additionally, the differing time elements between variables also posed challenges. The primary focus was the patient receiving VTE prophylaxis within 24 hours after leaving the operating room. HPPD, census, and workload were captured for the day of the operation; therefore causing variation in how many hours the patient was on the unit during the timeframe in which HPPD and census represented. Additionally, HPPD and census began with night shift starting at 2300, whereas workload began at 0001. Although a limitation, it is critical to acknowledge the importance of activities that surround the immediate postoperative period.

### **Recommendations for Future Research**

Several findings from this study demonstrate a need for further research. First, system capability, interface design, and automation can have key role in improving situational awareness. Because the institution's EMR was upgraded in June of 2014, it would be worthwhile to use this model to explore the impact of that change.

Additionally, since unit type was the primary predictor in the administration of VTE prophylaxis, it would be sensible to explore unit-specific cultures and norms. This study suggests that workload, a term denoting 'busyness' or 'churn', impacts nursing tasks and, therefore, warrants further research as it pertains to nursing practice.

### **Implications for Practice**

Situational awareness is a key concept in HROs. It is likely that comparable attention to situational awareness in nursing may improve patient safety (Institute of

Medicine, 2000; Salmon & Stanton, 2013; Sculli & Sine, 2011; Singh, Petersen, & Thomas, 2006). Recognizing and embracing the concept of situational awareness in nursing care delivery is vital: failure to achieve and maintain situational awareness can lead to poor patient outcomes in dynamic settings. The results of this study aim to improve the understanding of the role of situational awareness in the context of hospitalized surgical patients. Findings shed light on personnel and technological resources affecting the development of situational awareness in acute inpatient nursing, and uncover ideas that could lead to interventions and appropriate strategies to support situational awareness and improve patient outcomes. By providing key information for further inquiry into the development and maintenance of individual and team situational awareness in practice, this study provides a basis to analyze situational awareness in a theoretical framework. Additional insight as to how to measure situational awareness in the clinical environment was also achieved.

This study suggests several key aspects in the administration of VTE prophylaxis. Nursing administrators should be alert to the differences between surgical and non-surgical units and understand the impact of placing postoperative patients on non-surgical units. Additionally, careful attention should be paid to RN HPPD, and attempts to meet budgeted values should be achieved. Although census is sometimes uncontrollable, workload, as it relates to the turnover seen with frequent admissions and discharges should be considered as an important factor affecting nursing care. Additionally, this study supports policy issues related to staffing units with a larger proportion of baccalaureate-prepared nurses.

This study proposed a new model of examining situational awareness to overcome current limitations, providing greater insight into the knowledge that is currently lacking, and the factors predicting performance of actions. The study produced novel insights into understanding operational safety in nursing. The model created may serve as a valuable resource for the wider scientific community, because measurement limitations of the previous model of situational awareness have constrained the advancement of knowledge in this important area.

### APPENDIX A

### **MSQC Data Collection Process**

Excerpts from the MSQC 2.0 Data Collection Manual:

## 1.0 Collecting Data

This section of the operations manual describes the various "steps" in the MSQC data collection process, identifies available resources in data collection, and how to determine which data to collect. These steps will provide a framework to enable SCQRs to fulfill the program data collection requirements.

## 1.1 The Data Collection Process

The first step in collecting data is case selection. Cases to be included in the program are initially chosen from the operative log using established inclusion and exclusion criteria. The next step is to establish the included case in the MSQC Brower-based Workstation. The minimum data elements required to establish (or "open") a case are:

- Patient's Identification Number (IDN)
- Patient's Date of Birth
- Operation Date

Once a case is opened, the SCQR should then perform a thorough review of the electronic and/or paper medical record to collect the required variables. Obtaining postoperative outcome information from the patient and/or the surgeon's clinic/office notes is often necessary in order to obtain a full and accurate record of post-operative occurrences that transpired in the 30 days following the surgical procedure. All collected data are entered into the MSQC Browser-based Workstation then transmitted to the MSQC database when case details have been completed along with 30-day follow-up information. These steps must be completed prior to a case "locking", which occurs 120 days after the surgical procedure is performed. Prior to the lock-out date, the case remains accessible for edits, but once the case locks, changes can no longer be made.

## 1.2 Data Sources

Depending on the measure, data can be collected from different sources at a given site. Likely sources include, but are not limited to, medical records and administrative records/databases for billing or care management. Each of these sources may have other primary purposes, so, for the intent of the Program, it is critical for the SCQR to collect the data using precise and consistent methods by *always* applying the Program's standardized definitions to variables when abstracting the data. Knowing where data resides is the first step in data collection.

Medical record systems vary greatly from hospital to hospital, but certain patterns exist in every system that can be utilized as a guide in identifying data sources. To optimize time and effort, seek out individuals within the organization who have knowledge of the hospital's processes and systems. Directors and managers of departments are a good place to start, as they know what information is available and of use, and how it can be made accessible to the reviewer. For example, the Surgeon Champion can be of assistance in locating much of the needed information by identifying and introducing the SCQR to the right individuals.

## 1.2.1 Patient Medical Record

Traditional medical records are generally handwritten on paper and kept in folders. These folders are typically divided into sections, and active records are usually retained at the clinical site, but older records (e.g., those of the deceased) are often kept at off-site facilities. More recently, however, hospitals are utilizing electronic medical record (EMR) systems in order to increase the accessibility of patients' files. Because medical record types vary from institution to institution, it is important to identify, early on, what forms of medical documentation exist at a particular site. The patient medical record may be paper, electronic, or some combination of the two and it is important to follow the hospital's policy regarding medical records, regardless of the format.

- **1.2.1.1** <u>Paper Medical Record:</u> Site policy regarding medical record procurement and review must be followed. In reviewing paper medical records, ensuring access to any and all required records is a must. The two types of paper record that exist are:
  - Hospital medical record: This generally comprises the patient's inpatient and/or admission records. This documentation is usually located in the Medical Records or Health Information Management Department(s)
  - Clinic medical record: This usually consists of medical documentation related to a patient's outpatient or clinic visit. This record is retained either in the surgical clinic or in individual surgeon/physician's offices
- **1.2.1.2** Electronic Medical Record (EMR): The patient's electronic medical information may be contained in multiple databases at a given institution, and can exist in combination with a paper medical record. If access has not already been obtained, supervisory approval or approval through the Surgeon Champion should be immediately secured. A member of the IT Department may also be a resource in providing suggestions regarding the location of the medical record information, and may also assist the SCQR in obtaining access. Since most hospital databases are secured, the SCQR may be required to review the data being collected with responsible individuals before access can be granted.

### 1.2.2 Operative Log

The Operative Log is a list of the surgical procedures performed at a site, and this log is necessary in determining case eligibility based on MSQC inclusion and exclusion criteria. The site's IT staff, Surgical Administrator, or OR Nurse Manager are all good resources in

helping the SCQR gain regular access to this log, as well as assist the reviewer with collating and organizing the information contained in the log to optimize case selection.

OF NOTE: The Operative Log is to be used, NOT the Operative Schedule. The *Operative Schedule* is a list of patients *scheduled* for surgical procedures and is prepared the day before the operative procedure. The operative schedule will not list any emergency or other add-on procedures, so it is not reflective of the actual surgeries performed on a given day. The *Operative Log* documents the surgical procedures that were *actually performed*. This list includes elective, urgent, emergent, and add-on procedures. Any cancelled cases will not be on the list. The Operative Log is generally not available until at least the day after surgery (the exact time of availability is site-specific, and may take up to 30-45 days to be finalized). However, the Operative Log (non-finalized) will still provide you with important information such as the patient's name, medical record number, age and/or date of birth, name of the surgeon who performed the procedure, the procedure performed, the date and time of operation, OR room number, type of anesthesia administered, ASA class, and, sometimes, the wound classification.

\*Obtaining a list of surgical procedures that were <u>actually</u> performed (including any add-on or emergency cases) is critical: Operative Log. DO NOT use the list of surgical procedures that were <u>scheduled</u> to be performed.

## 1.3 8-Day Cycle Schedule

For purposes of the Program, each calendar year is divided into (46) 8-day cycles. To eliminate sampling bias, the first 25 consecutive procedures that meet program inclusion criteria are to be selected for a given 8-day cycle. This cycle rotates every 8 days to ensure that each cycle begins with a different day of the week. All hospitals will collect the first twenty-five (25) consecutive cases that meet inclusion criteria. This equals 1050 cases annually.

The 8-Day Cycle Schedule lists the date range for each of the 46 cycles, and is used to determine the start date for selecting cases of a particular cycle. Cycle 1 always begins on January 1<sup>st</sup> of the year. This schedule **must** be followed to ensure that case selection is performed in an unbiased fashion. This schedule is located in Appendix A of the Data Collection Manual and is also noted in the MSQC Browser-based workstation once a case is entered. Please note that the cycles begin at 00:00 or 12:00 am of the first day and end at 23:59 of the last day.

# 1.5 <u>Data Collection Process</u>

There are 4 steps to the data collection process:

- 1. Case Selection
- 2. Establishment of the Case (also known as "entering" or "opening the case)
- 3. Data Collection & Entry
- 4. Case Transmission

\*\*Each step is described in detail below, however, a flow chart of the entire process can also be found at the end of this section.\*\*

### 1.5.1 Case Selection

Case selection is the first step in the data collection process and includes three parts:

**Part 1:** Applying the 8-day cycle sampling methodology. Each SCQR will be expected to collect 1050 cases annually. If a site performs more than this number of program-eligible cases annually, the 8-day cycle sampling methodology must be applied to the case selection process.

**Part 2:** Applying program-specific criteria to determine whether a case will be included in or excluded from a cycle. This process is explained in subsequent paragraphs.

**Part 3:** Assigning the order of the included cases. This process is explained a little later on in this chapter.

## 1.5.1.1 8-Day Cycle Sampling Methodology

Due to the potentially large volume of cases that meet inclusion criteria and the need to prevent bias, the 8-day cycle methodology must be utilized in order to ensure systematic sampling of cases. The 8-Day Cycle Schedule will identify the date to use to start case selection. Adherence to the 8-Day Cycle Schedule is mandatory.

Sampling of cases begins on the first day of the cycle, and should include all consecutive cases meeting program inclusion criteria. If 25 cases do not meet inclusion criteria for a given day, sampling should continue into the cycle week, until the caseload requirement is met. Once the first 25 consecutive program-eligible cases have been identified, no further case selection is required. Case selection resumes with the start of the next 8-day cycle.

## 1.5.1.2 Determining Case Inclusion/Exclusion

After identifying the start date for a given cycle, what cases are to be included is the next step. In this step, the Operative Log will be required. As previously explained, the Operative Log will provide a list of surgical cases for a given procedure date. From it, the SCQR must consider inclusion and exclusion criteria in determining whether or not a case is eligible. The only acceptable source for identifying cases is the Operative Log. The log used must list ALL procedures performed on a given procedure date, including emergencies and add-ons. It should NOT be a listing of scheduled procedures. General rule of thumb: if the log is available prior to the surgical procedure date, it should not be used.

Once the Operative Log for the corresponding 8-day cycle has been accessed, the following criteria should be applied in order to determine case inclusion/exclusion.

\*\*Each step is described in detail below, however, a flow chart of the entire process can also be found in Appendix H of the Data Collection Manual.\*\*

## 1.5.1.2.1 <u>Determining Case Inclusion</u>

To determine case inclusion, the following information is needed:

- The procedure performed
- The CPT code of the performed procedure
- The age of the patient

This information is usually located in the Operative Log, with the exception of the CPT code. For program inclusion, the CPT code for the procedure must be on the program CPT code inclusion list, located in Appendix B (codes only) or Appendix C (codes with descriptions of the procedures) of the Data Collection Manual.

The CPT code must be accurately assigned, and is critical not only for case inclusion, but for data accuracy and reliability. The CPT code may not be available until several days after the surgical procedure is performed. The SCQR may assign a CPT code to the case, and once the CPT code has been assigned by the surgical billing staff or the surgeon, the code can be validated and assigned to the case. As a direct resource for cross-referencing and description, the SCQR should obtain a copy of the most-recently released edition of the CPT coding manual. Please note that while surgeons bill by CPT code, hospitals bill by both ICD-9 code (inpatient procedures) and CPT code (outpatient procedures). An up-to-date CPT code/ICD-9 crosswalk book will greatly assist in determining the CPT codes that correspond with ICD-9 procedure codes.

The source of truth for CPT code identification/assignment is the surgeon office billing department. The description of the procedure in the Operative Report should also be utilized to validate the code received from the surgeon's office (e.g., correct code for uterine weight and/or structures removed; surgical approach, etc.) <u>or</u> to assign a code in situations where the SCQR was unable to receive the code from the office. Clarification may also be received by discussion of the procedure with the Surgeon Champion or the attending surgeon. Additionally, CPT codes can be located through the Operative Log, an electronic billing program (e.g. IDX or Star) or via the hospital coders but only after utilizing the surgeon office billing department and/or Operative Report (Please see the priority algorithm listed in the definition for variable C2) "CPT Code".)

In addition, the MSQC browser-based workstation offers the functionality of a CPT code lookup. To determine program inclusion, simply enter the procedure name to search the database for the CPT code corresponding to the procedure performed.

### 1.5.1.2.2 Determining Case Exclusion

To determine if a case should be exempt, apply the following exclusion criteria:

- Patients under the age of 18 years
- More than 3 elective laparoscopic cholecystectomies in an 8-day cycle (see CPT code list in Appendix D of the Data Collection Manual)
- Trauma cases: A patient who is admitted to the hospital with acute trauma and has surgery(s) for that trauma will be excluded. Any operation performed after the patient has been discharged from the trauma stay will be included if other inclusion criteria are met

- (see Trauma Decision Tree in Appendix I of the Data Collection Manual).
- Transplant cases: A patient who is admitted to the hospital for a transplant and has a transplant procedure and any additional surgical procedure during the transplant hospitalization will be excluded. Any operation performed after the patient has been discharged from the transplant stay will be included, if inclusion criteria are met.
- ASA 6 (brain-death organ donors)
- Multiple cases within 30 days: Any case performed within 30 days of another surgical case that has been previously sampled by MSQC methodology performed on the patient will be excluded.
- Cases over and above the required 25 cases per 8-day cycle are not required for the program to generate a statistically significant report. The required number of cases per SCQR per cycle is 25.
- Concurrent Case: Operative procedures performed during the case by a different surgical team but under the same anesthesia (for example, a Hysterectomy procedure on a patient who is also undergoing a Total Colectomy) are not to be assessed separately. This additional procedure is to be reported as 'Concurrent' in the operative section for the assessed case.
- Cases falling within a vacation cycle. There are (46) 8-day cycles in a year. The SCQR is allowed four (4) cycles each program year (from September 1, XXXX August 31, XXXX) to use as vacation cycles. Cases are not required to be submitted during vacation cycles.

## 1.5.1.3 <u>Determining Consecutive Cases in an 8-Day Cycle</u>

What is needed to determine the consecutive order of cases for inclusion: the date of operation, in room time, and OR room number from the Operative Log. Consecutive order is determined first by the date of the operation, and then in order of the time the patient is brought into the operating room. If multiple patients have the same 'In Room' times, the OR room number (from lowest to highest) is used to determine the consecutive cases.

The first 25 consecutive cases that meet inclusion criteria will be assessed per cycle.

Revised: April 1, 2014 Copyright © 2014, Regents of the University of Michigan, All Rights Reserved For more information contact: Michigan Surgical Quality Collaborative, Patient Safety Organization (MSQC PSO) MSQCCustomerSupport@med.umich.edu (734) 998-8200

## **APPENDIX B**

# **MSQC CPT Code Inclusion List**

Excerpts from the MSQC 2.0 Data Collection Manual:

MSQC CPT Code Inclusion List - October 2014 MSQC Cohort 2014 Only MSQC 2.0 Data Collection Manual Revised: October 1, 2014 Copyright 2014 Regents of the University of Michigan

General Surgery	CPT Codes	Notes
Adrenalectomy	60540, 60545, 60650	
Appendectomy	44950, 44960, 44970,	
	44979	
Laparoscopic Cholecystectomy	47562, 47563, 47564	
Open Cholecystectomy	47600, 47605, 47610,	
	47612, 47620	
Partial Colectomy	44140, 44141, 44143,	Colorectal Procedure-Targeted
•	44144, 44145, 44146,	variables will be collected for
	44147, 44160, 44204,	cases with these CPT codes
	44205, 44206, 44207,	
	44208	
Total Colectomy	44150, 44151, 44210	Colorectal Procedure-Targeted
·		variables will be collected for
		cases with these CPT codes
Total Proctocolectomy	44155, 44156, 44157,	Colorectal Procedure-Targeted
,	44158, 44211, 44212	variables will be collected for
		cases with these CPT codes
Proctectomy	45110, 45111, 45112,	Colorectal Procedure-Targeted
,	45113, 45114, 45116,	variables will be collected for
	45119, 45120, 45121,	cases with these CPT codes
	45123, 45126, 45130,	EXCEPT FOR THESE CODES:
	45135, 45160, 45171,	45123, 45400, 45540,
	45172, 45395, 45397,	
	45400, 45402, 45540,	
	45550	
Colon Procedures	44186, 44187, 44188,	Colorectal Procedure-Targeted
	44227, 44300, 44310,	variables will be collected for
	44312, 44314, 44320,	cases with these CPT codes ONLY:
	44322, 44340, 44345,	44186, 44187, 44188,
	44346, 44602, 44603,	44227, 44300, 44310, 44312,
	44604, 44605, 44620,	44314, 44320, 44322, 44340,
	44625, 44626, 44640,	44345, 44346, 44602, 44603,
	44650, 44660, 44661,	44604, 44605, 44620, 44625,
	44800, 45120, 45136	44626, 44640, 44650, 44660,
		44661, 44800, 45120, 45136

Esophageal Procedures	43130, 43135, 43360,	
Esophiagean roceaules	43361	
Esophagectomy	43100, 43101, 43107,	
	43108, 43112, 43113,	
	43116, 43117, 43118,	
	43121, 43122, 43123,	
	43124	
Gastrectomy	43620, 43621, 43622,	
	43631, 43632, 43633,	
	43634	
Gastric Procedures	43500, 43501, 43502,	
	43659, 43832, 43840,	
	43999	
Hepatectomy	47120, 47122, 47125,	Use CPT Code 47379 (Unlisted
,	47130, 47379	laparoscopic procedure, liver) for
		laparoscopic hepatectomies
Ventral Hernia Repair	49560, 49561, 49565,	
ventian repair	49566, 49652, 49653,	
	49654, 49655, 49656,	
	49657	
Groin Hernia Repair	49505, 49507, 49520,	
C. C. III. C. III. I. C. III.	49521, 49525, 49550,	
	49553, 49555, 49557,	
	49650, 49651	
Umbilical Hernia Repair	49585, 49587, 49652,	
	49653	
Mastectomy	19303, 19304, 19305,	
,	19306, 19307	
Pancreatectomy	48105, 48120, 48140,	Use CPT Code 48999 ONLY if actual
•	48145, 48146, 48148,	procedure is a laparoscopic or
	48150, 48152, 48153,	robotic removal of either a portion
	48154, 48155, 48999	of, or all of, the pancreas
Anti-reflux surgery and Paraesophageal	43279, 43280, 43281,	Use CPT Code 43499 (Unlisted
Hernia Repair	43282, 43325, 43327,	procedure, esophagus) for a TIF
	43328, 43330, 43331,	(Transoral Incisionless
	43332, 43333, 43334,	Fundoplication)
	43335, 43336, 43337,	
	43499	
Small Bowel Resection & Stricturoplasty	44120, 44125, 44130,	Colorectal Procedure-Targeted
, ,	44202, 44615	variables will be collected for
		cases with these CPT codes
Surgery for Small Bowel Obstruction	44005, 44020, 44021,	Procedure is only included if the
	44050, 44055, 44180	"Postoperative ICD-9 Code" is
		entered into the workstation for
		"bowel obstruction" (560, 560.0,
		560.1, 560.2, 560.3, 560.30,
		560.31, 560.32, 560.39, 560.8,
		560.81, 560.89, 560.9)
Splenectomy	38100, 38101, 38102,	
	38115, 38120, 38129	
Thyroidectomy	60210, 60212, 60220,	
	60225, 60240, 60252,	
	60254, 60260, 60270	

	60271	
Gyne Surgery	CPT Codes	Notes
Hysterectomy - Deleted code (see	58150, 58152, 58180,	Hysterectomy Procedure-
Notes)	58200, 58210, 58240,	Targeted variables will be
	58260, 58262, 58263,	collected for cases with these CPT
	58267, 58270, 58275,	codes
	58280, 58285, 58290,	
	58291, 58292, 58293,	
	58294, 58541, 58542,	
	58543, 58544, 58550,	
	58552, 58553, 58554,	
	58570, 58571, 58572,	
	58573, 58548, 58950,	
	58951, 58952, 58953,	
	58954, 58956, 59525	
<u>Vascular Surgery</u>	CPT Codes	Notes
Amputations	27590, 27592, 27594,	
	27596, 27598, 27880,	
	27882, 27884, 27886	
Aneurysm Repair	35141, 35151	
Open AAA	34830, 34831, 34832,	
	35081, 35082, 35091,	
	35092, 35102, 35103	
Endo AAA	0236T, 34800, 34802,	
	34803, 34804, 34805,	
	34825	
Open Aortoiliac	35131, 35565, 35665	
Endo Aortoiliac	0238T, 37220, 37221,	
	37222, 37223	
Carotid Endarterectomy	35301	
Open Lower Extremity Bypass	35538, 35539, 35540,	
	35556, 35558, 35566,	
	35571, 35583, 35585,	
	35587, 35621, 35623,	
	35637, 35638, 35646,	
	35647, 35654, 35656,	
	35661, 35663, 35666,	
	35671	
Endo Lower Extremity Bypass	37224, 37225, 37226,	
	37227, 37228, 37229,	
	37230, 37231, 37232,	
	37233, 37234, 37235	

### APPENDIX C

### **MSQC Postoperative Occurrences**

Excerpts from the MSQC 2.0 Data Collection Manual:

**MSQC 2.0 Data Collection Manual** 

Revised: April 1, 2014 Copyright © 2014, Regents of the University of Michigan, All Rights Reserved For more information contact: Michigan Surgical Quality Collaborative, Patient Safety Organization (MSQC PSO)

MSQCCustomerSupport@med.umich.edu (734) 998-8200

## K1a) Superficial Incisional SSI

**Intent of Variable:** To capture the occurrence of infection that does not meet the more severe criteria

of deep incisional SSI or organ/space SSI.

**Definition:** Superficial incisional SSI must meet the following criterion:

Infection occurs within 30 days of the procedure

### and

involves only skin and subcutaneous tissue of the incision

### and

patient has at least 1 of the following:

- a. purulent drainage from the superficial incision
- b. organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial

incision

c. superficial incision that is deliberately opened by a surgeon, attending physician or other designee

and is culture-positive or not cultured

#### and

patient has at least one of the following signs or symptoms of infection: pain or tenderness; localized

swelling; redness; or heat. A culture negative finding does not meet this criterion

d. diagnosis of superficial incisional SSI by the surgeon or attending physician or other designee

### **Variable Options:**

- 1. Select "Superficial Incisional SSI" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

### **Notes:**

1. Do not report a stitch abscess (minimal inflammation and discharge confined to the points of

suture penetration) as an infection.

- 2. Do not report a localized stab wound or pin site infection as SSI.
- 3. "Cellulitis", by itself, does not meet criteria for superficial incisional SSI.
- 4. If the superficial incisional infection involves or extends into the fascial or muscle layers,

report as a deep incisional SSI only.

5. Report infection that involves the organ/space as an organ/space SSI, whether or not it also

involves the superficial or deep incision sites.

6. The term attending physician for the purposes of the SSI criteria may be interpreted to mean the

surgeon(s), infectious disease, other physician on the case, emergency physician or physician's

designee (nurse practitioner or physician's assistant).

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Nursing Flowcharts, Nursing

Notes, Physician Office Notes, ED documentation (presentation after discharge)

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

Healthcare-Associated Infection and Criteria for Specific Types of Infection in the Acute Care Setting.

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**MSQC 2.0 Data Collection Manual** 

## K1b) Deep Incisional SSI

**Intent of Variable:** To capture the occurrence of infection that does not meet the criteria of superficial

incisional SSI or organ/space SSI. These infections are typically more severe than the superficial SSI

category.

**Definition:** Deep incisional SSI must meet the following criterion:

Infection occurs within 30 days of the procedure

### and

involves deep soft tissues of the incision (e.g., fascial and muscle layers)

#### and

patient has at least one of the following:

a. purulent drainage from the deep incision

b. a deep incision that spontaneously dehisces or is deliberately opened by a surgeon, attending

physician or other designee and is culture-positive or not cultured

#### and

patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or

tenderness. A culture-negative finding does not meet this criterion.

c. an abscess or other evidence of infection involving the deep incision is found on direct examination,

during invasive procedure, or by histopathologic examination or imaging test.

d. diagnosis of a deep incisional SSI by a surgeon or attending physician or other designee

### **Variable Options:**

- 1. Select "Deep Incisional SSI" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

### **Notes:**

- 1. Classify infection that involves both superficial and deep incisional sites as deep incisional SSI.
- 2. Report infection that involves the organ/space as an organ/space SSI, whether or not it also

involves the superficial or deep incision sites.

3. The term attending physician for the purposes of the SSI criteria may be interpreted to mean the

surgeon(s), infectious disease, other physician on the case, emergency physician or physician's

designee (nurse practitioner or physician's assistant).

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Results, Nursing

Flowcharts, Nursing Notes, Physician Office Notes, ED documentation (presentation after discharge)

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

Healthcare-Associated Infection and Criteria for Specific Types of Infection in the Acute Care Setting.

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## **K1c) Organ/Space SSI**

**Intent of Variable:** To capture the occurrence of infection that does not meet the criteria of superficial

incisional SSI or deep incisional SSI. This category of infection is typically the most severe and is

more likely to require procedural intervention.

**Definition:** Organ/Space SSI must meet the following criterion:

Infection occurs within 30 days of the procedure

#### and

infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is

opened or manipulated during the operative procedure

and

patient has at least 1 of the following:

- a. purulent drainage from a drain that is placed into the organ/space
- b. organisms isolated from an aseptically-obtained culture of fluid or tissue in the organ/space
- c. an abscess or other evidence of infection involving the organ/space that is found on direct

examination, during invasive procedure, or by histopathologic examination or imaging test

d. diagnosis of an organ/space SSI by a surgeon or attending physician or other designee

# meets at least one criterion for a specific organ/space infection site listed in **Table 1**Table 1 - Site-Specific Classifications of Organ/Space Surgical Site Infection

Arterial or venous infection

Endometritis

Gastrointestinal tract (esophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis

**Hepatitis** 

Intra-abdominal, not specified elsewhere including gallbladder, bile ducts, liver (excluding viral hepatitis), spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, or other intra-abdominal tissue or area not specified elsewhere

Joint or bursa

Osteomyelitis

Other infections of the urinary tract (kidney, ureter, bladder, urethra, or tissue surrounding the retroperitoneal or perinephric space)

Other male or female reproductive tract (epididymis, testes, prostate, vagina, ovaries, uterus, or other deep pelvic tissues, excluding endometritis or vaginal cuff infections)

Vaginal cuff

# **Arterial or venous infection:** Arterial or venous infection must meet at least *1* of the following

criteria:

1. Patient has organisms cultured from arteries or veins removed during an invasive procedure

### and

blood culture not done or no organisms cultured from blood.

2. Patient has evidence of arterial or venous infection seen during an invasive procedure or

histopathologic examination.

3. Patient has at least 1 of the following signs or symptoms: fever (>38°C), pain\*, erythema\*, or heat at

involved vascular site\*

### and

more than 15 colonies cultured from intravascular cannula tip using semiquantitative culture method

### and

blood culture not done or no organisms cultured from blood.

- \* With no other recognized cause
- 4. Patient has purulent drainage at involved vascular site

### and

blood culture not done or no organisms cultured from blood.

**Endometritis:** Endometritis must meet at least *1* of the following criteria:

1. Patient has organisms cultured from fluid (including amniotic fluid) or tissue from endometrium

obtained during an invasive procedure or biopsy.

2. Patient has at least 2 of the following signs or symptoms: fever (>38°C), abdominal pain\*, uterine

tenderness\*, or purulent drainage from uterus\*.

\* With no other recognized cause

**Gastrointestinal tract infection:** Gastrointestinal tract infections, excluding gastroenteritis and

appendicitis, must meet at least *I* of the following criteria:

1. Patient has an abscess or other evidence of infection seen during an invasive procedure or

histopathologic examination.

2. Patient has at least 2 of the following signs or symptoms compatible with infection of the organ or

tissue involved: fever (>38°C), nausea\*, vomiting\*, abdominal pain\*, or tenderness\* or diarrhea\*

#### and

at least 1 of the following:

a. organisms cultured from drainage or tissue obtained during an invasive procedure or endoscopy or

from an aseptically-placed drain

b. organisms seen on Gram's or KOH stain or multinucleated giant cells seen on microscopic

examination of drainage or tissue obtained during an invasive procedure or endoscopy or from an

aseptically-placed drain

- c. organisms cultured from blood
- d. evidence of pathologic findings on imaging test
- e. evidence of pathologic findings on endoscopic examination (e.g., *Candida esophagitis* or *proctitisor*

toxic megacolon).

\* With no other recognized cause

**Hepatitis:** Patient has at least 2 of the following signs or symptoms: fever ( $>38^{\circ}$ C), anorexia\*,

nausea\*, vomiting\*, abdominal pain\*, jaundice\*, or history of transfusion within the previous 3

months

and

at least 1 of the following:

a. positive laboratory test for acute hepatitis A, hepatitis B, hepatitis C, or delta hepatitis and duration

of hospital stay consistent with healthcare acquisition

- b. abnormal liver function tests (e.g., elevated ALT/AST, bilirubin)
- c. cytomegalovirus (CMV) detected in urine or oropharyngeal secretions.
- \* With no other recognized cause

### **Notes**

- 1. Do not report hepatitis or jaundice of noninfectious origin (alpha-1 antitrypsin deficiency,
- etc.).
- 2. Do not report hepatitis or jaundice that result from exposure to hepatotoxins (alcoholic or
- acetaminophen- induced hepatitis, etc.).
- 3. Do not report hepatitis or jaundice that result from biliary obstruction (cholecystitis).

# Intra-abdominal infection, not specified elsewhere: Intraabdominal infections must meet at least I

- of the following criteria:
- 1. Patient has organisms cultured from abscess and/or purulent material from intraabdominal space
- obtained during an invasive procedure.
- 2. Patient has abscess or other evidence of intraabdominal infection seen during an invasive procedure
- or histopathologic examination.
- 3. Patient has at least 2 of the following signs or symptoms: fever (>38°C), nausea\*, vomiting\*,
- abdominal pain\*, or jaundice\*

### and

- at least *I* of the following:
- a. organisms cultured from drainage from an aseptically-placed drain (e.g., closed suction drainage
- system, open drain, T-tube drain, CT guided drainage)
- b. organisms seen on Gram's stain of drainage or tissue obtained during invasive procedure or from an
- aseptically-placed drain
- c. organisms cultured from blood and imaging test evidence of infection (e.g., abnormal findings on
- ultrasound, CT scan, MRI, or radiolabel scans [gallium, technetium, etc.] or on abdominal x-ray).
- \* With no other recognized cause

**Note:** Do not report pancreatitis (an inflammatory syndrome characterized by abdominal pain, nausea,

and vomiting associated with high serum levels of pancreatic enzymes) unless it is determined to be

infectious in origin.

**Joint or bursa:** Joint or bursa infections must meet at least *I* of the following criteria:

- 1. Patient has organisms cultured from joint fluid or synovial biopsy.
- 2. Patient has evidence of joint or bursa infection seen during an invasive procedure or histopathologic
- examination.

3. Patient has at least 2 of the following signs or symptoms with no other recognized cause: joint pain,

swelling, tenderness, heat, evidence of effusion or limitation of motion

### and

at least 1 of the following:

- a. organisms and white blood cells seen on Gram's stain of joint fluid
- b. positive laboratory test on blood culture or appropriate antigen test on blood, urine, or joint fluid
- c. cellular profile and chemistries of joint fluid compatible with infection and not explained by an

underlying rheumatologic disorder

d. imaging test evidence of infection (e.g., abnormal findings on x-ray, CT scan, MRI, radiolabel scan

[gallium, technetium, etc.]).

**Osteomyelitis:** Osteomyelitis must meet at least *1* of the following criteria:

- 1. Patient has organisms cultured from bone.
- 2. Patient has evidence of osteomyelitis on direct examination of the bone during an invasive

procedure or histopathologic examination.

3. Patient has at least 2 of the following signs or symptoms: fever (>38°C), localized swelling\*,

tenderness\*, heat\*, or drainage at suspected site of bone infection\* and

at least 1 of the following:

- a. organisms cultured from blood
- b. positive laboratory test on blood (e.g., antigen tests for *H influenzae* or *S pneumoniae*)
- c. imaging test evidence of infection (e.g., abnormal findings on x-ray, CT scan, MRI, radiolabel scan

[gallium, technetium, etc.]).

\* With no other recognized cause

Other infections of the urinary tract: Other infections of the urinary tract must meet at least I of the

following criteria:

1. Patient has microorganisms isolated from culture of fluid (other than urine) or tissue from affected

site.

2. Patient has an abscess or other evidence of infection seen on direct examination, during an invasive

procedure, or during a histopathologic examination.

Patient has at least 2 of the following signs or symptoms: fever (>38°C), localized pain\*, or localized

tenderness at the involved site\*

### and

at least 1 of the following:

a. purulent drainage from affected site

- b. microorganisms cultured from blood that are compatible with suspected site of infection
- c. imaging test evidence of infection (e.g., abnormal ultrasound, CT scan, magnetic resonance imaging

[MRI], or radiolabel scan [gallium, technetium]).

\*With no other recognized cause

# Other male or female reproductive tract infection: Other infections of the male or female

reproductive tract must meet at least 1 of the following criteria:

- 1. Patient has organisms cultured from tissue or fluid from affected site.
- 2. Patient has an abscess or other evidence of infection of affected site seen during an invasive

procedure or histopathologic examination.

3. Patient has 2 of the following signs or symptoms: fever (>38°C), nausea\*, vomiting\*, pain\*,

tenderness\*, or dysuria\*

### and

at least 1 of the following:

- a. organisms cultured from blood
- b. physician diagnosis.
- \* With no other recognized cause

**Vaginal cuff infection:** Vaginal cuff infections must meet at least *1* of the following criteria:

- 1. Posthysterectomy patient has purulent drainage from the vaginal cuff.
- 2. Posthysterectomy patient has an abscess at the vaginal cuff.
- 3. Posthysterectomy patient has pathogens cultured from fluid or tissue obtained from the vaginal cuff.

### **Variable Options:**

- 1. Select "Organ/Space SSI" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

### **Notes:**

1. Because an organ/space SSI involves any part of the body, excluding the skin incision, fascia.

or muscle layers, that is opened or manipulated during the operative procedure, the criterion for

infection at these body sites must be met in addition to the organ/space SSI criteria. For example, an appendectomy with subsequent subdiaphragmatic abscess would be reported as an

organ/space SSI at the intraabdominal specific site when both organ/space SSI and intraabdominal criteria are met. **Table 1** lists the specific sites that must be used to differentiate

organ/space SSI.

2. If a patient has an infection in the organ/space being operated on, subsequent continuation of

this infection type during the remainder of the surveillance period is considered an organ/space

SSI, if organ/space SSI and site-specific infection criteria are met.

3. The term attending physician for the purposes of the SSI criteria may be interpreted to mean the

surgeon(s), infectious disease, other physician on the case, emergency physician or physician's

designee (nurse practitioner or physician's assistant).

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Results, Nursing

Flowcharts, Nursing Notes, Physician Office Notes, ED documentation (presentation after discharge)

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

Healthcare-Associated Infection and Criteria for Specific Types of Infection in the Acute Care Setting.

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## K2a) Pneumonia

**Intent of Variable:** To identify patient(s) that developed an ongoing infectious process involving the

lung(s) postoperatively affecting their physiology as described.

**Definition:** Enter "Yes" if the patient has pneumonia meeting the definition below AND pneumonia

was not present preoperatively. Patients with pneumonia must meet criteria from both Radiology and

*Signs/Symptoms sections* listed as follows:

## **Radiology:**

Two or more serial chest radiographs (x-ray or CT)\* with at least **one** of the following:

- New *or* progressive and persistent infiltrate
- Consolidation or opacity
- Cavitation

\*\*Note: In patients without underlying pulmonary or cardiac disease (e.g. respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph (x-ray or CT) is acceptable.\*\*

## **Signs/Symptoms:**

FOR ANY PATIENT, at least **one** of the following:

- Fever (>380C or >100.40F)
- Leukopenia (<4000 WBC/mm³) or leukocytosis(≥12,000 WBC/mm³)
- For adults  $\geq$  70 years old, altered mental status with no other recognized cause

### And

At least **two** of the following:

- New onset of purulent sputum, or change in character of sputum (this change refers to the color, consistency, odor, and quantity), or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, or dyspnea, or tachypnea (respiration rate >25 breaths per minute)
- Rales (crackles) or rhonchi (bronchial breath sounds)
- Worsening gas exchange (e.g. O₂ desaturations (e.g., PaO₂/FiO₂ ≤ 240), increased oxygen requirements, or increased ventilator demand)

## **Variable Options:**

- 1. Select "Pneumonia" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** 

1. Serial radiographs should be no less than 12 hours apart and no more than 7 days apart. Assign

the occurrence on the date all of the PNA criteria is first met. Do not use the date of the second

radiograph as the date of the occurrence.

2. Physician diagnosis of pneumonia alone is not an acceptable criterion for healthcare-associated

pneumonia

3. If pneumonia was present preoperatively and resolved postoperatively and a new pneumonia is

identified within 30 days after surgery, the following criteria must be met in order to report as a

postoperative pneumonia occurrence:

☐ Patient must have completed the antibiotic course for the previous pneumonia
☐ Patient must have evidence of a clear chest x-ray after the previous pneumonia and
prior

to the new pneumonia

**Preoperative Risk** 

**Factor Assigned** 

**Potential** 

**Postoperative** 

Occurrence

Criteria to Assign

## **Postoperative Occurrence**

Pneumonia Pneumonia - Patient must have completed course of antibiotics for previous pneumonia

- Patient must have evidence of a clear chest x-ray after the previous pneumonia & before the new pneumonia

4. Pneumonia due to gross aspiration (for example, in the setting of intubation in the emergency

room or operating room) is considered healthcare associated if it meets any specific criteria.

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Reports, Nursing

Flowcharts, Nursing Notes, Physician Office Notes, ED documentation (presentation after discharge),

Respiratory Therapy Notes

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

Healthcare-Associated Infection and Criteria for Specific Types of Infection in the Acute Care Setting.

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## **K2b)** Unplanned Intubation for Respiratory/Cardiac Failure

**Intent of Variable:** To capture all unplanned intubations for respiratory or cardiac failure during

surgery or within the 30 days after the principal operative procedure.

**Definition**: Patient required placement of an endotracheal tube and mechanical or assisted ventilation

because of the onset of respiratory or cardiac failure manifested by severe respiratory distress, hypoxia,

hypercarbia, or respiratory acidosis. **Note whether this occurs in the intraoperative or the** 

### postoperative time period.

## **Variable Options:**

1. Select "Unplanned Intubation - Intraop" or "Unplanned Intubation - Postop" from the dropdown

menu

- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** 

1. In patients who were intubated for their surgery, unplanned intubation occurs after they have

been extubated after surgery.

2. In patients who were not intubated before the surgery start time, intubation at any time after the

procedure begins is considered unplanned.

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Results, Nursing

Flowcharts, Nursing Notes, Physician Office Notes, Respiratory Therapy Notes

## **K2c) Pulmonary Embolism**

**Intent of Variable:** The identification of a new blood clot in a pulmonary artery causing obstruction (complete or partial) of the blood supply to the lungs. The blood clots usually originate

in the deep leg veins or the pelvic venous system.

**Definition**: Enter "YES" if the patient has a V-Q scan interpreted as high probability of pulmonary embolism or a positive CT spiral exam, TEE, pulmonary arteriogram, 2-D echocardiogram

or CT angiogram.

## Variable Options:

- 1. Select "Pulmonary Embolism" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** 

- 1. Treatment usually consists of:
- Initiation of anticoagulation therapy
- Placement of mechanical interruption (for example Greenfield Filter), for patients in whom anticoagulation is contraindicated or already instituted.

**Suggested data sources/locations:** Progress Notes, Radiology Results, Nursing Flowcharts, Nursing

Notes, Physician Office Notes, ED documentation (presentation after discharge)

## **K3a)** Acute Renal Insufficiency and/or Failure

**Intent of Variable:** To identify the patient with significant renal compromise at their most severe

renal insufficiency/failure stage.

**Definition:** Indicate acute or worsening renal failure based on the presence of one or more of the

following:

a) Increase of serum creatinine to > 2.0 mg/dL, with value also being two times greater than the

most recent preoperative level

b) A new requirement for dialysis postoperatively (incl. peritoneal dialysis, hemodialysis,

hemofiltration, hemodiafiltration, or ultrafiltration)

## **Variable Options:**

- 1. Select "Acute Renal Insufficiency and/or Failure" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** Enter this variable as a postoperative occurrence even if a patient requires

dialysis, but refuses

to have it.

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Nursing Flowcharts, Nursing

Notes, Dialysis Flowsheet, Physician Office Notes, ED documentation (presentation after discharge)

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## **K3b)** Urinary Tract Infection

**Intent of Variable:** To identify patient(s) who developed a symptomatic (SUTI) or catheter-associated

urinary tract infection (CAUTI) within 30 days of the principal operative procedure. Urinary tract

infections (UTIs) are tied with pneumonia as the second most common type of healthcare-associated

infection, second only to SSIs which serves to underscore its importance in risk stratification.

**Definition:** Indicate the presence of either a symptomatic urinary tract infection (SUTI) or catheterassociated

urinary tract infection (CAUTI) within 30 days of the principal operative procedure. **Note** that CAUTI is assigned (instead of SUTI) when the patient either has a catheter in place, or is

within 48 hours of catheter discontinuation, at the time of specimen collection for UA/culture.

Diagnosis must meet the following criteria:

- 1. At least 1 of the following with no other recognized cause:
- Fever ( $> 38^{\circ}$  C)
- Urgency
- Frequency
- Dysuria
- Suprapubic Tenderness
- Costovertebral Angle Pain or Tenderness

### **AND** either:

# 2a. A positive urine culture of ≥105 colony-forming units (CFU)/ml with no more than 2 species

of microorganisms

OR

### 2b. A positive urinalysis demonstrated by at least 1 of the following findings:

- Positive dipstick for leukocyte esterase and/or nitrite
- Pyuria (urine specimen with  $\geq 10~\rm WBC/mm^3$  of unspun urine or  $> 5~\rm WBC/high$  power field of spun

urine)

- Microorganisms seen on Gram stain of unspun urine

A positive urine culture of  $\geq 10^3$  and < 105 CFU/ml with no more than 2 species of microorganisms

### Variable Options:

1. Select "Urinary Tract Infection (UTI) – SUTI"" or "Urinary Tract Infection (UTI) - CAUTI" from

the dropdown menu

- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude:

- 1. Asymptomatic Urinary Tract Infection
- 2. Patients with indwelling urinary catheters who do not display signs or symptoms **Notes:**
- 1. Elements of the criterion must occur within a timeframe that does not exceed a gap of

calendar day between the two adjacent elements (two adjacent elements are either #1 and #2a

or #1 and #2b).

2. Date of diagnosis will be when symptoms occur and urine specimen is collected, NOT when

UA/culture results are available.

3. If the patient has a recent history of an indwelling urinary catheter but there is no documentation to confirm that it was discontinued within 48 hours of specimen collection.

record the UTI as an "SUTI".

4. If SUTI/CAUTI was assigned preoperatively, please note the following before also assigning

postoperatively:

a) You may assign a new postoperative SUTI/CAUTI anytime within the 30 day postoperative

period if the cultured uropathogen is completely different/new from the uropathogen that was cultured preoperatively.

b) You may NOT assign a postoperative occurrence of SUTI/CAUTI until at least POD 7 (1 week after the date of the principal operative procedure) if the cultured uropathogen is the same as the uropathogen that was cultured preoperatively.

### **Preoperative Risk**

**Factor Assigned** 

**Potential** 

**Postoperative** 

Occurrence

Criteria to Assign

### **Postoperative Occurrence**

**Urinary Tract** 

Infection

Urinary Tract

Infection

- 1. New uropathogen cultured anytime within 30 days postop
- 2. Same uropathogen cultured cannot assign until at least POD 7

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Nursing Flowcharts, Nursing

Notes, Physician Office Notes, ED documentation (presentation after discharge)

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

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## K4a) Stroke/CVA

**Intent of Variable:** To identify patient(s) who developed an acute cerebral vascular accident or acute

stroke after surgery affecting their physiology as described.

**Definition**: Patient develops an embolic, thrombotic, or hemorrhagic vascular accident or stroke with

motor, sensory, or cognitive dysfunction (for example, hemiplegia, hemiparesis, aphasia, sensory

deficit, impaired memory) that persists for 24 or more hours.

## **Variable Options:**

- 1. Select "Stroke/CVA" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** 

1. If there is no documentation of a specific time frame for the occurrence, but a stroke has been

diagnosed, assign the occurrence.

2. Do not assign the occurrence if there is documentation that specifically states that the dysfunction

resolved within the 24 hour timeframe.

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Results, Nursing

Flowcharts, Nursing Notes, Dialysis Flowsheet, Physician Office Notes, ED documentation

(presentation after discharge)

# K5a) Cardiac Arrest Requiring CPR

**Intent of Variable:** To identify patient(s) who experienced a cardiac arrest or dysfunction and

required the initiation of CPR.

**Definition**: The absence of cardiac rhythm or presence of chaotic cardiac rhythm, either intraoperatively or within the 30 days following the principal operative procedure, which results in a

cardiac arrest requiring the initiation of CPR, which includes chest compressions. **Note** whether the

occurrence was during the intraoperative or postoperative time period. Variable Options:

1. Select "Cardiac Arrest req. CPR - Intraop" or "Cardiac Arrest req. CPR - Postop" from the

dropdown menu

- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

### **Include:**

- 1. Patients who are in a pulseless VT or VFib in which defibrillation is performed
- 2. PEA arrests requiring chest compressions

**Exclude:** Patients with automatic implantable cardioverter defibrillator (AICD) that fire but the patient

has no loss of consciousness

**Notes:** N/A

**Suggested data sources/locations:** Progress Notes, Nursing Flowcharts, Nursing Notes, Physician

Office Notes, Medication Administration Record (MAR), Code Documentation, ED documentation

(presentation after discharge)

## K5b) Myocardial Infarction

**Intent of Variable:** To identify patient(s) who sustain an acute myocardial infarction (intraop or

postop) affecting their physiology as described.

**Definition**: The term acute myocardial infarction (MI) should be used when there is evidence of

myocardial necrosis in a clinical setting consistent with acute myocardial ischaemia. Under these

conditions any of the following criteria meets the diagnosis for MI:

• Detection of a rise and/or fall of cardiac biomarker values [preferably cardiac troponin (cTn)] with at

least one value above the 99th percentile upper reference limit (URL) and with at least one of the

following:

- \_ Symptoms of ischaemia
- \_ New or presumed new significant ST-segment -T-wave (ST-T) changes or new left bundle branch

block (LBBB)

- \_ Development of pathological Q waves in the ECG
- \_ Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- \_ Identification of an intracoronary thrombus by angiography or autopsy
- Cardiac death with symptoms suggestive of myocardial ischaemia and presumed new ischaemic ECG

changes or new LBBB, but death occurred before cardiac biomarkers were obtained, or before cardiac

biomarker values would be increased.

# Note whether the occurrence was during the intraoperative or postoperative time period.

## **Variable Options:**

1. Select "Myocardial Infarction - Intraop" or "Myocardial Infarction - Postop" from the dropdown

menu

- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

**Include:** N/A **Exclude:** N/A

**Notes:** 

- 1. Symptoms of ischaemia include (but are not limited to):
- Angina pectoris/chest pressure or pain
- Neck or jaw pain
- Shoulder or arm pain
- Clammy skin
- Shortness of breath
- Nausea and vomiting
- 2. STEMI ST-segment elevation caused by a transmural infarction of the myocardium (resulting

from complete obstruction of a coronary artery)

3. Non-STEMI – no ST-segment as there is no transmural infarction although there is ischemia

resulting from a partial dynamic block to coronary arteries

4. Physician diagnosis of myocardial infarction alone is not an acceptable criterion for a myocardial infarction.

**Suggested data sources/locations:** Progress Notes, Laboratory Results, Radiology Results, ECG

Report, Nursing Flowcharts, Nursing Notes, Physician Office Notes, ED documentation (presentation

after discharge)

**Reference:** Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD; the Writing

Group on behalf of the Joint ESC/ACCF/AHA/WHF Task Force for the Universal Definition of

Myocardial Infarction. Third universal definition of myocardial infarction. *Circulation*. 2012;126:000–

000.

# **K5c) Cardiac Dysrhythmias**

**Intent of Variable:** To capture those patients who have experienced a cardiac dysrhythmia that was

significant enough to require treatment within 30 days of the principal operative procedure. There is an

association between dysrhythmias and the development of complications such as stroke and/or heart

failure.

**Definition**: Answer "Yes", and note the date of the first time that a patient has a NEW onset of a

cardiac dysrhythmia (sustained ventricular tachycardia, ventricular fibrillation, atrial fibrillation, atrial

flutter, second degree heart block, third degree heart block, symptomatic bradycardia) that requires

treatment with any of the following modalities:

- 1. Ablation therapy
- 2. AICD
- 3. Pacemaker
- 4. Pharmacological treatment (incl. anticoagulation)
- 5. Electrocardioversion

## **Variable Options:**

- 1. Select "Cardiac Arrhythmia" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

**Include:** N/A **Exclude:** N/A

Notes: Answer "Yes" only if the dysrhythmia is newly diagnosed and is NOT a

recurrence of a

dysrhythmia that was present preoperatively.

**Suggested data sources/locations:** Progress Notes, Nursing Flowcharts, Nursing Notes, Physician

Office Notes, Medication Administration Record (MAR), Cardiac Cath Lab Documentation,

Electrophysiology Lab Documentation, ED documentation (presentation after discharge)

# K6a) Transfusion w/in First 72 hours Postop

**Intent of Variable:** To identify those patients for whom it was deemed to be in the patient's best

interest to transfuse blood products (specifically red blood cell & whole blood products) and to

quantify the units utilized/initiated up to 72 hours postoperatively.

**Definition**: Indicate the transfusion of packed or whole red blood cells up to, and including, 72 hours

after the surgery end time. Record the date as the date when the initial unit was transfused but also

record the total number of units given.

## **Variable Options:**

- 1. Select "Transfusion w/in first 72 hrs postop" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter number of units range: 1- 200
- 3. Enter comments (optional)

**Include:** N/A

**Exclude:** Transfusions of fresh frozen plasma (FFP) or platelets

**Notes:** N/A

Suggested data sources/locations: Progress Notes, Nursing Flowcharts, Nursing Notes,

Blood Bank

Documentation, Transfusion Flowsheet

## K6b) Deep Vein Thrombosis (DVT) requiring Therapy

**Intent of Variable:** To identify patient(s) that developed a new blood clot or thrombus within the

venous system postoperatively affecting their physiology and requiring treatment as described.

**Definition**: The identification of a new blood clot or thrombus within the **deep** venous system which

may be coupled with inflammation. **The clot must require therapy.** This diagnosis is confirmed by a

duplex, venogram, or CT scan, **AND** the patient must be treated with anticoagulation therapy and/or

placement of a vena cava filter or clipping of the vena cava.

## **Variable Options:**

- 1. Select "Deep Vein Thrombosis req. Therapy" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

#### **Include:**

1. Clots/thrombi found in the axillary, brachial, deep femoral, femoral (which may be referred to

as "superficial femoral" but is actually a deep vein), iliac, internal jugular, peroneal, popliteal,

radial, subclavian, tibial, and ulnar veins – also the vena cava and the portal vein.

2. Patients who require therapy but refuse.

#### **Exclude:**

- 1. Clots that occur in the basilic, cephalic, gastroc, hepatic renal, or mesenteric veins.
- 2. Clots that occur in other superficial veins.
- 3. Clots that occur in arteries.
- 4. Chronic venous thrombus/thrombi present preoperatively, which are also noted postoperatively

but without evidence of new progression.

**Notes:** If there is documentation of an internal jugular (IJ) line clot or a PICC line clot, you may only

assign this variable if the clot is in the vein, not in the catheter.

**Suggested data sources/locations:** Progress Notes, Nursing Notes, Physician Office Notes.

Laboratory Results, Radiology Reports, ED documentation (presentation after discharge)

## K6c) Sepsis

**Intent of Variable:** To capture the patient who has developed an acute infectious process postoperatively affecting their physiology as described.

**Definition:** Indicate the presence of sepsis in the 30 days following surgery. You may assign this

variable if the patient meets the below criteria:

- **1. Sepsis** assign "Sepsis" if the patient meets the below criteria:
- a) A recent history of new infection, within the 30 days following the principal operative

**procedure -** possible infections include, but are not limited to, pneumonia, empyema, UTI,

acute abdominal infection, meningitis, skin/soft tissue infection, bone/joint infection, wound infection, bloodstream catheter infection, endocarditis, implantable device infection,

acute appendicitis, acute cholecystitis, acute diverticulitis, and/or sinus infection.

#### AND

# b) Any 2 of the following signs & symptoms (must be both present AND new to the patient):

- Temp > 38.3 °C (101.0 °F) or < 36 °C (96.8°F)
- HR > 90 bpm
- RR > 20 breaths/minute
- WBC >12,000 cell/mm3 or <4000 cells/mm3
- Hyperglycemia (plasma glucose >140 mg/dL or 7.7 mmol/L) in the absence of diabetes
- Acutely altered mental status

### **Variable Options:**

- 1. Select "Sepsis" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

**Include:** N/A **Exclude:** N/A

#### **Notes:**

1. To assign "Sepsis", there must be documentation of a source of infection – language such as

"Suspected Sepsis", "Sepsis Manifestation", and/or "Septic Syndrome" cannot be used as

replacement for a documented source of infection, even in the presence of the appropriate signs

and symptoms.

2. Intraoperative findings/results are **NOT** allowable for assigning postoperative sepsis. The

reporting of this variable must be supported by **information that was available postoperatively.** This includes, but is not limited to, clinical presentation, laboratory results,

vital signs, physician and/or nurse documentation, physician diagnosis, radiology/diagnostic testing.

3. When considering the presence of infections such as pneumonia, UTI, wound infection, and

bloodstream infection, it is preferable that the diagnosis be supported by documentation that

matches the MSQC definitions for these infections, however, in the absence of such documentation, a physician diagnosis is acceptable.

4. If the patient has a recent history of new infection and is receiving antibiotics for that infection.

you may still assign "Sepsis" as long as the patient still meets the overall criteria.

5. If a patient is receiving beta blockers and you wish to use their heart rate as one of the criteria

to assign the variable, you may only use the patient's documented heart rate, not what the patient's heart rate would/could be if they were not receiving beta blockers.

6. "Hyperglycemia (plasma glucose > 140 mg/dL) in the absence of diabetes" may still

counted as one of the required number of s/s even if the hyperglycemia is directly related to the

patient receiving steroids.

7. If Sepsis or Severe Sepsis was assigned preoperatively, please note the following before also

assigning Sepsis postoperatively:

a. You may assign a postoperative Sepsis anytime within the 30 day postoperative period

the source of infection is completely different/new from the source of infection that was

## used to assign Sepsis preoperatively.

b. You may **NOT** assign a postoperative Sepsis until at least POD 7 (1 week after the date of

the principal operative procedure) if the source of infection is the same as the source of infection used to assign Sepsis preoperatively.

**Preoperative Risk** 

**Factor Assigned** 

**Potential** 

Postoperative

Occurrence

Criteria to Assign

#### **Postoperative Occurrence**

Sepsis Sepsis 1. New source of infection – anytime within 30 days postop

2. Same infection as preop -

cannot assign until at least POD 7

Severe Sepsis Sepsis 1. New source of infection –

anytime within 30 days postop 2. Same infection as preop -

cannot assign until at least POD 7

**Suggested data sources/locations:** Laboratory Results, Physician Progress Notes, Nursing Notes,

Nursing Flowcharts, ED documentation (presentation after discharge)

## **K6d)** Severe Sepsis

**Intent of Variable:** To capture the patient who has developed an acute infectious process postoperatively affecting their physiology as described.

**Definition:** Indicate the presence of severe sepsis in the 30 days following surgery. You may assign

this variable if the patient meets the below criteria:

## 1. A diagnosis of "Sepsis" based on the following:

# a) A recent history of new infection, within the 30 days following the principal operative

**procedure -** possible infections include, but are not limited to, pneumonia, empyema, UTI,

acute abdominal infection, meningitis, skin/soft tissue infection, bone/joint infection, wound infection, bloodstream catheter infection, endocarditis, implantable device infection.

acute appendicitis, acute cholecystitis, acute diverticulitis, and/or sinus infection.

#### AND

# b) Any 2 of the following signs & symptoms (must be both present AND new to the patient):

- Temp > 38.3 °C (101.0 °F) or < 36 °C (96.8°F)
- HR > 90 bpm
- RR >20 breaths/minute
- WBC >12.000 cell/mm3 or <4000 cells/mm3
- Hyperglycemia (plasma glucose >140 mg/dL or 7.7 mmol/L) in the absence of diabetes
- Acutely altered mental status

#### AND

#### 2. The presence of at least 1 of the following organ dysfunction criteria:

- Systolic Blood Pressure (SBP) < 90 mmHg or Mean Arterial Pressure (MAP) < 70 mmHg
- Systolic Blood Pressure (SBP) decrease > 40 mmHg from baseline
- Bilateral pulmonary infiltrates with a new (or increased) oxygen requirement to maintain  $\mbox{SpO2} > 90\%$
- Bilateral pulmonary infiltrates with PaCo<sub>2</sub>/FiO<sub>2</sub> ratio <300
- Creatinine > 2.0 mg/dl (176.8 mmol/L) or Urine Output < 0.5 ml/kg/hour for at least 2 hours despite adequate fluid resuscitation
- Bilirubin > 2mg/dl (34.2 mmol/L)
- Platelet count < 100,000
- Coagulopathy (INR > 1.5 or aPTT > 60 secs)
- Lactate/Lactic Acid > 1 mmol/L

## **Variable Options:**

- 1. Select "Severe Sepsis" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

Include: N/A Exclude: N/A

**Notes:** 

1. Intraoperative findings/results are **NOT** allowable for assigning postoperative severe sepsis.

The reporting of this variable must be supported by **information that was available postoperatively.** This includes, but is not limited to, clinical presentation, laboratory results.

vital signs, physician and/or nurse documentation, physician diagnosis, radiology/diagnostic

testing.

2. When considering the presence of infections such as pneumonia, UTI, wound infection, and

bloodstream infection, it is preferable that the diagnosis be supported by documentation that

matches the MSQC definitions for these infections, however, in the absence of such documentation, a physician diagnosis is acceptable.

3. If the patient has a recent history of new infection and is receiving antibiotics for that infection,

you may still assign "Severe Sepsis" as long as the patient still meets the overall criteria.

4. To assign "Severe Sepsis", the organ dysfunction must be present at a site remote from the site

of infection (with the exception of bilateral pulmonary infiltrates) and must not be considered

to be a chronic condition.

5. If a patient is receiving beta blockers and you wish to use their heart rate as one of the criteria

to assign the variable, you may only use the patient's documented heart rate, not what the patient's heart rate would/could be if they were not receiving beta blockers.

6. "Hyperglycemia (plasma glucose > 140 mg/dL) in the absence of diabetes" may still be

counted as one of the required number of s/s even if the hyperglycemia is directly related to the

patient receiving steroids.

7. Do not assign "Severe Sepsis" based on criteria which is not present at the time but might have

been if the patient had not been receiving certain treatments or medications. You must use

documented criteria. For example, if a patient is receiving vasopressors to maintain their blood

pressure, you may only utilize what's documented for their blood pressures to assign the variable – you may NOT assign "Severe Sepsis" based on the assumption that their blood pressures would be low enough to meet the listed criteria if they were not receiving vasopressors.

8. If Sepsis or Severe Sepsis was assigned preoperatively, please note the following before also

assigning Severe Sepsis postoperatively:

a) You may assign a postoperative Sepsis or Severe Sepsis **anytime** within the 30 day postoperative period if the source of infection is **completely different/new from the** 

## source of infection that was used to assign Severe Sepsis preoperatively.

b) You may **NOT** assign a postoperative Sepsis or Severe Sepsis until at least POD 7 (1 week

after the date of the principal operative procedure) if the source of infection is **the same** as

### the source of infection used to assign Severe Sepsis preoperatively.

9. If only Sepsis was assigned preoperatively, you may assign a postoperative Severe Sepsis

**anytime** within the 30 day postoperative period if the patient's condition deteriorates to the

point of Severe Sepsis.

### **Preoperative Risk**

**Factor Assigned** 

**Potential** 

**Postoperative** 

Occurrence

Criteria to Assign

## **Postoperative Occurrence**

Sepsis Severe Sepsis If patient's condition deteriorates,

can assign anytime within 30

days postop

Severe Sepsis Severe Sepsis 1. New source of infection –

anytime within 30 days postop

2. Same infection as preop -

cannot assign until at least POD 7

Suggested data sources/locations: Laboratory Results, Physician Progress Notes,

Nursing Notes,

Nursing Flowcharts, ED documentation (presentation after discharge)

#### **K6e)** C-difficile

**Intent of Variable:** To capture those patients who develop c-difficile within 30 days of the principal

operative procedure as a complication of surgery.

**Definition**: To answer "Yes", Clostridium difficile (C. diff) must be verified by laboratory detection of

the toxin in the stool or by a positive stool culture. Please assign using the date of the collection of

specimen (NOT the date when result was positive).

## **Variable Options:**

- 1. Select "C-difficile" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

**Include:** N/A

**Exclude:** Exclude any positive results reported < 72 hours after admission to the hospital (NOT < 72

hours before time of surgery) in order to rule out those infections that are community-associated

(versus healthcare-associated)

**Notes:** N/A

Suggested data sources/locations: Progress Notes, Nursing Notes, Physician Office

Notes,

Laboratory Results, ED documentation (presentation after discharge)

## **K6f) Central Line-Associated Bloodstream Infection (CLABSI)**

**Intent of Variable:** To identify those patients develop a central line-associated bloodstream infection

(CLABSI) within 30 days of the principal operative procedure as a complication of surgery.

**Definition**: Answer "Yes" to the presence of a central line-associated bloodstream infection (CLABSI)

if one of the below 2 criteria are met:

**Criterion 1:** Patient has a recognized pathogen cultured from one or more blood cultures and organism

cultured from blood is not related to an infection at another site.

#### OR

**Criterion 2:** Patient has at least one of the following signs or symptoms: fever (>38°C), chills or

hypotension and signs and symptoms and positive laboratory results are not related to an infection at

another site and common commensal (i.e. diptheroids [Corynebacterium spp. not c.diptheriae],

Bacillus spp. [not B. anthracis], Propionibacterium spp., coagulase-negative staphylococci [including

S. epidermis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or

more blood cultures drawn on separate occasions. Criterion elements must occur within a timeframe

that does not exceed a gap of 1 calendar day between two adjacent elements.

## **Variable Options:**

- 1. Select "Central Line-Associated Bloodstream Infection (CLABSI)" from the dropdown menu
- 2. Enter date in mm/dd/yyyy format
- 3. Enter comments (optional)

**Include:** N/A **Exclude:** N/A

#### **Notes:**

1. In Criterion 1, the phrase "one or more blood cultures" means that at least one bottle from a blood

draw is reported by the laboratory as having grown organisms (i.e., is a positive blood culture).

2. In Criterion 1, the term "recognized pathogen" does not include organisms considered common

commensals. A few of the recognized pathogens are S. aureus, Enterococcus spp., E. coli, Pseudomonas spp., Klebsiella spp., Candida spp., etc.).

- 3. The phrase "two or more blood cultures drawn on separate occasions" means
- a) that blood from at least two blood draws were collected within two days of each other (e.g., blood

draws on Monday and Tuesday or Monday and Wednesday would be acceptable for blood cultures

drawn on separate occasions, but blood draws on Monday and Thursday would be too far apart in time

to meet this criterion), and

b) that at least one bottle from each blood draw is reported by the laboratory as having grown the same

common commensal (i.e., is a positive blood culture). For example, an adult patient has blood drawn at

8 a.m. and again at 8:15 a.m. of the same day. Blood from each blood draw is inoculated into two

bottles and incubated (four bottles total). If one bottle from each blood draw set is positive for

coagulase-negative staphylococci, this part of the criterion is met.)

c) "Separate occasions" also means blood draws collected from separate sites or separate accesses of

the same site, such as two draws from a single lumen catheter or draws from separate lumens of a

catheter. In the latter case, the draws may be just minutes apart (i.e., just the time it takes to disinfect

and draw the specimen from each lumen). For example, a patient with a triple lumen central line has

blood drawn from each lumen within 15 minutes of each other. Each of these is considered a separate

blood draw.

4. A central line is defined as an intravascular catheter that terminates at or close to the heart or in one

of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The

following are considered great vessels for the purpose of reporting central-line BSI: aorta, pulmonary

artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian

veins, external iliac veins, common iliac veins, femoral veins, and in neonates, the umbilical

artery/vein.

**Suggested data sources/locations:** Progress Notes, Nursing Notes, Physician Office Notes,

Laboratory Results, ED documentation (presentation after discharge)

**Reference:** Centers for Disease Control and Prevention. CDC/NHSN Surveillance Definition of

Healthcare-Associated Infection and Criteria for Specific Types of Infection in the Acute Care Setting. NHSN Patient Safety Component Manual 2013

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