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MEDICATION, ENVIRONMENTAL, AND PATIENT FACTORS THAT
INFLUENCE MEDICATION ADMINISTRATION DELIVERY TIMES

By

Catherine F. Medved

A Thesis
Submitted to the Faculty of Graduate Studies
Through the Faculty of Nursing
In Partial Fulfillment of the Requirements for
The Degree of Master of Science in Nursing at the
University of Windsor

Windsor, Ontario, Canada

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By

Catherine F. Medved

APPROVED BY:

Dr. K. Milne
Faculty of Human Kinetics

Dr. S. Fox-Wasylyshyn
Faculty of Nursing

Dr. M. Freeman, Advisor
Faculty of Nursing

April 5, 2016

AUTHOR'S DECLARATION OF ORIGINALITY

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ABSTRACT

The purpose of this study was to identify the medication factors, environmental factors, and patient factors that predict medication time errors by registered nurses in an acute care setting. A sample of 1032 observations was analyzed using multivariate logistic regression using generalized estimating equations modeling. The findings suggested that time errors during medication administration were independently associated with time-critical medications, the number of medications that the patient received at the scheduled administration time, and the patient's swallowing ability. This study also found that the time of administration for the majority of medications was not accurately documented.

DEDICATION

To my late father Tomo Medved, who is the epitome of hard work and dedication. You have passed onto me your incredible work ethic and ambition to succeed. Although you are not physically here with me today, I know that you are proudly watching down on me from heaven.

To my loving and supportive husband, Tom Murtagh, who has endlessly encouraged me to follow my dreams. Thank-you for always supporting me with achieving this academic goal.

To my mom, Anne Marie Medved, who has eternally supported and praised me throughout life in everything I do. Thank you for always cheering me on.

And to my sisters, brothers, and extended family, thank-you for your endless encouragement. All of you have been very supportive through this journey.

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As my internal advisor, Dr. Susan Fox, went well above and beyond her expected role for this research project. She continuously challenged my thinking throughout this process and provided me with the necessary insight to make this project a success. Her attention to detail and meticulous editing has made me a better writer. Thank you for your immense involvement with the project from the very start and for exceeding my expectations as an internal advisor.

My external reader, Dr. Kevin Milne, offered valuable insights from an objective perspective at the proposals. Thank you for agreeing to be a part of my committee.

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CHAPTER 1

Background

The *rights to safe medication administration* are standards outlined by professional organizations that are intended to safeguard the medication administration process for both nurses and patients (Cohen, 1999; College of Nurses of Ontario [CNO], 2015; Department of Health, 2004). The CNO is a governing body for registered nurses (RNs), registered practical nurses (RPNs), and nurse practitioners in Ontario, Canada (CNO, 2015). The CNO (2015) outlined eight rights as a practice standard for nurses related to the medication administration process that include: the right client, the right medication, the right reason, the right dose, the right frequency, the right route, the right site, and the right time. Other literature identified these practices as the five rights (Cohen, 1999; Department of Health, 2004; Institute for Safe Medication Practices [ISMP], 2007) and the nine rights (Elliot & Yiu, 2010). All of these sources include the right time as one of their criteria. Following the *rights to safe medication administration* implies that a medication error will not occur and that the safety of the patient will be maintained (Cohen, 1999; CNO, 2015; Kim, Kwon, Kim, & Cho, 2011). Although the *rights to safe medication administration* have been a standard of practice for several years, researchers are beginning to notice that these rights are not the be all and end all to safe medication administration (Cohen, Robinson, & Mandrack, 2003; ISMP, 2007; Macdonald, 2010). This means that following the rights will not necessarily prevent a medication error from occurring as a multitude of factors, such as patient characteristics, can play a role (Jones & Treober, 2010; Maricle et al., 2007).

Failure to administer medications at *the right time* is the error that occurs most

frequently

in the medication administration process (Biron, 2009; Elliot & Liu, 2010; Keers et al., 2013). The literature demonstrates that between 23% (Teunissen et al., 2013) to 73% (Berdot et al., 2012) of all medications in the acute care setting are administered at the wrong time, with the majority being late. Nurses are expected to administer medications on time (CNO, 2015; Lilley & Guanci, 1994; Elliot & Liu, 2010). Depending on the organization, recommended medication administration times fluctuate between the *thirty minute* and *sixty minute rules*, whereby the nurse is expected to administer the medication within either 30 or 60 minutes before or after the scheduled medication time.

Administering a medication outside of the allotted timeframe is considered a medication error (Cohen, 1999; Department of Health, 2004; Elliot & Liu, 2010; Hall & Fraser, 2006).

While the majority of researchers define late administration based on the *thirty minute rule* (Bullock, Manias & Galbraith, 2007; Cohen, 1999; Elganzouri, Standish, & Androwich, 2009; Hall & Fraser, 2006), others suggest that a medication can be administered within 60 minutes of its scheduled time before it is considered a medication error (Agyemang & While, 2010; Maricle et al., 2007; Teunissen, Bos, Pot, Pluim, & Kramers, 2013; Tissot et al., 2003). Other researchers and professional organizations are vague in defining an acceptable timeframe, citing that it is crucial that medications be administered in a timely fashion (CNO, 2015; Lilley & Guanci, 1994; Elliot & Liu, 2010).

In a survey of 17,500 nurses, the ISMP (2011) found that 70% of respondents communicated that they took dangerous short cuts to comply with the *thirty minute rule*

and that the rule was unsafe, unnecessary, and impossible to follow. Other studies reported similar findings, whereby nurses felt pressured to meet rigid time schedules and took short cuts in order to meet these time constraints (Elganzouri et al., 2009; Maricle et al., 2007). These short cuts included: pre-pouring patients' medications, skipping important independent double checks, administering medications before assessing vital signs or critical lab values (ISMP, 2011), preparing more than one patients' medications at a time (Elganzouri et al., 2009; ISMP, 2011), deviating from scheduled medication times and hospital policies (ISMP, 2011; Maricle et al., 2007), and failing to check patient identity before administering a medication (Manias, Aitken, & Dunning, 2005). All of these shortcuts have the potential to jeopardize patient safety. Many nurses often disagree with what constitutes a wrong-time error; as late administration is often tied to events outside of the nurses' control; such as delayed delivery from pharmacy or patient absence from the unit at medication time (Stokowski, 2012).

In response to the aforementioned findings, the Centers for Medicare and Medicaid Services (CMS) in the United States recognized that it was no longer best practice in today's clinical environment to implement the *thirty minute rule*, and therefore withdrew this time requirement for medication administration (CMS, 2011). This resulted in recommendations by the CMS (2011), and the United Kingdom's National Patient Safety Agency [NPSA] (2010), for the removal of the time pressures in medication administration. It was suggested that organizations develop their policies on medication delivery times based on the knowledge of time-critical and non-time-critical medications. The ISMP United States developed a list of time-critical and non-time-critical medications as a guide for agency medication administration policies (ISMP,

2011). For unknown reasons, the ISMP Canada has not yet adopted these guidelines, nor have they developed their own set of guidelines on scheduled medication times in relation to time-critical medications. The CNO practice standards do not currently outline specific requirements for timely medication administration, and state only that medications should be administered in *a timely manner* (CNO, 2015). The CNO has stated that it is up to the individual agency or organization to outline their own time requirements regarding medication administration. Interestingly, the practice standards of other nursing bodies, such as the Nurses Association of New Brunswick (2013), provide medication guidelines based on the ISMP time requirements.

Several factors have been identified as influencing errors in medication administration time in acute care settings. Research demonstrates that nurse workload (Biron, 2009; Davis, Keogh, & Kim, 2011; Duffield et al., 2011) and staffing (Deans, 2005; Duffield et al., 2011; Kim et al., 2011; Jones & Treober, 2010) may influence a nurses ability to administer a medication on time. Nursing factors such as age (Fasolino, 2009) and experience (Fasolino, 2009; Jones & Treober, 2010) have also been shown to be related to the occurrence of medication errors in the acute care setting. Further, the requirement that certain high-alert medications be double-checked with a second nurse takes additional time (ISMP, 2013; Jarman, Jacobs, & Zielinski, 2002b). Jarman et al. (2002b) found this step to add 20 minutes to the medication administration process, suggesting that this factor may contribute to medication administration time errors in the clinical setting.

Despite the abundance of research on medication administration errors, the majority of the research (Davis et al., 2011; Deans. 2005; Jones & Treober, 2010; Kim et

al., 2011) focused on nurses' perceptions of factors that influence medication administration errors. Only four studies (Biron, 2009; Kelly, Wright, & Wood; Teunissen et al., 2013; Thomson et al., 2009) used quantitative methods to examine the predictors of medication errors with respect to the wrong time; only one of which (Teunissen et al., 2013;) used multivariate analyses to examine this phenomenon. Further, only two studies examined factors that influence wrong time medication errors in an acute care setting (Biron, 2009; Teunissen et al., 2013). Although nurses' perceptions of why medication errors occur is significant, identifying specific factors that influence why medication time errors may occur is essential to further validate research findings. The lack of understanding of factors that influence medication administration time errors demonstrates a gap in the literature. By understanding which factors influence these errors, the knowledge generated from this study may assist in improving the efficiency and safety of the medication administration process for both nurses and patients.

Purpose of the Study

In light of the previously identified gaps in knowledge related to factors that influence medication administration time errors, the primary aim of this study was to identify the medication factors, environmental factors, and patient factors that are predictive of the occurrence of medication time errors by RNs in an acute care setting. Therefore, the research question for this study was: what are the medication, environmental, and patient factors that predict whether a medication is administered on time versus not on time?

Significance of the Study

Little is known about the factors that influence the timely administration of

medications. The majority of research has examined predictors of medication errors in general rather than factors that influence whether a medication is administered on time.

New guidelines on scheduled medication times and time-critical medications have challenged the ability of nurses to meet these constrained timeframes. Keohane and colleagues (2008) found that nurses spend 26.9% of their time on medication-related activities alone; this accounts for the single largest amount of nursing related time. A considerable amount of research demonstrates that it takes a nurse longer than the proposed 30 and 60 minute timeframes to administer medications to their patients (Elganzouri et al., 2009; Garrett & Craig, 2010; Teunissen et al., 2013). On average, medication administration rounds for four to six patients in the acute care setting can take nurses anywhere between 1 and 1.5 hours (Elganzouri et al., 2009) to an average of 2 hr ($M = 1$ hr and 56 min; $SD \pm 29$ min)(Garrett & Craig, 2010).

From a safety perspective, only a subset of medications require strict adherence to their scheduled medication times. The half-life and peak action of a medication are directly related to the importance of correct timing of administration. For certain medications, deviating from this time can lessen the therapeutic effect, with consequences to the patient (da Silva & Camerini, 2012; Hall & Fraser, 2007). For example, to achieve adequate pain control, a patient must receive regular fixed doses so that a constant level of pain medication is maintained (Hall & Fraser, 2006). In hospitalized patients with Parkinson's disease, strict adherence to daily dosing schedules is vital, as failure to administer medications on time can increase patient morbidity and decrease the quality of patient care (Hou et al., 2012). For some critical medications or conditions, such as those used to treat patients with sepsis or pulmonary embolisms,

delays in medication administration can cause serious harm or death (National Patient Safety Agency, 2010; Volling, Hyland, & U, 2003). Other medications such as insulin and antibiotics must be given at precise times to maintain therapeutic blood levels for the patient (Hall & Fraser, 2006).

Medication errors can have significant cost and health implications for the institution and patient, thus causing increased lengths of stay and hospital expenditures (Bates, Spell, Cullen, Burdick, Laird, Petersen et al., 1997; Hug, Keohane, Seger, Yoon, Bates, 2012; Karnon, Campbell, & Cxoski-Murray, 2009). In one study, on average a single medication error was associated with an increased hospital stay of approximately 5 days and excess cost of nearly \$6000, translating to an estimated annual cost of nearly \$3 million for a 700-bed teaching hospital (Bates et al., 1997).

The findings from this study may be useful in improving the safety and efficiency of the medication administration process in an acute care setting. Adding to the knowledge of factors that influence errors in the timing of medication administration can inform changes in the medication administration process. By improving the timeliness of administration for certain medications, the knowledge obtained in this study has the potential to: reduce patient morbidity and mortality; reduce lengths of stay; reduce hospital costs; and improve patient care and overall patient outcomes.

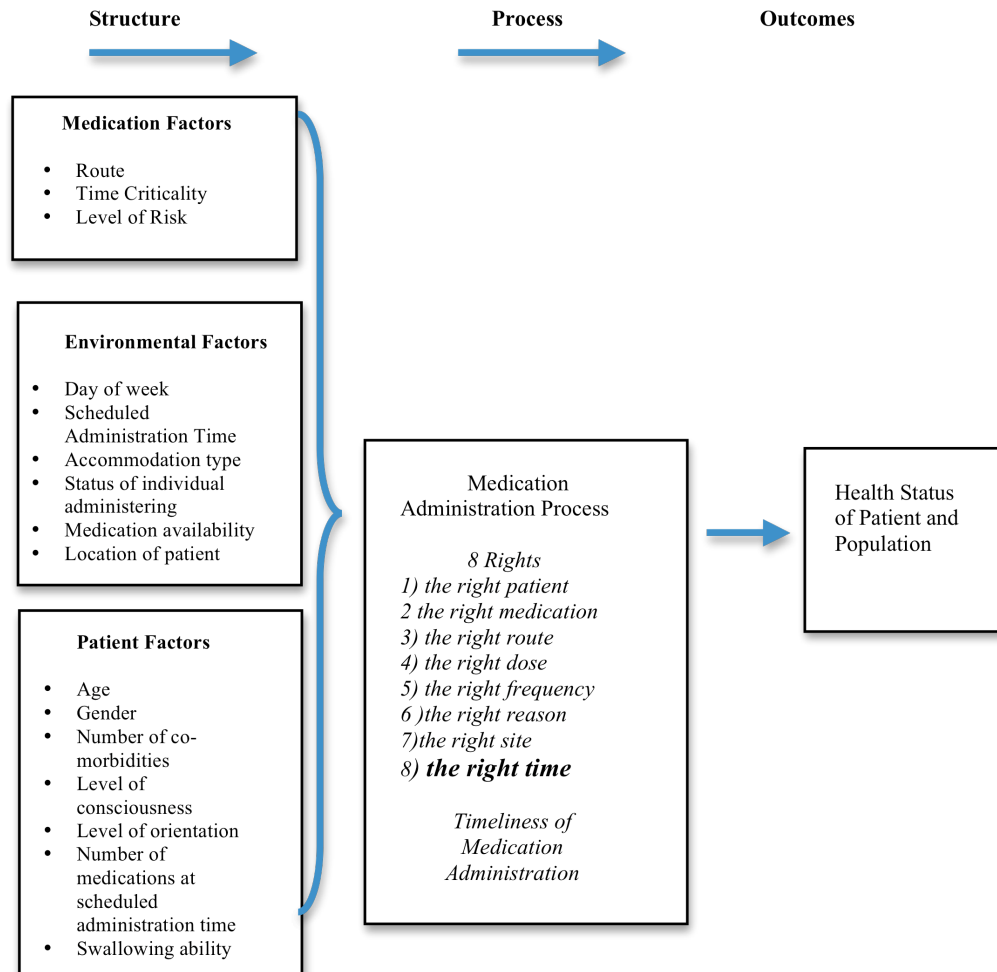
Conceptual Framework

Overview of Quality Health Outcomes Model

Donabedian's (1996) structure, process, and outcomes model served as the overarching conceptual framework for this study. Donabedian's model theorizes a linear relationship between the three constructs that influence the quality of care; these include structure, process, and outcome (Donabedian, 1988).

Structure represents the characteristics of the setting where care occurs, the quality of material and human resources, and the organizational structure. In this study, structure variables included medication, environmental, and patient factors. The specific variables that were used in this study are depicted in Figure 1. In the case of medication factors, an example would be medication route and the influence of this factor on the timeliness of administration (Davis et al., 2005; Teunissen et al., 2013). For example, injectable medications sometimes take longer to prepare and may take longer to administer because of the need to position patients correctly (site exposure and appropriate land-marking) prior to administration.

Figure 1. Framework for proposed factors that may influence timeliness of medication administration in the acute care setting



Process is defined as the activities of providing care (by the practitioners) and receiving care (by the patient) (Donabedian, 1988). In this study, process was the actual medication administration process, which includes the preparation and administration of medications by the nurse while adhering to the *rights* of safe medication administration. In this study, *the right time*, was the only *right* examined. Process symbolized whether or not a medication was administered on time (medication time error). Two separate

definitions of *on time* were used, based on whether the medication was time-critical (30 minutes) or non-time-critical (60 minutes).

Finally, outcome identifies the effects of care on the health status of patients and populations (Donabedian, 1988). Donabedian (1988) theorized that good structure enhances the possibility of good processes, which in turn enhances good (quality) outcomes. In the context of medication administration, structure variables as well as the process of medication administration influence outcome.

Other studies have adapted this model to include the patient as an additional construct influencing the process and outcomes of quality of care. For example, the Quality Health Outcomes Model created by Mitchell , Ferketich, and Jennings (1998) theorized a reciprocal interaction between the constructs. However, for the purpose of this exploratory study, Donabedian's original structure, process and outcome theory was used. The examination of individual nurse factors, considered a potential predictor of medication administration time errors, was not included in this study because of time and resource constraints. Further, this study did not examine patient outcomes as it relates to timeliness of medication administration.

CHAPTER 2

Literature Review

This chapter begins with a description of the search strategy. Gaps in the literature related to this topic are discussed. The literature review is organized according to the concepts in Donabedian's model (1988) and focuses on the variables that were examined in this study.

Search Strategy

The following nursing electronic databases were systematically searched: Cumulative Index of Nursing and Allied Health, Proquest, MEDLINE, Ovid, and PubMed. The search was limited to English literature with no restrictions on publication date and geographical region. Internet search engines such as Google and Google Scholar, websites specific to medication safety with research and publications, as well as professional nursing associations and governing regulatory bodies were searched using key words and related content. Institutional policies from two local hospitals in the Windsor-Essex County region were reviewed. Reference lists of relevant articles and online documents (ancestry searching) were used to locate relevant sources. Related books were reviewed for content that covered safe medication administration and the pharmacology of specific classes of medications. Key words and subject terms used in a variety of combinations included: medication times, scheduled medications, the five rights, the eight rights, the nine rights, medication errors, medication safety, nurses' perceptions, factors that influence medication times, drug times, drug errors, scheduled drugs, time barriers, and serum half-lives.

Factors Influencing Administering Medications on Time

A literature review of the factors that may influence the timely administration of medications, organized according to the theoretical framework, follows.

Structure Factors

Medication factors. Although a limited amount of research exists regarding the influence of medication factors on medication administration times, a small number of studies have examined the influence of medication properties (route, time criticality, level of risk) on medication administration time errors.

Route. Teunissen et al. (2013) employed explorative cross-sectional methods to investigate the importance and relevance of medication time errors in the acute care setting. Data were collected from two units (surgery and neurology) of a 650-bed general teaching hospital in the Netherlands. The researchers collected emptied packaging material of medications after each medication round and compared this to the patients' medication orders. Compared with the oral route, rectal medications were associated with a significant increase in the frequency of administration time errors (*OR* 2.368; 95% *CI* 1.141-4.915), while the injection or infusion routes were associated with a significant decrease in the frequency of these errors (*OR* 0.247; 95% *CI* 0.117-0.524).

Kim et al. (2011) conducted a cross-sectional descriptive survey using convenient snowball sampling from seven hospitals where nurses' ($N = 220$) perceptions of factors contributing to medication errors were explored. Nurses ($n = 152$; 67.2%) reported that medication errors occurred mostly during intravenous administration (Kim et al., 2011). Although perceptions about errors related to administration times were not specifically examined, the results suggested that nurses felt medication route played a major factor in

medication errors.

Davis et al. (2005) conducted focus groups to examine nurses' attitudes and perceptions toward medication policies and factors that influence their adherence and ability to follow their hospitals' medication policies. Nurse participants ($N = 32$) identified that having multiple drugs (particularly intravenous) due at the same time influenced their ability to adhere to medication times.

Time criticality. Although one might expect that nurses might give priority to administering time-critical medications on time, it is not known if this is the case. No studies were found that specifically examined the extent to which medication time errors were related to the time criticality of medications. However, to compare the timing of insulin administration by hospital staff versus self-administration, Gangopadhyay et al. (2008) used auditing methods to collect data on the timing of meals and insulin administration. The timing of insulin was considered appropriate for analogue insulin if administered within 5 minutes before or after the meal, and between 10 to 30 minutes before the meal for non-analogue insulin (non-modified human insulin). In patients who self-administered their insulin, 78% of timing was accurate. However, only 19% of insulin administration times were accurate when administered by hospital staff. Although this study compares patients' self-administration to nurse administration, the results demonstrate that nurses were frequently unable to administer this specific time-critical medication within the appropriate timeframe. This is an understudied area that requires further investigation.

While research demonstrates that the majority of medications are not time-critical, several medications require strict adherence to scheduled medication times as therapeutic

effect can be negatively influenced by incorrect timing of administration (da Silva & Camerini, 2012; Hall & Fraser, 2007). Time-critical medications are defined as: (a) medications with a dosing schedule more frequent than every 4 hours; (b) opioids used for chronic pain or palliative care (Hall & Fraser, 2006; ISMP, 2011; NPSA, 2010); (c) immunosuppressive agents used to prevent solid organ transplant rejection or to treat myasthenia gravis; (d) medications that must be administered apart from other medications such as antacids or fluoroquinolones; (e) medications requiring administration during a specified time period; such as before, after or with a meal; which would include insulins (Hall & Fraser, 2006; Heatlie, 2003; ISMP, 2011; NPSA, 2010a; NPSA, 2010b), and oral anti-diabetics, alderonate, and pancrealipase (ISMP, 2011); and (f) medications used for specific diagnoses such as Parkinson's disease (Hou et al., 2012; ISMP, 2011; NPSA, 2010a) and sepsis (ISMP, 2011; NPSA, 2010a). It is recommended that these medications be administered as close to the scheduled time as possible or within 30 minutes before or after the scheduled dose (ISMP, 2011). For example, thyroid medications, such as levothyroxine, interact with several medications that can affect its absorption and therapeutic effect. It is therefore recommended that this medication be taken first thing in the morning on an empty stomach, apart from an other medication (Neafsey, 2004).

Non-time-critical medications are defined as medications that are scheduled daily, weekly, or monthly; as well as those scheduled more frequently than daily, but not more than every four hours (ISMP, 2011). The ISMP (2011) recommends that these medications be administered within 2 hours of the scheduled dose for daily, weekly, and monthly scheduled medications, and within 1 hour before or after the scheduled dose for

those medications prescribed more frequently than daily, but no more frequently than every 4 hours.

Level of risk. No studies were found that specifically examined the extent to which medication time errors were related to risk level of medications. However, in the previously discussed study (Gangopadhyay et al., 2008), the researchers found that insulin administration, also considered a high-alert medication, was not given on time. The need to perform independent double checks on high-alert medications such as insulin is known to lengthen the time of the medication administration process (ISMP, 2013; Jarman, Jacobs, & Zielinski, 2002b), and can add 20 minutes to the process (Jarman et al., 2002b). These findings suggest that high-alert medications may influence medication administration delivery times; however, further research is needed.

Environmental Factors. Although there is a considerable amount of research investigating the relationship between environmental factors and medication errors, only a small number of studies have investigated the influence of environmental factors (scheduled administration time; specific units; and student nurse administration) on medication administration errors with respect to time.

Day of week. Teunissen et al. (2013) examined whether the day of the week influenced whether or not medications were administered on time. This variable was demonstrated to have no relationship with medication time errors.

Scheduled administration time. Biron (2009) used a prospective correlational design to examine the predictive power of medication administration complexity, work interruptions, and nurse workload in relation to medication administration errors. Data were based on a convenience sample of 102 medication rounds performed by 18 RNs

with at least 6 months of professional working experience. Morning (10:00) and evening (17:00) medication times were significant predictors of wrong time administration errors. Afternoon (12:00 and 14:00) periods were not related to wrong time administration errors.

Thomson and colleagues (2009) conducted a study in a long-term care facility in Toronto, Ontario using time-motion methods to time RNs and RPNs ($N = 141$) in all steps of the medication administration process. The longest administration process occurred in the morning, when it took an average of 78 to 104 minutes to complete medication rounds. The shortest medication administration process was at noontime, when nurses took from 46 to 68 minutes to complete medication rounds (Thomson et al., 2009). Evening hours were not reported. However, the researchers (Biron, 2009 & Thomson et al. 2009) in the above-described studies did not adjust for confounding variables such as number of medications due at the respective times. In hospital, most medications are administered during morning and evening hours which might explain the studies' results.

In a study using multivariate analyses, Teunissen et al. (2013) found time of day to be related to the occurrence of administration time errors such that medications administered at noon ($OR\ 0.416$; 95% CI 0.236–0.725) and 3 p.m. ($OR\ 0.197$; 95% CI 0.083–0.465) were associated with reduced medication error rates compared to the reference time of 07:00 a.m. (Teunissen et al., 2013).

Status of Individual Administering. Wolf et al. (2005) examined the largest adverse drug event database in the United States (MEDMARX) and found that wrong

time errors occurred in 17% ($N = 1305$) of the nursing students' records, a rate that was three times higher than other reported wrong time errors.

Patient Factors. A small number of studies have examined patient factors that influence medication time errors in the acute care setting. Patient characteristics such as acuity level (Jones & Treiber, 2010) and the number of medications (Jones & Treiber, 2010) prescribed for each patient were found to be associated with timing-related medication administration errors.

Age/gender/co-morbidities. Patient age, gender and the presence of neurological problems were found to be unrelated to errors in medication administration times (Teunissen et al., 2013). However, in a study examining nurses' ($N = 202$) perceptions of why and how medication errors occur, over half ($n = 202$; 54%) of the study participants rated patient acuity level as a very important contributing factor in medication errors (Jones & Treiber, 2010).

Total number of medications due at scheduled administration time. The total number of medications due at scheduled administration times has been shown to lengthen the medication administration process. Thomson et al. (2009) found that the longest medication administration process was in the morning, when residents in a long-term care facility received the majority of their medications (range 60 to 214 medications). A major limitation of this study was that the authors did not conduct multivariate analysis to examine whether time or the number of medications was the likely contributing factor.

Jones and Treiber (2010) employed a mixed methods descriptive design to examine nurses' perceptions of why and how medication errors occur. Participants ($N = 202$) were active registered nurses, with 62% working in a hospital environment. Fifty

eight percent of nurses ($n= 117$) identified the large number of medications scheduled at peak times as a very important factor that contributed to medication errors (Jones & Treiber, 2010). Using quantitative methods, Teunissen et al. (2013) found that the number of medications the patient was receiving at individual administration times had no effect on administration time errors.

Swallowing ability. Kelly and colleagues (2011) conducted a study on both elderly and neurology wards in four acute care hospitals in England using observation to detect medication administration errors by nurses. Medications ($N=2129$) administered to 625 patients were observed. Thirty two percent of the patients had swallowing impairments. Although the most common error was either late or early administration (greater than an hour), statistical analyses found that swallowing impairment (dysphagia) was not associated with medication administration time errors. However, the researchers recorded medications as wrong time errors only if no other error was found. For example, if the wrong dose of a medication was administered, it was coded as wrong dose even if it was given at the wrong time as well. As a result, the number of medications not given on time for those with swallowing impairments may have been underestimated.

Other variables of interest. A number of variables appear not to have been studied. However, personal and anecdotal experience suggests that a number of other factors may impact the timeliness of medication administration. Accommodation type (i.e., private, semi-private and ward accommodation) may influence whether a medication is administered on time because of frequent interruptions that are common in rooms with more patients. Medication availability was also thought to influence whether

a medication was administered on time. In the acute care setting, nurses commonly document “unavailable” on the medication administration record if the medication is not available on the unit at the scheduled time of administration. Medications may be unavailable because they: (a) were not delivered to the unit, (b) may be new orders, or (b) were “borrowed” for administration to a different patient. Whatever the reason, this is an important factor to understand as it prevents the nurse from administering medications on time. The location of patient at the scheduled administration time was also thought to influence whether or not a medication was administered on time. Patients are frequently taken off their units for various diagnostic tests, which prevent nurses from administering their medications as scheduled.

Summary of Findings

There is a paucity of literature that examines the factors that contribute to medication administration time errors for inpatients in the acute care setting. It is not known whether medication, environmental, and patient factors are significant predictors of whether or not a medication is administered on time. Despite a comprehensive literature search, very few empirical studies were found that address this gap in knowledge. Overall, there is a body of research that suggests that scheduled medication times are influenced by medication, environmental, and patient-related contextual factors, as nurses are unable to meet scheduled medication times according to the *thirty minute rule* (Elganzouri et al., 2009; Garrett and Craig, 2010; Thomson et al., 2009). However, this body of literature is quite small, and provides inconsistent findings.

This study will assist in identifying which structure factors within an acute care setting influence the process of administering medications within recommended

timeframes. By identifying which factors predict the timeliness of medication delivery, this study can assist hospitals and organizations in improving the safety and efficiency of the medication administration process. This in turn has the potential to reduce hospital expenditures, adverse events, and patient mortality.

CHAPTER 3

Methodology

Research Design

A quantitative cross sectional exploratory retrospective review of hospital records was conducted to explore the independent predictors of late administration of medications.

Sample and Setting

Data were collected from the inpatient medical records of patients who were admitted to the respiratory medical unit of an acute care community hospital in southwestern Ontario. It includes two campuses with a total of 579 beds, and is one of the largest hospitals in Ontario, Canada. The research setting had 30,030 admissions between the two campuses during the fiscal year from April 1, 2012 to March 31, 2013.

A conservative effect size was used when calculating the sample size because of the wide variation in the incidence of medication administration time errors and the exploratory nature of this study. To estimate the statistical power for the proposed study, G*power 3.1.9.2 was used (Faul, Erdfelder, Buchner, & Lang, 2009). The estimated required sample size was 721 medication administration events to achieve a study power of .80, a two-tailed alpha of .05 and an effect size of .20 (Faul, Erdfelder, Buchner, & Lang, 2009).

Inclusion criteria. Scheduled medications events were included in the study if the patients to whom they were prescribed were: (a) inpatients on a medical-respiratory care unit) during the study timeframe (April 14 to April 19 2015); and (b) 18 years of age or older.

Exclusion criteria. Medications were excluded from the study if they were: (a) held because the patient was not permitted anything by mouth; (b) administered on an as needed (PRN) basis, (c) ordered as a STAT one time dose; and (d) recently (within the previous 4 hours) ordered. In addition, medications were excluded if the patient for whom they were ordered was: (a) recently (within the past 12 hours) transferred from other inpatient units such as critical care, special procedures, pediatrics, surgery and the emergency department; or (b) discharged home the previous day. Medications administered to patients whose medical records were no longer available on the unit were also excluded.

Data collection Procedure

Following clearance from the relevant research ethics boards (University of Windsor and the hospital agency), the researcher requested patient census from the previous day that indicated patients currently on the unit. Once eligible cases were identified, the researchers abstracted data from patients': (a) admission medical records, (b) medicine flowsheets, (c) clinical databases, (d) CMARs; and (e) hypoglycemic records (diabetes specific medications such as insulins are documented here). The required data pertaining to medication, environmental, and patient factors were transcribed onto a data collection record (Appendix A) that was developed by the researcher. The researcher abstracted medication specific information from the previous day's CMAR. From this, the researcher was able to determine all medications that were scheduled for each patient on the previous day, as well as the documented time of administration. The research setting's pharmacy maintains records of all medications that are withdrawn for patient administration from the Pyxis Medstation. The Pyxis

Medstation ® is a secure automated medication dispensing system that is only accessed by nurses through identification verification of a password and finger scan. The machine is stocked by the pharmacy and maintains an inventory of all the pharmaceuticals dispensed over time. Pharmacy records can be sorted according to patient and day; outlining all medications that were withdrawn by the nurses. From pharmacy-generated data (knowledge portal system), the researcher obtained the preceding day's medication removal record for each patient outlining medication withdrawal time. This information was also transcribed onto the data collection record. For those medications that were not withdrawn from the Pyxis (e.g., insulin and some intravenous antibiotics), the documented medication administration time on the CMAR was used to determine the medication administration time. This process continued until the required cases were achieved.

Protection of Human Subjects

Prior to data collection, ethical approval was obtained from the Research Ethics Boards (REB) at the University of Windsor and the research setting. Since this study did not involve any patient contact, and required only data abstraction from patients' medical records, a waiver of consent was obtained. To ensure anonymity, each patient case was assigned a study code that corresponded to the data collected. Only the nurses' coded identification numbers were provided from the pharmacy generated data, which ensured the nurses anonymity and disconnection from medication withdrawal times. For medications that were not withdrawn from the Pyxis, the nurse who administered was coded on the data collection record. The research assistants also conducted all data collection and coding on site to further ensure patient and nurse anonymity. To ensure

patient confidentiality all paper data was kept in a locked cabinet and computer files stored in a password-protected computer in which only the primary researcher has access.

Variable Definitions

The following text provides the conceptual and operational definitions for the variables to be used in this study. The author identified potential risk factors associated with medication administration time error through a review of the literature, personal nursing experience, and the expert opinions of nursing faculty at the University of Windsor and nursing staff located at the research setting.

Medication Factors. Medication factors refer to the characteristics of the medication that may influence the timing of medication delivery. The specific factors examined in this study were: (a) medication route, (b) time criticality (c) level of risk.

Medication route is defined as the method by which the medication is introduced into the body and was operationalized as a categorical variable with the following levels: oral (PO), rectal (PR), G-tube, subcutaneous (SC), intramuscular (IM), intravenous (IV), transdermal (TD), ophthalmic (OPH), and inhalation (INH).

Time criticality refers to the degree to which it is important that a medication be administered within a specific timeframe in order to maintain the required therapeutic effects in the body. It was operationalized as either *time-critical* or *non-time-critical*.

Time-critical medications were defined as: (a) medications with a dosing schedule more frequent than every 4 hours; (b) opioids used for chronic pain or palliative care (Hall & Fraser, 2006; ISMP, 2011; NPSA, 2010b); (c) immunosuppressive agents used to prevent solid organ transplant rejection or to treat myasthenia gravis; (d) medications that must be administered apart from other medications such as antacids or fluoroquinolones; (e)

medications requiring administration during a specified time period; such as before, after or with a meal; which would include insulins (Hall & Fraser, 2006; Heatlie, 2003; ISMP, 2011; NPSA, 2010a; NPSA, 2010b), and oral antidiabetics, alderonate, and pancrealipase (ISMP, 2011); and (f) medications used for specific diagnoses such as Parkinson's disease (Hou et al., 2012; ISMP, 2011; NPSA, 2010a; NPSA, 2010b) and sepsis (ISMP, 2011A; NPSA, 2010a). Non-time-critical medications included all medications that do not fit the criteria of time-critical medications.

The level of risk of a medication refers to the extent to which a medication is likely to be associated with causing significant patient harm when administered in error. This is a categorical variable with two levels: (a) high-alert medications and (b) non-high-alert medications. *High-alert medications* are those that have the potential to cause serious patient harm when administered incorrectly. Based on the hospital's High-Alert Medication Policy (Research Setting, 2011), the following medications were classified as high alert: (a) concentrated electrolytes (intravenous potassium chloride, intravenous potassium phosphate, intravenous sodium chloride in concentrations greater than 0.9%, intravenous magnesium sulphate); (b) narcotics and opiates; (c) heparin and low molecular weight heparins (anticoagulants); (d) sedatives and benzodiazepines (psychoactive medications); and (e) all types of insulin. All other medications not identified above were classified as non-high alert medications.

Medication Class refers to the medication group in which a medication is classified according to the condition/disease that are treating and/or the body system primarily affected.

After initial data collection, medications were classified into the following groups:

(a) cardiac, anti-hypertensive, & diuretic medications; (b) diabetic medications; (c) antibiotic/antifungal medications; (d) anticoagulant/anti-platelets medications; (e) respiratory medications; (f) analgesia/inflammatory medications; (g) vitamins/mineral/hematopoietic medications; (h) antipsychotics/antidepressants/neurological medications; (i) gastrointestinal/genitourinary medications; and (j) other (statins, endocrine, ophthalmic, antispasmodics) medications.

Cardiac, anti-hypertensive, diuretic medications included any medication used for the management of blood pressure, heart rate, and arrhythmia (e.g. metoprolol, ramipril, furosemide, etc.).

Diabetic medications included any medication used for the management of diabetes/ blood glucose control (e.g. Metformin, Januvia, Diamicon, insulins, etc.).

Antibiotic/anti-fungal medications included any medication used to treat infectious diseases such as pneumonia, cellulitis, etc. (e.g. ceftriaxone, ciprofloxacin, metronidazole, etc.).

Anticoagulants/anti-platelets medications included any medications used in the treatment/prevention of blood clots (e.g. heparin, warfarin, aspirin, etc.).

Respiratory medications included any medication used in the treatment for respiratory conditions/diseases such as emphysema, asthma, etc. (e.g. Ventolin, Spiriva, etc.).

Analgesia/anti-inflammatory medications included any medication used for the treatment of pain and/or inflammation (e.g. morphine, Percocet, Tylenol, Ibuprofen, etc.).

Vitamins/mineral/hematopoietic medications included any medication used to support nutrition (e.g. vitamin D, calcium carbonate, ferrous gluconate, etc.).

Antipsychotics/antidepressants/neurological medications included any medications used to treat psychiatric/neurological disorders such as Alzheimer's, depression, Parkinson's, etc. (e.g. seroquel, donepezil, etc.).

Gastrointestinal/genitourinary medications included any medication used to treat diseases/disorders that affected the gastrointestinal and urinary system (e.g. domperidone, pantoprazole, lactulose, etc.).

Other (statins, endocrine, ophthalmic, antispasmodics) medications included all other medications that had too low of a sample size to create their own individual medication group (e.g. synthroid, atorvastatin, etc.).

Environmental factors. Environmental factors refer to characteristics of the unit/organization that may influence the timing of medication delivery. The specific factors examined in this study were: (a) day of week; (b) scheduled administration time; (c) accommodation type; (d) status of individual administering the medication; (e) medication availability; and (f) location of patient at the scheduled administration time.

Day of week was defined as the date the medication is administered and will be operationalized as a categorical variable with the following levels: (a) Monday; (b) Tuesday; (c) Wednesday; (d) Thursday; (e) Friday; (f) Saturday; (g) Sunday.

Scheduled administration time was defined as the time that the medication is due to be given, as documented on the CMAR.

Accommodation type was defined as the type of room the patient was in when the medication was administered. It was operationalized as a categorical variable with three levels: single room, semi-private room, or ward. The patients' room numbers were available on the CMARs and were used to determine their accommodation type.

Status of individual administering was defined as the qualifications of the individual who administered the medication. This is a categorical variable with two levels: (a) registered nurse or (b) nursing student. Credentials that accompany the signature of the individual who administered the medication determine this information.

Medication availability was defined in terms of whether or not the medication was accessible by the nurse at the scheduled time of administration, and was operationalized as a dichotomous variable (available/not available). Medications that were not available were typically documented as such on the CMAR. Those that were not documented as “not available” were deemed to have been available.

Location of the patient at the scheduled time of administration was defined by whether the patient was off the unit at the scheduled medication time, and was operationalized as a dichotomous variable (on unit/off unit). When patients are off the unit for diagnostic tests such as x-ray, nurses typically document on the CMAR beside the medication that the patient is “off unit.” Those that were not documented as “off unit” were deemed to have been on the unit at the time the medication was scheduled for administration.

Patient Factors. Patient factors refer to characteristics of the patient that may influence the timing of medication delivery. Due to limited research, anecdotal experience of the author and colleagues were used to determine the patient factors that may influence medication delivery times. The specific factors examined in this study were: (a) patient age, (b) patient gender, (c) number of patient co-morbidities, (d) level of consciousness, (e) level of orientation, (f) number of medications due at scheduled administration time, and (h) swallowing ability.

Patient age was defined as the patient's age in years at the time of admission as indicated by age documented on the admission face sheet and was measured as a continuous variable.

Patient gender was defined as the patients sex as documented on the admission face sheet and will be measured as a dichotomous variable (male/female).

Number of patient co-morbidities was defined as the number of medical conditions listed under the client's medical history on the clinical data-base and was operationalized as a continuous variable.

Level of consciousness was defined as the patient's awareness of environmental surroundings on the day the medication was administered. This is a categorical variable with two levels: alert or impaired. Those who were attentive and responded appropriately were deemed to have been alert. This data was also abstracted from the patient's medicine flowsheet on which nurses document their assessment of the patients' current level of consciousness. In contrast, patients who responded only to verbal or painful stimuli, or who are unresponsive at the time of administration were deemed impaired. This data will also be abstracted from the patients' medicine flowsheet where the primary nurse has documented his/her assessment.

Level of orientation is reflective of the patient's cognitive status and was defined as the patient's orientation to person, place and time as documented on the flowsheet. Level of orientation was operationalized as a nominal variable with the following levels (as recorded in the chart): (a) oriented X 1, (b) oriented X 2, (c) oriented X 3, and (d) not oriented. The research assistants assessed this based on data provided in the patient's medicine flowsheet where the primary nurse has documented his/her assessment.

Number of medications due at scheduled administration time was defined as the number of medications for which the patient was scheduled, as written on the CMAR, on the day and time that the index medication was scheduled. This did not include medications ordered as PRNs, STAT and one-time doses, or recently ordered medications. This was operationalized as a continuous variable.

Swallowing ability refers to a patient's capability of swallowing oral medications whole. This is a categorical variable with two levels: (a) impaired or (b) not impaired. Patients who required their medications in liquid form or crushed prior to oral administration were deemed impaired. This data was extracted from the patients' CMARs where nurses and/or pharmacy personnel document patients who require medications crushed or in the form of an elixir prior to oral administration. Those not documented as such were deemed not impaired.

Dependent Variable.

Timeliness of medication administration refers to whether or not a medication was administered on time (outside the recommended time outlined by literature and hospital policy). This variable was measured as a dichotomous variable: on time or not on time. The criteria for determining whether or not a medication was given on time depended on whether or not the medication was a time-critical one. Time-critical medications were deemed to be not on time if it was administered 30 minutes or more before or after its scheduled time. Non-time-critical medications were deemed to be not on time if it was administered 60 minutes or more before or after its scheduled time. To determine if a medication was on time, the scheduled time on the CMAR was compared to the time it was removed from the Pyxis Medstation (provided in the pharmacy-generated report).

Experience suggested that nurses often don't accurately document the time of administration on the CMAR. Therefore, the Pyxis time was used as it provided the exact time the medication was removed for administration. For medications not withdrawn from the Pyxis, the scheduled time on the CMAR was compared to the documented medication administration time on the CMAR and/or hypoglycemic record. Medications defined as time-critical, had to have been withdrawn from the Pyxis or documented on the CMAR (for those medications not withdrawn from the Pyxis) within 30 minutes before or after the scheduled time to be classified as on time. Medications defined as non-time-critical must have been withdrawn from the Pyxis machine or documented on the CMAR (for those medications not withdrawn from the Pyxis) within 60 minutes before or after the scheduled time to have been classified as on time. A medication was defined as not on time if: (a) it was removed from the Pyxis more than 30 minutes before or after the scheduled administration time for time-critical medications; and (b) it was removed from the Pyxis more than 60 minutes before or after the scheduled administration time for non-time-critical medications. Medications that were not stored in the Pyxis machine were deemed to be not on time if they were documented as having been administered greater than 30 minutes before or after the scheduled dose for time-critical medications, and greater than 60 minutes before or after the scheduled dose for non-time-critical medications.

Accuracy of documentation

During the course of data collection, discrepancies between Pyxis removal times and documented administration time were found. The expectation is that nurses remove medications from the Pyxis machine and administer them shortly after (i.e., within 5

minutes of removal). It was frequently found, however, that a medication was removed 30 minutes early (e.g., at 08:30), yet documented as administered at the expected time (e.g., 09:00). Similarly, many medications were documented as having been administered “on time” when in fact they were withdrawn from the Pyxis machine 30 or more minutes after the documented time of administration for time-critical medications, and 60 minutes or more for non-time-critical medications. In light of these serendipitous findings, it was decided to collect and report on these discrepancies in documentation. Medications were deemed accurately documented if the Pyxis removal time was within 5 minutes before or after the CMAR documented time. If the Pyxis removal time was greater than 5 minutes before or after the CMAR documented time, it was deemed as not accurately documented. When medications had no Pyxis removal time (i.e., they were taken from the refrigerator), conclusions about accuracy of documentation could not be made.

Data Screening and Analysis Procedure

Prior to analysis, all data was screened for violations of bivariate and multivariate assumptions (missing data, outliers, and normality distribution). Descriptive statistics were used to summarize sample characteristics such as general frequencies, means, and standard deviations (Field, 2010). All data was analyzed using SPSS software packages (Version 21.0). Criteria for establishing statistical significance for this study included a 95% confidence interval (CI) and/or a two-tailed alpha of .05. Because of the dependent nature of the data in which patients contributed more than one observation, a series of generalized estimating equation (GEE) models using multivariate binary logistic regression was used. With repeated observations, the correlation among values must be

taken into account; GEE adjusts standard errors to account for this (Liang & Zeger, 1986). Logistic regression is most often used to predict dichotomous outcomes (on time/not on time) and allows the researcher to analyze the relationship between multiple independent variables and a single dependent variable (Polit, 2010).

CHAPTER 4

RESULTS

In this chapter, the result of the statistical analyses of the proposed research question is presented. Data screening and preparation as well as a summary of patient and observation characteristics are provided.

Data Screening and Preparation

Prior to data screening and preparation, initial data entry was checked for accuracy by comparing the original dataset(s) with each corresponding observation. Then, simple frequencies and descriptive statistics were conducted to screen for any missing or miscoded data. Nurse codes (N = 123) were not generated, and were therefore missing, for medication administration events associated with medications that are stored outside of the Pyxis machine (e.g., antibiotics and insulin, which are refrigerated). Since nurses are responsible for administering all of their patients' medications, it was assumed that the nurse who removed a patient's other medication from the Pyxis administered the refrigerated medications as well. The research assistants verified this by checking the nurses' initials on the medication records. The missing data were therefore replaced with the codes that corresponded to the nurses who administered other medications to that patient at that time (or during that shift, when only the index medication was due at the time). There were also 173 missing data points for Pyxis removal time because of the medications (as described above) that are not stored in the Pyxis system. These data were not replaced as the documented medication administration time on the CMAR was used to determine the medication outcome of on time and not on time (see limitations). The final sample consisted of 1032 convenient observations (i.e., unique medication

administrations/receipts; hereafter referred as *medication events*). Post-hoc power analysis of the final sample yielded a total power of .94, using a two-tailed alpha of .05 and an effect size of .20 (Faul, Erdfelder, Buchner, & Lang, 2009).

Each medication was classified as either time-critical or non-time critical, as previously defined and then classified as either on time or not on time, as previously defined. Prior to analysis, the database was examined for assumptions of logistic regression (normal distribution, and absence of outliers and multicollinearity) (Tabachnick & Fidell, 2007). Outliers are cases that are different from the majority of data values in the data set that can skew the study results (Tabachnick & Fidell, 2007). Presence of outliers for the continuous variables were examined using a Z-score cut off of ± 3.29 , stem and leaf plots, and boxplots (Tabachnick & Fidell, 2007). There were no outliers detected. Distributions of the continuous variables were assessed using the cutoff points for skewness and kurtosis of ± 1.96 , and histograms with a normal curve. No violations were found for normal distribution of continuous variables.

Multicollinearity occurs when there is a high correlation between two or more independent variables, which may lead to redundancy and statistical error (Tabachnick & Fidell, 2007). Since *scheduled administration time* and *shift* were related, only *scheduled administration time* was included in the regression analysis. Collinearity diagnostics (i.e., Cramer's V) were performed on the other variables and revealed no evidence of multicollinearity.

Some categorical variables in the dataset had multiple categories/levels with marginal frequencies. Thus, some categories were collapsed and recoded to improve the distribution among the categories of the variables. *Medication route*, for example,

initially had 9 levels. However, the decision was made to collapse SC, IM, and IV medications into a single level called *injectables*, while rectal, transdermal, inhalation, ophthalmic, and g-tube routes were collapsed into an “other” category. This resulted in three levels of medication route: oral, injectables, and other. Day of week, initially with seven categories, was recoded to weekdays and weekends. Scheduled administration time was recoded from a continuous variable to a categorical variable that included: midnights (20:00-06:00), early morning (07:30-08:00), routine time (09:00), early afternoon (11:30, 12:00, 13:00), and late afternoon/evening (16:00, 16:30, 17:00, 18:00). *Status of individual administering* was excluded from analyses because only RNs administered medications during the data collection period. The variables *medication availability*, *location of patient at scheduled administration time* and *level of consciousness* were also removed from the analysis because the split for these two variables was too extreme (i.e., 99:1 for medication availability). Tabachnick and Fidell (2007) support removing dichotomous variables with extremely uneven splits (i.e., > 90:10) because the category with fewer cases may be more influential than the category with a larger number of cases.

Patient Factors

Table 1 provides an overview of the patient characteristics, as well as the results of univariate analyses comparing patient factors whose medications were administered on time versus those whose medications were not on time. Forty-five patients contributed 1032 medication events that were administered by 55 nurses. The mean age of patients was 75.60 ($SD \pm 11.97$; range = 48–98). More than half of the sample was female (60%; $n = 27$). The majority of patients were admitted with respiratory medical diagnoses

(40%, $n = 18$), followed by infectious disease (11.5%, $n = 5$). The patients had a mean of 6.78 ($SD \pm 2.87$) co-morbidities. Over a quarter of the patients had a swallowing impairment (26.7%; $n = 12$). Further, the majority of patients were both alert (93.3%; $n = 42$) and oriented to person, place, and time (71.7%; $n = 32$). The majority (60%; $n = 27$) of patients were accommodated in 4-bed wards, while the remaining 40% ($n = 18$) were in semi-private rooms. The minimum number of medication events that each patient contributed was 4, while the maximum of was 82 ($X = 22.96$; $SD \pm 15.39$).

Prior to regression analysis, unadjusted analyses (i.e., t-test & chi-square) were used to compare the characteristics of patients whose medications were delivered on time ($n = 32$) versus those whose medications were not on time ($n = 13$). Because each patient contributed more than one medication event, *only the first medication event* was used to examine the influence of patient characteristics on the outcome variable. Based on these unadjusted analyses, age was the only patient factor that was significantly ($p < .05$) associated with whether or not the medication was administered on time. As displayed in Table 1, patients who received their medications on time were younger than those who did not receive medications on time ($t = 2.43$, $p = .02$). There were no statistically significant differences between the two groups concerning other patient characteristics. However, two additional variables (gender, swallowing ability) met the criterion ($p \leq 0.25$) for inclusion in the multivariate regression analysis (Hosmer & Lemeshow, 1989).

Table 1

Patient factors: comparison of medication event status (on time versus not on time)

Variable	Groups		Total (N = 45)	χ^2/t	p
	On Time (n = 32)	Not on Time (n = 13)			
Age [mean (SD)]	78.2 (10.3)	69.2 (13.7)	75.6 (12.0)	2.43	.02
Number of patient co-morbidities [mean (SD)]	6.69 (2.8)	7.00 (3.1)	6.78 (2.9)	-.33	.75
Gender [n (%)]					
Male	15 (83.3)	3 (16.7)	18 (40)	.22	.11
Female	17 (63.0)	10 (37.0)	27 (60)		
Accommodation [n (%)]					
Semi	20 (74.1)	7 (25.9)	27 (60)	.29	.59
Ward	12 (66.7)	6 (33.3)	18 (40)		
Swallowing Ability [n (%)]					
Not Impaired	26 (78.8)	7 (21.2)	33 (73.3)	3.55	.06
Impaired	6 (50)	6 (50)	12 (26.7)		
Level of Consciousness [n (%)]					
Alert	31 (73.8)	11 (26.2)	42 (93.3)	----	----
Impaired	1 (33.3)	2 (66.7)	3 (6.7)		
Orientation [n (%)]					
Not Oriented	3 (75)	1 (25)	4 (8.9)	1.39	.71
Oriented X 1	4 (66.7)	2 (33.3)	6 (13.3)		
Oriented X 2	3 (100)	0 (0)	3 (6.7)		
Oriented X 3	22 (68.8)	10 (31.3)	32 (71.7)		

Note. χ^2 = Chi-square; t = t-test;

---- indicates statistic not calculated due to extreme uneven split.

Medication Event Characteristics

A summary of medication event characteristics is presented in Tables 2 and 3.

Descriptive statistics were conducted to describe the characteristics of the 1032 medication events. The results reveal that the mean number of medications that patients received per day was 16.0 ($SD \pm 7.66$; range = 4-36) with an average of 5.7 ($SD \pm 3.6$;

range = 1-16) medications due at each scheduled administration time. The majority of medications administered were: cardiac/antihypertensive (21.2%; $n = 219$) medications, followed by gastrointestinal/genitourinary (14.3%; $n = 148$) and antidepressant/antipsychotic (13.2%; $n = 136$) medications. Antibiotics/anti-fungals (10.1%, $n = 104$) followed by analgesics/anti-inflammatory (7.4%; $n = 76$) medications, comprised the majority of time-critical medications.

Table 2 demonstrates that the majority of medications were administered orally (68.5%; $n = 707$). Of the medications administered, 26% ($n = 268$) were time-critical and 11.2% ($n = 116$) were classified as high-alert. The data suggest that the majority of medication events occurred on weekdays (71.7%; $n = 740$), with most medications administered during routine (51.5%; $n = 531$) and midnight (27%; $n = 279$) scheduled administration times.

Table 2 displays the unadjusted analyses that were conducted to compare on time ($n = 768$) versus not on time ($n = 264$) medication events with respect to environmental and medication-related factors. Of the medications administered, 74.4% ($n = 768$) were on time, while 13.4% ($n = 138$) were administered early, followed by 12.2% ($n = 126$) that were administered late. For medications not administered on time, the mean time difference between scheduled administration time and pyxis removal time was examined for both time-critical and non-time-critical medications. The mean time difference for non-time-critical medications was 81.49 minutes (SD +32.35; range=61-260). Therefore, non-time critical medications, on average, were removed for administration almost 22 minutes early or later than the expected time (2 hour window). For example, a medication scheduled for 0900 should have been given between 0800 and 1000.

However, it would have been given at 0738 if administered early and at 1022 if administered late. The mean time difference for time-critical medications was 55.86 minutes ($SD \pm 25.59$; range= 31-240). Therefore, time-critical medications, on average, were removed for administration almost 26 minutes early or later than the expected time (1 hour window). For example, a medication scheduled for 09:00 should have been given between 08:30 and 09:30. However, it would have been given at 0804 if administered early and at 09:56 if administered late. Approximately 30% of all high-alert medications were not administered on time, and half of all time-critical medications were not administered on time ($\chi^2 = 106.56, p = <.001$).

Table 2

Medication and environmental factors: comparison of medication event status (on time versus not on time).

Variable	Group		Total (N = 1032)	χ^2/t	P
	On Time (n = 768)	Not On Time (n = 264)			
	[mean(SD)]	[mean(SD)]	[mean(SD)]		
Number of medications due at administration time	5.53 (3.3)	6.29 (4.2)	5.73 (3.6)	-2.7	<.001
[mean(SD)]					
	[n (%)]	[n (%)]	[n (%)]	18.7	<.001
Route [n (%)]					
PO	554 (78.4)	153 (21.6)	707 (68.5)		
Injectable	98 (67.6)	47 (32.4)	145 (14.1)		
Other	116 (64.4)	64 (36.6)	180 (17.4)		
Time Criticality [n (%)]				106.56	<.001
Non-Time-Critical	632 (82.7)	132 (17.3)	764 (74.0)		
Time-Critical	136 (50.7)	132 (49.3)	268 (26.0)		
Level of Risk [n (%)]				.955	.329
Non-High Alert	686 (74.9)	230 (25.1)	916 (88.8)		
High Alert	82 (70.7)	34 (29.3)	116 (11.2)		
Day of Week [n (%)]				4.44	.04*
Weekday	564 (76.2)	176 (23.8)	740 (71.7)		
Weekend	204 (69.9)	88 (30.1)	292 (28.3)		

Early Afternoon	51 (69.9)	22 (30.1)	73 (7.1)
Late Afternoon/Early Evening	103 (88.0)	14 (12.0)	117 (11.3)

Note. χ^2 = Chi-square; t = t-test;

Table 3 compares medications administered on time versus not on time by type (classification) of medication. Of the medication types administered, 36.8% ($n = 14$) of diabetic, 46.2% ($n = 48$) of antibiotics/antifungals, 35.5% ($n = 27$) of analgesia/anti-inflammatory, and 48% ($n = 36$) of other medications were not administered on time. Given their significance levels ($p < 0.25$), all non-patient characteristics except level of risk were included in the regression analysis.

Table 3

Comparison of medication event status (on time versus not on time) by medication class

Variable	Groups		Total ($N = 1032$)	χ^2	p
	On Time ($n = 768$)	Not on Time ($n = 264$)			
Medication Classification	[n (%)]	[n (%)]	[n (%)]	73.2	<.001
Cardiac, Anti-hypertensive, diuretic [n (%)]	182 (83.1)	37 (16.9)	219 (21.2)		
Diabetic*	24 (63.2)	14 (36.8)	38 (3.7)		
Antibiotic/ Anti-fungal*	56 (53.8)	48 (46.2)	104 (10.1)		
Anticoagulants/ Anti-platelets	83 (87.4)	12 (12.6)	95 (9.2)		
Respiratory	31 (86.1)	5 (13.1)	36 (3.5)		
Analgesia/ Anti-inflammatory*	49 (64.5)	27 (35.5)	76 (7.4)		
Vitamins/ Mineral/ Hematopoietic	83 (79.9)	22 (21)	105 (10.2)		
Antidepressants/ Antipsychotics/ Neurological	110 (80.9)	26 (19.1)	136 (13.2)		

Gastrointestinal/ Genitourinary	111 (75.0)	37 (25.0)	148 (14.3)
Other (Statins, Endocrine, Ophthalmic, Antispasmodics)*	39 (52.0)	36 (48.0)	75 (7.3)

Note. χ^2 = Chi-square; *Indicates medication group that contain time-critical medications

Predictors of Medication Event Status: On-Time versus Not On-Time

Table 4 summarizes the results of the binary logistic regression using generalized estimating equations (GEE) to determine the predictors of medication event status. Three variables were found to be independent predictors of medication event status. The number of medications due at the scheduled administration time was a significant predictor of medication event status, such that patients who were scheduled a larger number of medications at a given time were 1.18 times more likely to receive their medications not on time (95% *CI* 1.06-1.31). Swallowing impairment was also a significant predictor of medication event status. Patients with swallowing impairments (i.e., those who required their medications to be crushed prior to administration) were 2.76 times more likely to receive their medications not on time compared to patients with no swallowing impairment (95% *CI* 1.13-6.76). The findings also suggest that time-critical medications were 7.22 times (95% *CI* 4.41-11.84) more likely to be administered not on time compared to non-time-critical medications.

It was noted during data collection that there were discrepancies between documented medication administration times and Pyxis removal times. The majority of medications (65%; $n = 671$) were not accurately documented on the medication record. This was determined because the majority of medications are withdrawn from the Pyxis machine assuming that administration would follow shortly thereafter. However, several

CMARs were signed off at the scheduled administration time when in actuality the medications were removed for administration several minutes prior to, or following, the scheduled administration times. For example, a scheduled medication for 09:00 was initialed as administered at 09:00, when in fact the Pyxis reports demonstrated that the medication wasn't removed for administration until 09:28.

Table 4

Binary logistic regression using generalized estimating equations (GEE) to determine the predictors of medications event status.

Variables	β	SE	P	OR	95% CI
Age	-.029	.0165	.083	.97	.94-1.00
Number of Medications due at scheduled administration time	.161	.0549	.003	1.18	1.06-1.31
Gender					
Female	.118	.3936	.764	1.13	.52-2.44
Male (reference group)	-----	-----	-----	-----	-----
Swallowing Impairment					
Impaired	1.016	.4569	.026	2.76	1.13-6.76
Not impaired (reference group)	-----	-----	-----	-----	-----
Route					
PO	-.091	.5586	.871	.91	.31-2.73
Other (reference group)	-----	-----	-----	-----	-----
Injectables	-.477	.5645	.398	.62	.21-1.88
Other (reference group)	-----	-----	-----	-----	-----
Time Criticality					
Time-Critical	1.977	.2521	.000	7.22	4.41-11.84
Non-Time-Critical (reference)	-----	-----	-----	-----	-----
Day of Week					
Weekday	.177	.3429	.61	1.19	.61-2.34
Weekend (reference)	-----	-----	-----	-----	-----
Scheduled Administration Time					
Midnight	.176	.4948	.72	1.19	.45-3.15
	-----	-----	-----	-----	-----

Routine Time	-.284	.6306	.65	.75	.22-2.59
	-----	-----	-----	-----	-----
Early Afternoon	.102	.5247	.85	1.11	.40-3.10
	-----	-----	-----	-----	-----
Late Afternoon/evening	-.950	.4931	.054	.387	.15-1.02
Early Morning (reference)	-----	-----	-----	-----	-----

Note. *B* = unstandardized coefficient; *SE* = standard error; *OR* = odds ratio;

CHAPTER 5

DISCUSSION

Failure to administer medications at *the right time* is the error that occurs most frequently medication administration process (Biron, 2009; Elliot & Liu, 2010; Keers et al., 2013) with between 23% (Teunissen et al., 2013) to 73% (Berdot et al., 2012) of all medications in the acute care setting administered at the wrong time. Administering a medication outside of the allotted timeframe is considered a medication error (Cohen, 1999; Department of Health, 2004; Elliot & Liu, 2010; Hall & Fraser, 2006), and can result in harm to the patient. Although nurses are expected to administer medications on time (CNO, 2015; Elliot & Liu, 2010; Lilley & Guanci, 1994); little is known about the the factors that influence the timely administration of medications. The Canadian adverse events drug study published in 2004 revealed that 185,000 patients admitted to acute care hospitals yearly experienced an adverse event; 24% of which were drug related (Baker et al., 2004) (not all of which are wrong time errors). Medication errors cost not only human lives; they cost hospitals worldwide billions of dollars each year due to additional care required as a result of these errors (i.e., lost income, disability, increased length of stay) (Institute of Medicine, 1999).

In this chapter, the findings from this study examining the medication, environmental and patient factors that predict whether or not a medication is administered on time is compared to the literature. Implications and recommendations for practice and research are presented. The discussion is organized according to the theoretical model used to guide this study, specifically the *structure* of the medication administration process (medication, environmental and patient factors) and their relationship to the

process of timeliness of medication administration.

Medication factors: Predictors and non-predictors of medication administration time errors

The model used to guide this study suggested that medication route, time criticality, and level of risk would influence whether or not a medication was administered on time. However, only time criticality was found to be significant. *Time Criticality.* The study findings suggest that time criticality was a significant predictor of whether or not a medication was administered on time. However, the nature of this association is very concerning, as the medications for which timely administration is most crucial (i.e., time-critical medications) were those that were least likely to be given on time. Twenty five percent of all medications administered during the study timeframe were time-critical medications, of which approximately half were not given on time. Further, on average, time-critical medications were administered 26 minutes before or after the medication policy time frame of 30 minutes. The lack of adherence to timely administration of the medications deemed time-critical may result in non-therapeutic levels of medications in affected patients.

The study results are difficult to discuss within the context of previous research, as the only study that examined medication time errors in time-critical medications was specific to insulin only (Gangopadhyay et al., 2008). Consistent with the current findings, however, the authors reported that insulin was seldom administered on time. Given the dearth of previous research in this area, further study is needed to verify the current findings.

There are a number of plausible explanations for the finding that time-critical medications were associated with time errors. The first relates to nurses' knowledge about time-critical medications and/or the extent to which the hospital communicates and emphasizes its medication policy in relation to time-critical medications. We do not know if nurses in the research setting had sufficient knowledge about time-critical medications in terms of: (a) which specific medications are time-critical, (b) the importance of ensuring that they be given on time, and/or (c) the hospital's medication policy as it relates to time-critical medications.

The errors related to time-critical medications might also be related to their scheduled administration times. Most of the time-critical medications in this study were antibiotics/antifungals, which are usually administered on 8 (e.g., 05:00, 13:00, & 21:00 hours) or 12 hour (e.g., 10:00 hours and 22:00 hours) dosing schedules. These dosing schedules generally result in administration times that are different from that of routine medication administration times (e.g., 09:00 and 17:00). In an attempt to better organize their workload, nurses may give such time-critical medications early or late in an effort to cluster them together with other tasks (i.e., personal care, toileting, dressings, or other medications). For example, Jennings et al. (2011) found that medications scheduled at 08:00 and 10:00 were given at 09:00. They also found that when patients requested PRN medications (e.g., for pain management) close to scheduled medications, nurses often administered all scheduled medications with the pain medication in order to make only one visit. Further, when more than one IV antibiotic is scheduled concurrently, administering each medication on time may be unrealistic (Jennings, et al., 2011). In the medication policy of the research setting, recommended IV antibiotic infusion times

range from 20 to 60 or more minutes for each medication. Yet, multiple antibiotics were scheduled for the same time for some patients in this study, which made it impossible for nurses to administer each within the recommended timeframe.

Although nurses believe that *medication route* influences medication administration times (Davis et al., 2005), it was found not to be a significant predictor of medication time errors in this study. These findings are inconsistent with previous research (Teunissen et al., 2013) where medication route, specifically the rectal route, was associated with time errors. However, the authors did not conduct multivariate analyses to assess the influence of other confounding variables (e.g., such as the administration time, number of medications due at that time) on the outcome. In this study, the majority of medications were administered orally. Given that a very small number of patients received medications by rectal, nasogastric, and g-tube routes; these routes were collapsed into a single “other” category that included other less common medication routes (i.e., inhalation & ophthalmic). Future studies should ensure the study population contains sufficient samples of various medication routes to allow for examination of the unique contribution of each route to delivery time error.

The *level of risk* of a medication (i.e., high-alert versus non-high-alert) was found not to be a predictor of medication time errors. This finding was somewhat unexpected since high-alert medications lengthen the medication administration process as a result of the need to complete independent double check prior to administration (ISMP, 2013; Jarman, Jacobs, & Zielinski, 2002b). No known studies have examined this variable and how it influences medication administration times. Given the dearth of previous research in this area, further study is needed.

Environmental factors: Predictors and non-predictors of medication administration time errors

Environmental factors examined in this study included day of week and scheduled administration time, which were not predictive of delivery time. Consistent with other literature (Teunissen et al., 2013), *day of week* was found not to influence delivery time errors. This finding is interesting as weekdays tend to be more busy and interruptive for nurses due to an increased presence of managers, doctors, and support staff competing for patients' time and their charts. Day of week may have not shown to be significant as data collection occurred over a one-week time-period. However, the findings suggest that day of week does not influence a nurse's ability to administer medications on time.

This study found that *scheduled administration* was not a predictor of errors in delivery time. These findings differ from that of others (Biron, 2009; Teunissen et al., 2013; Thomson et al., 2009) who found that medications administered during the early afternoon period were associated with reduced medication time error rates. However, in two of these studies (Biron, 2009 & Thomson et al. 2009), the researchers did not adjust for confounding variables such as the number of medications due at the respective times. Thus, their results might be related to the fact that fewer medications tend to be administered during the early afternoon. Future studies should control for other confounding variables (i.e. number of medications due at scheduled administration time) that may influence medication delivery time errors to determine whether scheduled administration time is a significant predictor of medication time errors in hospital.

Patient factors: Predictors and non-predictors of medication administration time errors Patient factors that were examined as potential predictors of medication

administration delivery status included: age, gender, number of co-morbidities, number of medications at scheduled time of delivery, and swallowing ability. Of these, only number of medications at scheduled time of delivery and swallowing ability were shown to be significant predictors of delivery time errors.

In this study, nurses administered 1 to 16 medications per patient at each medication pass and the *number of medications* did influence delivery time errors. Specifically, medication time errors were more likely to occur when more medications for a single patient were scheduled together. Thomson et al. (2009) found similar results in a long-term care setting using univariate analysis, while Teunissen et al. (2013) reported that the total number of medications that a patient received at a given time had no effect on delivery time errors. These conflicting results demonstrate a need for additional research. Future studies should examine how this variable predicts medication administration delivery time errors while controlling for other confounding variables (i.e., time of day) that may also influence this outcome.

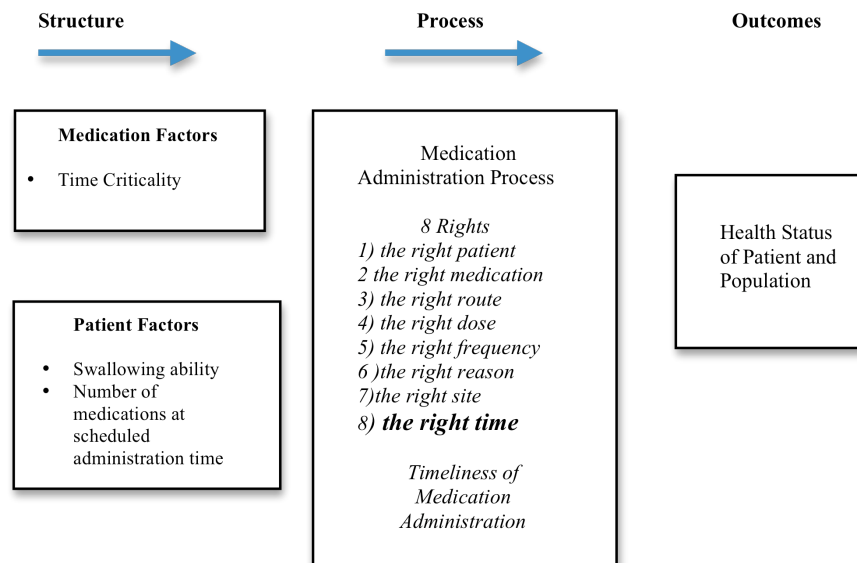
Swallowing ability. The study findings suggest that medication time errors were more likely to occur in patients whose swallowing was impaired. In addition to crushing and mixing medications with food or liquids prior to administration, nurses must also assist such patients in swallowing the medication, thus consuming more of the nurses' time. Further, nurses frequently administer medications to patients with swallowing impairments last, so that their other patients will receive their medications on time (Jennings et al., 2011). Although these practices may explain the study results, others (Kelly, Wright, & Wood, 2011) have found that swallowing ability was not associated with delivery time errors. However, the researchers may have underestimated the

number of wrong time errors. In this particular study, (Kelly et al., 2011) medications were only documented for one type of error (e.g., wrong dose), even if the medication was also given at the wrong time. Thus, medications were only recorded as wrong time errors if no other type of medication error existed (e.g. wrong route). The inconsistent findings and limited literature in this area demonstrates a need for further research.

Implications and Recommendations

The findings of this study suggest that the number of medications due at scheduled administration time, time-critical medications, and patients with swallowing impairments were all predictive of whether or not medications were administered on time (Figure 2). The following text provides a discussion of the research findings in areas of clinical practice, medication administration, theory, and future research is provided, followed by an acknowledgement of the study's limitations.

Figure 2: Framework for factors that influence timeliness of medication administration in the acute care setting



Nursing Practice/Medication Administration

The medication administration process has been described as a complex process during which nurses must manage varied and competing demands from patients, the physical environment, institutional policies, and the medications (Jennings et al., 2011). When preparing and administering medications, nurses often juggle competing priorities with frequent interruptions. Time management is a constant challenge for nurses on medical-surgical units, where in addition to other demands, nurses are required to administer medications several times per day to several patients. Research has shown that nurses spend almost a third of their day administering medications to their patients (Keohane et al., 2008).

Nurses in hospitals use CMARs to guide medication administration. In the research setting, CMARs are printed on paper and organized into binders. Nurses then compare each medication with the CMAR and the original order prior to administering the medication to the patient. Further, all new medication orders must be faxed to the pharmacy where they are verified and dispensed by pharmacy personnel. The administering nurse then double checks the order with a second nurse prior to administration. Some institutions with more advanced technology use a bar-coding method for medication administration. With this method, a medication cart is linked to a computer based system that requires scanning patients' individualized bar codes and each medication prior to administration. This process allows the nurse to validate and document the administration of medications. The bar-coding method is thought to increase the safety and efficiency of the medication administration process. However,

averaging around \$7,000 per machine, this is costly to implement (Foote & Coleman, 2008).

Medication administration is not a simple task as a nurse must understand and follow several steps in the process to ensure patient safety. In addition to following the *rights* of safe medication administration, a nurse must also assess their patients holistically. For example, a nurse must critically consider a patient's vital signs, allergies, medical history, current laboratory results, and contraindications prior to medication administration.

Currently, pharmacists, based on their knowledge of medications, influence when medications must be administered. This does not take into account the factors that may influence a nurse's ability to adhere to these policies. Although standardized times are valuable in providing consistency of care, literature demonstrates that nurses are often unable to follow these *time rules* without jeopardizing patient safety.

Although medication administration processes vary from institution to institution, they have often been criticized for being designed without input from nurses. The responsibility for medication errors should not fall solely on the nurse; but rather on faulty systems, processes and conditions that are currently in place that lead people to make mistakes or fail to prevent them. The *wrong time* is the most frequently occurring medication error (Biron, 2009; Elliot & Liu, 2010; Keers et al., 2013). However, an informal survey of provincial hospitals in Southwestern Ontario region revealed that current medication designs do not highlight time-critical medications to alert nurses to which medications require timely administration. Further, medication design does not consider the potential factors (i.e., number of medications) that influence a nurse's ability

to administer medications on time. This study found that approximately one in five non-time critical medications were not administered on time. Of greater concern was the finding that half of all time-critical medications were administered outside the therapeutic window. If time-critical medications are indeed time sensitive, institutions should be monitoring and auditing medication administration to determine whether these medications are being administered on time since patient care and clinical outcomes may be negatively affected.

In hospital, the majority of medications are administered during routine times; however, this practice may be unintentionally harming patients as nurses are spending large amounts of time administering all medications to their patients rather than prioritizing medications based on their time criticality. For example, this study found that almost half of all medications scheduled during early morning hours (07:30-08:00) and one-third during midnight hours (20:00-06:00) were not given on time. The majority of medications scheduled during these times are time-critical. Further, from a nursing workload perspective, the typical timing of routine medications (09:00 and 17:00) interferes with several other factors that compete for nurses' time. For example, at 09:00, nurses are not only administering medications but are also assisting their bathing with bathing, toileting, and consulting with doctors who frequently make their rounds during this time. Moving routine times to another time when there are fewer demands on the nurse may reduce the number of time related medication errors.

Given that the term "time-critical medication" was only recently introduced by the ISMP (2011), nurses may be unaware of the concept. Thus it is important that hospital in-services and nursing curricula educate nurses and nursing students about time-

critical medications so that practice will change accordingly. An informal review of current undergraduate nursing pharmacology textbooks in Canada (Adams & Urban, 2015; Lilley, 2010; Williams, 2012) found that time-critical medication(s) is not a topic covered. Pharmacology courses should include this topic so students learn the significance of time-critical medications before they begin practicing as nurses. Further, as previously stated, the CNO medication practice standards (2015) do not currently outline specific requirements for timely medication administration, especially time-critical medications. Given the importance of these medications for patient outcomes the CNO should offer some guidance on practice expectations.

This study found that three variables affected a nurses' ability to administer medications on time. To improve the safety and efficiency of the medication administration process, and the timely administration of time-critical medications, a multidisciplinary approach to medication redesign is required. Nurse-patient assignments should take into consideration patient factors that can cause time errors, such as swallowing impairment and the number of medications that patients are scheduled to receive. Patients with swallowing impairments and those scheduled a greater number of medications consume additional nursing time. Therefore, management must consider these factors and arrange the nurse-client workload accordingly to prevent medication delivery time errors.

The ISMP (2011) also recommends considering patient acuity levels, types of medications, quantity of time-critical medications, and frequency of medication administration as factors that may affect nurses' ability to administer time-critical medications on time. Further, staffing levels on units and in the pharmacies should be

planned to facilitate timely order review, and dispensing and administration of medications. By maintaining appropriate staffing levels, delays in medication availability and administration can be avoided (ISMP, 2011).

The CMAR should be redesigned to clearly identify time-critical medications, thus allowing nurses to prioritize medication administration around these medications. Hospital policy should allow nurses to organize medication administration based on individual patient requirements and time-critical medications. Given that only time-critical medications require strict adherence to scheduled administration times (ISMP, 2011), hospital policies could incorporate greater flexibility with respect when non-time critical medications must be administered. That is, the acceptable timeframe for administering non-time-critical medications could be extended to more than 60 minutes before or after their scheduled administration time. For example, if a time-critical antibiotic is scheduled for 07:30, it could be acceptable for a nurse to administer a non-time-critical medications scheduled for 09:00 concurrent with the 07:30 antibiotic. To make the medication administration process both timely and safe, institutions should introduce flexibility when the risk is minimal to patients (Stokowski, 2012). However, there is a concern that medications will be omitted if nurses do not adhere to scheduled medication administration times (ISMP, 2011).

Organizations should use the ISMP's guidelines for time-critical and non-time-critical medications or create their own when redeveloping their medication policies. These lists could be placed in the medication rooms to remind nurses of the agency and/or unit-specific time-critical medications.

Self-administration of medications by capable patients could greatly reduce the time nurses spend preparing and administering routine medications. The CNO (2008) encourages self-administration of medications for patients who are competent and capable, as it promotes autonomy and independence. Studies show that hospitalized patients feel that the timing of medication administration revolves around the nurse's schedule, and are not individualized to meet patients' needs (Jarman, Jacobs, Walter, Witney, & Zielinski, 2002; Manias et al., 2005). Patients also found that the timing of medication administration in hospital does not match with their medication schedules at home (Jarman et al., 2002a; Manias et al., 2005). Macdonald (2010) explained that hospitalized patients want to play a larger role in the medication administration process. Research suggests that patients who experienced medication self-administration reported a greater sense of autonomy, control and independence (Manias et al., 2005). Although patient self-administration of medications is not a common practice in acute care settings, encouraging this practice may help reduce the amount of medication time errors by RNs in hospital. However, this practice would require additional assessment from nurses and doctors to determine which patients can appropriately administer their own medications.

The medication policy in the research setting requires that nurses accurately document the precise time of administration when it is different from that of the scheduled time. A disconcerting finding, however, was that the actual administration time of the majority of medications were not accurately documented on the CMARs or diabetic records. This finding is consistent with other literature (ISMP, 2011) reporting that nurses admitted to documenting administration at the scheduled time (e.g., 0900), rather than at the actual administration time (e.g., 08:30). Accurate documentation is an

important part of medication administration and should reflect the actual time that a medication was administered (CNO, 2014; College of Association of Registered Nurses of Alberta, 2014; Hall & Fraser, 2006). This ensures accurate communication between health care professionals and minimizes the occurrence of medication errors (Hall & Fraser, 2006). The importance of accurate documentation of delivery times needs to be reinforced.

Documenting the exact time that a medication was administered assists nurses in evaluating dosing schedules by providing the necessary information to help the nurse avoid early administration of a medication that was previously administered late, thus resulting in a dosing interval that is too short or too long (ISMP, 2011). Nurses should also be required to document the reason for early, late, or omitted administrations. Hospitals should have established procedures in place to follow when medications are early or delayed (ISMP, 2011). This would assist nurses in maintaining appropriate medication dosing schedules so that adverse outcomes can be avoided. The ISMP (2011) also recommends establishing a process for event reporting of untimely administration of time-critical medications. Reported events can be examined for learning purposes to further understand the causes of untimely administration so that improvements can be made (ISMP, 2011).

Nursing Theory and Research

Donabedian's structure, process and outcomes theory was a useful guide for this study and should be used in future studies where similar variables are examined in relation to medication administration. However, the research findings only partially support the conceptual model used to guide this study. Only one medication and two

patient factors were predictive of medication administration delivery time errors. Other factors were shown not to influence medication administration delivery time errors in the research setting. Since *the right time* was the only dependent variable examined in this study, conclusions cannot be drawn on how medication, environmental, and patient factors influence the other *rights* in the medication administration process. Although the literature supports the timely administration of time-critical medications, this study did not examine whether medication administration time errors influenced the health status of the affected patients (*outcome*). Further testing while examining all three parts (*structure, process, and outcome*) of this model may provide additional insight and further validate the factors that predict medication delivery time errors by RNs in an acute care setting.

Few studies have examined the medication, environmental, and patient factors that predict whether or not medications are administered on time. Further, it is believed that this is the first study to examine the relationship between time criticality of a medication on medication administration delivery time errors. Future studies are needed to validate the findings that these variables are indeed predictive of medication administration delivery time errors in hospital. In this study, half of all time-critical medications were not administered on time. The findings suggest that future research is needed to better understand *why* medication administration time errors were more likely to occur with time-critical medications as opposed to non-time medications. For example, are medication delivery time errors a result of limited nursing knowledge, the current design of medication delivery or current CMAR design? This phenomenon is unknown and requires further investigation. It would also be interesting for future studies

to examine routine versus non-routine scheduled administration times to see whether this as a variable influences medication delivery time errors.

The study findings also present some conflicting results from that of previous research (i.e. number of medications, time of day, route). Although the findings from this study are important, further research is warranted. It is recommended that this study be repeated in other hospitals and units (i.e. surgical, neurological) to further verify its findings and generalizability. Disguised observation studies have been described as the gold standard for evaluating medication administration errors (Flynn, Barker, Pepper et al., 2002; Barker & McConnell, 1962). Prospective observation studies may better capture the medication administration process and timing of administration for medications, especially with certain time-critical medications such as IV antibiotics and insulins that are removed from an uncontrolled refrigerator (as opposed to a Pyxis machine) prior to administration. A prospective research design would also allow the inclusion of other factors that may influence a nurse's ability to adhere to medication administration times (i.e., nurse-patient ratio, interruptions, nursing experience, etc.). Further, future research could examine the extent to which medication administration delivery time errors affect patient outcomes (i.e. health status, length of stay, etc.).

Limitations

Although this study examined medication administration by individual nurses, it did not examine individual nurse factors that have been found to influence medication time errors in previous studies: age (Fasolino, 2009) and experience (Fasolino, 2009; Jones & Treober, 2010), and environmental factors such as staffing (Deans, 2005; Kim et al., 2011; Jones & Treober, 2010); and workload (Biron, 2011; Davis et al., 2005; Jones

& Treober, 2010). In addition, Thomson et al. (2009) found the time required for nurses to complete the medication administration process varied between types of units (behavioral care, dementia care, and physical support), suggesting that this variable may influence the timeliness of medication administration in an acute care setting. This study was conducted on only one unit and thus its findings are not generalizable to other units or hospitals. Additionally, patients' LOC and orientation were measured (as documented in the chart) at only two points in time (day and night shift). It may have failed to identify fluctuations that occurred outside of these two timeframes.

Given the finding in this and other studies that nurses often document that medications have been given on time when in fact they are given either early or late (ISMP, 2010), the study may have been subject to misclassification of medication time errors. Medication removal time was unavailable for several time-critical medications (i.e., IV antibiotics, insulin) that are stored and removed from a refrigerator on the unit prior to administration. Medication administration for these medications may have been early or late with associated documentation suggesting that it was given on time. Further, insulin administration must accompany a patient's meal. If meals were early or delayed from dietary, or the patient did not eat at the scheduled time, then it would be expected that a nurse administer the insulin different from that of the scheduled time. However, due to the nature of data collection it is not known if this is the case. Thus, the number of medications not administered on time may have been underestimated, contributing to the possibility of a Type II error.

Given that medications in this study were grouped together into categories, some medication classes did not exclusively represent time-critical medications. For example,

the medication class analgesics/ anti-inflammatory included all medications used for pain relief. However, based on the ISMP guidelines, only certain medications in this group (i.e., morphine, fentanyl) are deemed time-critical. Therefore, in this study it was not determined which specific time-critical medications were not given on time.

The retrospective nature of the study precludes inferring causation by variables that were found to be associated with time delays. Further, the presence of the research assistants on the unit at the time of data collection may have alerted nurses to be more precise with medication administration times.

Since certain *medication routes* occurred infrequently, this study was unable to examine the contribution of specific routes that other studies found to be related to administration time errors. Other variables not documented (i.e. frequency of admissions, transfers, and discharges per day) may have influenced nurses' ability to adhere to medication administration times. Certain variables (i.e., LOC, accommodation type, location of patient at the time of administration, medication availability, status of nurse administering); lacked sufficient data variance to be included in the analyses. It would have been interesting to determine whether these variables also predicted medication administration delivery time errors in an acute care setting. A prospective research design such as an observational study might better address these variables

Conclusion

The results of this study indicate that one medication factor (time criticality), and two patient factors (number of medications at scheduled administration time, and swallowing ability) were independent predictors of medication administration delivery time errors in the research setting. The medication administration processes is a complex

phenomenon, requiring that nurses administer all of their patients' medications on time throughout the day. However, several variables outside of nurses' control influence their ability to do so. This study revealed that half of all time-critical medications were not administered on time. For some patients, this can be detrimental to their health and clinical outcome. In order to improve the safety and efficiency of the medication administration process and ensure the timely administration of time-critical medications, redesign of the medication process is warranted. Although the results of this study are important and may be useful to nursing educators, clinical practice managers, and policy developers, further exploration is necessary to verify the findings of this study.

Appendix A

Data Collection Record: Medication, Environmental, and Patient Factors

Coded Patient ID: _____ Data Collection Date _____

Age: _____

Patient Gender: M F

Primary diagnoses _____

Number of Co-morbidities: _____

Accommodation Type: Single Semi Ward

Swallowing Ability: Medications Crushed Not Crushed

Day of Week: MON TUES WED THURS FRI SAT SUN

DAY SHIFT

Level of Consciousness: Alert Impaired

Level of Orientation: Oriented X1 Oriented X2 Oriented X3 Not oriented

Medication #1	Medication #2	Medication #3	Medication #4	Medication #5
Name:	Name:	Name:	Name:	Name:
Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>
Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>
Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>
# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time
Scheduled Time:	Scheduled Time:	Scheduled Time:	Scheduled Time:	Scheduled Time:
Documented Time:	Documented Time:	Documented Time:	Documented Time:	Documented Time:
Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:
Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>
Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.
Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>
Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>
Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>
Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>

Coded Patient ID: _____

Data Collection Date _____

Age: _____

Patient Gender: M F

Primary diagnoses _____

Number of Co-morbidities: _____

Accommodation Type: Single Semi Ward

Swallowing Ability: Medications Crushed Not Crushed

Day of Week: MON TUES WED THURS FRI SAT SUN


NIGHT SHIFT

Level of Consciousness: Alert Impaired

Level of Orientation: Oriented X1 Oriented X2 Oriented X3 Not oriented

Medication #1	Medication #2	Medication #3	Medication #4	Medication #5
Name:	Name:	Name:	Name:	Name:
Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> SC <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>	Route: PO <input type="checkbox"/> PR <input type="checkbox"/> IM <input type="checkbox"/> IV <input type="checkbox"/> TD <input type="checkbox"/>
Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>	Available: YES <input type="checkbox"/> NO <input type="checkbox"/>
Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>	Location of patient: ON unit <input type="checkbox"/> OFF unit <input type="checkbox"/>
# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time	# of Meds due at delivery time
Scheduled Time:	Scheduled Time:	Scheduled Time:	Scheduled Time:	Scheduled Time:
Documented Time:	Documented Time:	Documented Time:	Documented Time:	Documented Time:
Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:	Pyxis Delivery Time:
Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>	Status of Individual Admin. RN <input type="checkbox"/> SN <input type="checkbox"/>
Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.	Coded Nurse Admin.
Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>	Time Criticality Time Critical <input type="checkbox"/> Not Critical <input type="checkbox"/>
Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>	Level of Risk High-alert <input type="checkbox"/> Non-High-alert <input type="checkbox"/>
Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>	Outcome On time <input type="checkbox"/> Not on Time <input type="checkbox"/>
Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>	Early Admin YES <input type="checkbox"/> NO <input type="checkbox"/>

Appendix B: Research Ethics Board Approval, University of Windsor



Office of the Research Ethics Board
401 Sunset Avenue
Windsor, Ontario, Canada N9B 3P4
T 519-253-3000 ext. 3948
www.uwindsor.ca/reb

Today's Date: April 15, 2015
Principal Investigator: Mrs. Catherine Medved
REB Number: 32205
Research Project Title: REB# 15-005: "Medication, Environmental, and Patient Factors that Influence Medication Administration Delivery Times"
Clearance Date: April 15, 2015 (Conditions are Removed)
Project End Date: April 30, 2016
Milestones:
Renewal Due-2016/04/30(Pending)

This is to inform you that the University of Windsor Research Ethics Board (REB), which is organized and operated according to the Tri-Council Policy Statement and the University of Windsor Guidelines for Research Involving Human Subjects, has granted approval to your research project on the date noted above. This approval is valid only until the Project End Date.

A Progress Report or Final Report is due by the date noted above. The REB may ask for monitoring information at some time during the project's approval period.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the REB. Minor change(s) in ongoing studies will be considered when submitted on the Request to Revise form.

Investigators must also report promptly to the REB:

- a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
- b) all adverse and unexpected experiences or events that are both serious and unexpected;
- c) new information that may adversely affect the safety of the subjects or the conduct of the study.


Forms for submissions, notifications, or changes are available on the REB website: www.uwindsor.ca/reb. If your data is going to be used for another project, it is necessary to submit another application to the REB.

We wish you every success in your research.

Alan Scoboria, Ph.D.
Chair, Research Ethics Board
Lambton Tower, Room 1102 A
University of Windsor
519-253-3000 ext. 3948
Email: ethics@uwindsor.ca

c.c. Dr. Michelle Freeman, Supervisor, Nursing

Appendix C: Research Ethics Board Approval, Research Setting

 **WINDSOR REGIONAL HOSPITAL**
OUTSTANDING CARE – NO EXCEPTIONS!

**Research Ethics Board
Windsor Regional Hospital
1995 Lens Avenue
Windsor, ON N8W 1L9**

Meeting Review Date: March 25, 2015

Project Title: MEDICATION, ENVIRONMENTAL AND PATIENT FACTORS THAT INFLUENCE TIME CRITICAL MEDICATION ADMINISTRATION DELIVERY TIMES

Principal Investigator: Catherine F. Medved

REB File Reference: 15-300

Submissions Reviewed:

- Ethics Submission Form For Research Involving Humans
- Appendices #A, B, C, D, E, F, G, H, I

This research has received Category A – Approval.

This Research Ethics Board is constituted and operated in accordance with the Tri-Council Policy Statement for Ethical Conduct of Research Involving Humans (TCPS2), Canadian Food & Drug Regulations, Division 5 (Clinical Trials), ICH Good Clinical Practice Guidelines E6, U.S. Code of Federal Regulations Title 21 & 45 and the Personal Health Information Protection Act, 2004 (PHIPA).

Only Research Ethics Board members who are independent of the investigator(s) conducting the study participated in decisions relating to this research.

Any amendments to protocol must be submitted for REB approval. Please use above REB reference number on all correspondence. This approval is for one year and expires on **March 24, 2016**. If you wish to continue the research beyond this, application for renewal must be submitted. Applicable forms are available by email from lucie.bessant@wrh.on.ca.

March 25, 2015

Wallace Liang, MD., CCFP, JD, MHsc.
Chair, Research Ethics Board
Windsor Regional Hospital

Date

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VITA AUCTORIS

Catherine Medved was born in 1986 in Windsor, Ontario. She obtained a Bachelor of Science in Nursing degree from the University of Windsor in June 2012 and entered the Master's of Science in Nursing program in September 2012. She is currently a candidate for the Master's of Science in Nursing degree at the University of Windsor, and will graduate in June 2016.