THE RELATIONSHIP BETWEEN NURSES’ WORK HOURS, FATIGUE, AND OCCURRENCE OF MEDICATION ADMINISTRATION ERRORS

DISSERTATION

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By

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Nurses are responsible for the safety of their patients. Nursing factors such as long work hours and fatigue are concerns as they may affect patient safety. One area of patient safety to consider is medication use, specifically medication administration errors.

Quantitative data in the form of observational studies are needed to assess the impact of nurses’ work hours and fatigue on medication administration errors. This non-blinded, observation-based study took place at an academic medical center in Columbus, OH. The medication administration process was observed in volunteer nurses at three points in time over a single 12-hour shift: 0-2 hours (7am-9am), 6-8 hours (1pm-3pm), and 10-12 hours (5pm-7pm). In addition to the data collected through observation, each nurse completed three questionnaires: demographic and work-related, acute fatigue, and chronic fatigue. A pilot study was conducted in both the ED and medical intensive care unit (MICU) in order to decide which setting was more feasible for this study design.

Eligible nurses for the study worked in either the MICU or ED (depending on pilot results), were registered nurses, and did not work straight night shifts. Using SPSS 16.0, linear regression, repeated measures ANOVA, and frequencies were used to analyze the medication administration and nursing data.

A total of 548 medication administrations were observed among the 30 MICU nurses who volunteered for this study. Within order-based errors, dose errors were the
most common (6%). Administration technique errors (10.7%) were the most common within the preparation/administration-based errors, followed by administration time errors (5.7%). Within errors of process variation, not checking the patient’s armband (79.6%), not double checking the MAR (16.6%), and not washing hands (12.5%) were the most common. Error rates for administration time, not washing hands, not checking armbands, and pre-charting differed significantly across the three time periods of observation. Error rates per nurse were the following: 1.5% order-based, 5.6% preparation/administration-based, and 15.9% process variation. No significant relationship existed between either work hours or fatigue and occurrence of medication administration errors. Overall, the findings of this observation-based study indicate a need for improvement in some aspects of medication administration.
Dedicated with love to my parents
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The purpose of this dissertation is twofold: to determine the relationship between nurses’ work hours and the occurrence of medication administration errors and to determine the relationship between fatigue and the occurrence of medication administration errors. This chapter establishes the problem and then provides some background information on medication administration errors and nurses’ work. The significance of this study, the conceptual framework used for it, and the study objectives are established. A brief overview of the study design is given. Finally, an overview of this dissertation is given.
1.1 Establishment of the Problem

Nurses are responsible for the safety of their patients; however, a recent Institute for Safe Medication Practices (ISMP) “Nurse Advice,” said that “patient safety should NOT be a priority in healthcare” (Patient safety should NOT be a priority in healthcare, 2008). This statement directly contradicts Lucian Leape’s statement that “patient safety [became] a national priority” after To Err is Human was released (L. Leape, Epstein, & Hamel, 2002). Why would ISMP say such a thing? The bulletin goes on to discuss patient safety as a value that should be associated with all priorities and actions within healthcare. Priorities can be reordered; patient safety should never be anything but the primary concern in all healthcare arenas.

The Institute of Medicine (IOM) considers nurses’ work environments, specifically long work hours, a threat to patient safety (Page & Institute of Medicine, 2004). At the same time, the American Nurses Association (ANA) requires nurses to “take an active role in addressing the environmental system factors and human factors that present increased risk to patients” (American Nurses Association, 2007). An Agency for Healthcare Research and Quality (AHRQ) evidence report considered the effect of healthcare working conditions on the incidence of medical errors. One of the working conditions considered is workforce staffing, which includes volume of work assigned to individuals, professional skills needed for job assignments, duration of experience in a job category, and effects of work schedules. Limited evidence for the workforce-staffing category was uncovered (Oregon Health and Science University Evidence-based Practice Center, 2003). Prior to finalizing its 2008 goals, the Joint Commission listed “prevent patient harm associated with healthcare worker fatigue” as a potential 2008 National
Patient Safety goal; fatigue plays an important role in keeping patients safe (The Joint Commission).

In 1999, the IOM reported that medication errors account for over 7,000 deaths per year (Kohn, Corrigan, & Donaldson, 2000), a finding that highlights the need for research in the field of medication safety. Error data from a 14-day log showed that risk for making an error doubled when nurses worked at least a 12.5-hour shift (L. D. Scott, Rogers, Hwang, & Zhang, 2006). Workloads affect nurses’ perceptions of the quality of care their patients receive, and poorer quality scores are related to an increased number of adverse patient outcomes (Sochalski, 2001).

Recently, the AHRQ-commissioned study on nurse staffing and quality of patient care was released (Kane, Shamliyan, Mueller, Duval, & Wilt, March 2007). This comprehensive review of the literature noted that increases in total nurse hours per patient day were associated with reduced hospital mortality, death among those patients who developed an adverse occurrence, and other adverse events. The study supports the need for evaluation of the effect of work hours, especially as it relates to patient safety. The occurrence of medication administration errors contributes to overall patient safety, and the work hours of nurses contribute to their accuracy in administering medications. To date, self-reported log books and questionnaires have been used to gather data. More quantitative data in the form of observational studies are needed to better assess the impact of nurses’ work hours and fatigue on medication administration errors.
1.2 Background Information

1.2.1 Medication Administration Errors and the Role of Nurses

Medication errors occur at different stages in the medication use process. Research shows that the physician ordering, or prescribing stage, contains the most errors (39%) with nurse administration closely following with 38% of errors that resulted in adverse drug events. Adverse drug events are medication errors that result in patient injury. Nurses are the most likely member of the healthcare team to intercept errors that occur in the prescribing, transcribing, or dispensing stage upon administration of the medication. Administration errors, however, are infrequently intercepted by the nurse. Proximal causes for nursing administration errors include lack of drug knowledge, misuse of infusion pumps, memory lapses, and lack of double-checking the drug and dose (L. L. Leape et al., 1995).

Additional research in 36 sites that represent Joint Commission on Accreditation of Healthcare Organizations accredited hospitals, non-accredited hospitals, and skilled nursing facilities determined that medication administration errors were common, occurring in 19% of the administered doses. Types of error include wrong time, dose omission, wrong dose, and unauthorized drug (Barker, Flynn, Pepper, Bates, & Mikeal, 2002). Medication administration error studies have also been carried out in specialty units such as psychiatric hospitals, adult intensive care units (ICU), and neonatal (NICU) and pediatric ICUs (PICU) (Girotti, Garrick, Tierney, Chesnick, & Brown, 1987; Haw, Dickens, & Stubbs, 2005; Raju, Kecskes, Thornton, Perry, & Feldman, 1989). Results among these studies varied in both findings and the way in which error data were reported.
When nurses were asked about the factors contributing to medication administration errors, 39% identified personal factors such as failure to double check patient identification arm bands, failure to check for new medication orders, lack of medication knowledge, incorrect reading of medication labels, leaving medications at the patient’s bedside, and miscalculations. Thirty-two percent of nurses attributed contextual factors to medication errors: short staffing, large numbers of assigned patients, frequency of change in patient assignments, distractions during preparation of medications, high acuity, and lack of knowledge of the patient (Conklin, MacFarland, Kinnie-Steeves, & Chenger, 1990).

Two recent studies have considered the effect of nurses’ work hours on patient safety (Rogers, Hwang, Scott, Aiken, & Dinges, 2004; L. D. Scott et al., 2006). In two, self-reported 14-day logbooks, nurses recorded their hours worked and time of day worked along with answering questions about errors and near errors among other things. Number of errors and near errors was used to assess patient safety. The first study considered nurses who were members of the ANA. Fifty-eight percent of the reported errors and 56% of the reported near errors involved administration of medications. Increases in work duration, overtime, and number of hours worked per week had significant effects on the likelihood of making an error. In a random sample of nurses who were members of the American Association of Critical-Care Nurses (AACN), 38% of the nurses recalled making at least one error during the two month study period. When nurses worked greater than 12.5 consecutive hours, the risk of that nurse making an error almost doubled compared to nurses who worked 8.5 consecutive hours or less.
1.2.2 Nurses’ Work

Twelve-hour work shifts are prevalent across industries, and much research has considered the impact of these shifts on workers. In general, the advantages of 12-hour shifts include greater opportunity for time off per week, increases in job satisfaction, and fewer commuting trips. Some of the disadvantages of the 12-hour shift are increased fatigue, greater number of health problems in workers, more errors at work, and increase in risk for an accident (Bendak, 2003).

Among healthcare professionals, fatigue has been found to increase over the duration of a shift, regardless of the length of it (Poissonnet & Veron, 2000). In nurses specifically, an extended workday of nine hours led to greater fatigue and a greater number of health complaints in nurses compared to an 8-hour shift. Nurses also reported that the quality of their work suffered with the introduction of 9-hour shifts to their workday (Josten, Ng-A-Tham, & Thierry, 2003).

Data collected from the Maastricht Cohort Study on Fatigue at Work showed that working more hours per week resulted in a greater need for recovery from work in women than in men (Jansen, Kant, van Amelsvoort, Nijhuis, & van den Brandt, P., 2003). This finding is important given that 95% of the nursing workforce is female (Trinkoff, Geiger-Brown, Brady, Lipscomb, & Muntaner, 2006). This study also found that women working six or fewer hours per day had significantly lower levels of need for recovery time when compared to women who work eight hours per day (Jansen et al., 2003).

Recent data collected as part of the Nurses Work Life and Health Study showed that 16.5% of general duty staff nurses work more than 12 hours per day. In hospitals, 19.4% of nurses work more than 12 hours per day. A larger percentage of nurses working
in specialty areas work more than 12 hours per day: adult critical care (35.9%), neonatal or pediatric critical care (27.3%), and emergency (25.6%). Of all nurses, those working as hospital staff were the most likely to work 12 or more hours per day, but they were half as likely to work six to seven days per week. Nurses with more than one job and single parent nurses were more likely to work 12 or more hours per day and long weeks (50-60 hours) compared to nurses as a whole (Trinkoff et al., 2006).

Aside from work hours, level of knowledge of medications, expectations by physicians, and workload (amount of work and staffing levels) were associated with nurses’ compliance with medication administration best practices (McKeon, Fogarty, & Hegney, 2006). Nurses are caregivers both at work and outside of work. Among a random sample of ANA members, caregiver responsibilities for dependent children and elderly adults led to increased sleepiness, physical fatigue, and mental fatigue. Data from this sample also indicate that the likelihood of making an error while at work was twice as high for nurses who provide elder care at home (L. Scott, Hwang, & Rogers, 2006).

1.3 Significance

This research fills a significant gap because it is the first in-depth, observation-based examination of nurses’ work hours and the occurrence of medication administration errors. Previous studies have considered a relationship between the two, but the data were collected through self-report in the form of questionnaires or log books. Observation of nurses’ work provides detailed information about frequency and type of medication administration errors, rather than relying on subjective self-report. Observation based studies have been shown to be the gold-standard in adverse drug event and medication error research (Jha et al., 1998).
Development of an additional link between fatigue and errors contributes further to the value of this research, as fatigue is generally considered the result of long work hours. In this study, fatigue will be measured at both the chronic and acute level. Fatigue among healthcare workers is a current issue of concern as it is related to patient safety.

Finally, this study is significant as it will observe nurses who work in either an ICU or an emergency department (ED). These two areas of nursing have the greatest proportion of nurses working long hours. Few studies have been published in which medication errors were observed in an ICU setting (Calabrese et al., 2001; Girotti et al., 1987; Tissot et al., 1999), and none of these studies investigated associations with nurses’ work hours or fatigue. No identified studies assessed medication errors in the ED. In a patient perception study, 38% of ED patients reported experiencing at least one concern during their visit, and medication errors were the concern among 16% of the patients (Burroughs et al., 2005). This finding further supports the need for a study of medication errors in the ED.

1.4 Conceptual Framework

The framework for this research is based on the work of Donabedian, in which he categorized medical care in terms of structure, process, and outcome in order to determine indicators of quality (Aday, Begley, Lairson, & Balkrishnan, 2004; Donabedian, 1980). Medication administration errors can serve as quality indicators, but more importantly, they are a proxy measure for patient safety in an institutional setting.

In this study, structure has two components: the individual nurse and the institution. Characteristics of each nurse, such as length of work shift, care for dependents, additional employers, etc., contribute to his/her effectiveness in properly
administering medications to a patient. Each institution has guidelines in place to improve medication safety and reduce variation among nurses in how they administer medications to their patients; however, these guidelines are institution or health-system specific and will be accounted for in this study. Process is the administration of medications to patients in an inpatient setting by nurses. Finally, the primary outcome of interest is the occurrence of medication administration errors.

In using Donabedian’s framework, the overall quality of medication administration in a hospital setting will be established. From a policy and decision-making perspective, the need for continuous quality improvement within a hospital exists. This research is applicable to policies and decisions regarding medication administration and, ultimately, patient safety. Figure 1.1 represents the theoretical framework for this research.

![Conceptual framework for this study](image)

Figure 1.1: Conceptual framework for this study
1.5 **Study Objectives**

Objective 1: Determine the relationship between nurses’ work hours and the occurrence of medication administration errors.

1.1 Observe nurses’ administering medications to patients.

1.2 Examine the relationship between demographic/personal characteristics of the nurses and the occurrence of medication administration errors.

1.3 Classify the types of medication errors that occur during nurses’ administration of medications to patients.

Objective 2: Determine the relationship between fatigue and the occurrence of medication administration errors.

2.1 Using reliable and valid instruments, assess the chronic and acute fatigue of nurses.

2.2 Examine the relationship between work hours and fatigue.

Objective 3: Determine the progression of errors over a nurse’s work shift based on observations during three time periods.

Objective 4: Explore the quantity and type of interruptions that nurses experience while administering medications to their patients along with the nurse’s response to the interruption.

1.6 **Overview of Study Design**

This non-blinded, observation-based study took place at an academic medical center in Columbus, OH. The medication administration process was observed in volunteer nurses at three points in time over a single 12-hour shift: 0-2 hours (7am-9am), 6-8 hours (1pm-3pm), and 10-12 hours (5pm-7pm). In addition to the data collected
through observation, each nurse completed three questionnaires: demographic and work-related, acute fatigue, and chronic fatigue. A pilot study was conducted in both the ED and medical intensive care unit (MICU) in order to decide which setting was more feasible for this study design. Eligible nurses for the study worked in either the MICU or ED (depending on pilot results), were registered nurses, and did not work straight night shifts.

1.7 Overview of this Dissertation

The remainder of this dissertation is divided into four chapters. Chapter Two consists of a literature review of research related to this study. The third chapter provides an explanation of the methods used for this study. The results of this study are located in Chapter Four. This dissertation concludes in Chapter Five with a discussion of the results, limitations, applications for the findings of this study, and possible future research.
1.8 References


CHAPTER 2

REVIEW OF RELATED LITERATURE

The first section of this literature review provides background information and studies related to medication errors in general, medication errors in the intensive care unit, medication errors in the emergency department, and nurses’ perceptions of medication errors. The second section of this literature review provides background on the nursing-specific components of this study: work conditions, work hours and shift work, fatigue and sleep, and interruptions.
2.1 Medication Errors

2.1.1 Patient Safety, Adverse Drug Events, and General Medication Errors

The IOM’s *To Err is Human: Building a Safer Health System* reports that medical errors result in 44,000 to 98,000 American deaths annually. Using the lower estimate, more deaths are attributable to medical errors than motor vehicle accidents, breast cancer, or AIDS. One in 131 outpatient deaths and one in 854 inpatient deaths are due to medication errors. In general, patients view medical errors as issues with an individual provider rather than a system-wide failure to deliver adequate care (Kohn, Corrigan, & Donaldson, 2000). IOM defines an error as “the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim. An error may be an act of commission or an act of omission.” At the same time, an adverse event is defined as resulting “in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient” (Aspden & Institute of Medicine, 2007).

When thinking about the human component of the healthcare system, two types of errors are important to consider. The first is active errors: unsafe actions taken by people with direct patient contact whose effects are realized almost immediately. The second is latent errors that may rest within a system for years only to become evident when aligning with other factors to create an accident opportunity. Latent conditions within a system can be identified and defended against before an adverse event actually occurs (J. T. Reason, 1990; J. Reason, 2000). James Reason also discusses the different approaches that one can take when examining errors. The person approach, or blame approach, focuses the errors on the “people at the sharp end” such as nurses, physicians,
pharmacists, etc. In contrast, a system approach recognizes that human accidents happen and looks to see how and why defenses within the system failed (J. Reason, 2000).

According to the National Coordinating Council for Medication Error Reporting and Prevention, "a medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" (National coordinating council for medication error reporting and prevention, 2008). The Food and Drug Administration (FDA) received over 22,000 reports of medication errors from 1992 to 2003. Given that its reporting system is voluntary, the actual number of errors is though to be much higher. According to the FDA, there is no “typical” medication error, and reported errors likely stem from poor communication, misinterpreted handwriting, drug name confusion, lack of employee knowledge, and lack of patient understanding about a drug’s instructions (Meadows, 2003).

In a study of all nonobstetric adult patients at two Massachusetts hospitals, Leape and his colleagues reviewed records in order to identify errors related to drug use. Most of the 334 errors occurred in the physician ordering (39%) or nursing administration (38%) nodes of the system. Almost half of the physician ordering errors were intercepted, and 86% of these interceptions were by nurses. Dosing errors were the most common, accounting for 28% of all errors. Proximal causes and system failures were also identified for the errors (L. L. Leape et al., 1995). Errors that resulted in preventable adverse drug
events (ADEs) occurred most often at the physician ordering (56%) and administration (34%) stages of the system. Forty-eight percent of these errors were intercepted at the physician ordering stage compared to 0% upon administration (Bates et al., 1995). These same data were also used to analyze costs associated with ADEs. Patients with ADEs stayed 2.2 days longer in the hospital, had charges that were $6341 higher, and had costs that were $3244 higher than patients without ADEs who were matched for pre-event length of stay. For patients with a preventable ADE, length of stay was 4.6 days longer than control patients, charges were $11,524 higher, and costs were $5857 higher. ADEs resulted in additional costs of $2595 for the hospital itself (Bates et al., 1997). Data from the 1992 National Clinical Pharmacy Services database showed that 2.26 ± 3.98 medication errors occur per occupied hospital bed per year. One in 20 of the medication errors reported were attributed to adverse patient care outcomes (Bond, Raehl, & Franke, 2001).

Based on the Summary of Information Submitted to MEDMARX in the Year 2001: A Human Factors Approach to Understanding Medication Errors, 37% of errors originated in the administering node of the medication use system, and most commonly reported cause of error was performance deficit (38%) followed by procedure/protocol not followed (20%). Administering node errors are often the most easily detected because the patient is involved directly (United States Pharmacopeia, 2002). Accurate drug administration may be challenging for nurses because they are working in an environment that is demanding, characterized by long work hours, staffing shortages, high patient and staff turnover, and constant interruptions (Aspden & Institute of Medicine, 2007).
Barker and his colleagues (K. N. Barker, Flynn, Pepper, Bates, & Mikeal, 2002) conducted an observation-based study of 36 healthcare facilities in order to determine the prevalence of medication administration errors. The mean error rate for the accredited hospitals, nonaccredited hospitals, and skilled nursing facilities was 19%, or the equivalent of one error for every five doses administered to a patient. At the University of Arkansas Medical Center, Barker reported an error rate of 25.9% (13.0% when not including wrong time errors) for the control group of a study in which the effect of an experimental pharmacy system on medication errors was considered (K. N. Barker, 1969). On three high-medication use units at a tertiary care hospital in western New York, an observation-based study identified an error rate of 5% (Maricle, Whitehead, & Rhodes, 2007). Tissot et al. (E. Tissot et al., 2003) conducted an observation-based study on a geriatric unit and a cardio-thoracic surgery unit, and the medication administration error rates were 14.9% (wrong time errors included) and 11.1% (wrong time errors excluded). Nurses’ workload was identified as a risk factor for medication administration errors on both units of this study.

2.1.2 Medication Errors: Intensive Care Unit

General medical errors in the MICU of an urban teaching hospital occurred at a rate of 89.3 medical events per 1000 ICU days according to report data (Osmon et al., 2004). When looking more specifically at adverse events, observation-based data from the Critical Care Safety Study identified 80.5 adverse events per 1000 patient days, of which 47% were medication-related. The rate of serious errors occurring in this ICU of an academic, urban hospital was 149.7 per 1000 patient days, and medications were responsible for 78% of the serious errors (Rothschild et al., 2005).
When it comes to measuring medication errors in the ICU, research methods vary. Cullen et al. (Cullen et al., 1997) conducted a comparative study of preventable ADEs in ICUs and medical-surgical units at two hospitals. Data about preventable and potential ADEs were gathered through self-report from nurses and pharmacists and through daily chart reviews. The rate of preventable and potential ADEs in ICUs was twice the rate of medical-surgical units. When controlling for the number of medications given in the previous 24-hour period, ICUs and medical-surgical units did not differ. The medical ICU had a rate of 25 events per 1000 patient days and was significantly greater than the surgical ICU rate of 14 events per 1000 patient days. Overall, the most errors occurred in the prescribing and administration nodes of the system. Finally, this study found that preventable ADEs and potential ADEs were more likely to be severe in the ICUs.

Several studies have looked at rates of medication administration errors in adult ICUs (Calabrese et al., 2001; Girotti, Garrick, Tierney, Chesnick, & Brown, 1987; Kopp, Erstad, Allen, Theodorou, & Priestley, 2006; E. Tissot et al., 1999; van den Bemt, PM. et al., 2002) and in pediatric ICUs (PICUs) (Buckley, Erstad, Kopp, Theodorou, & Priestley, 2007; Raju, Kecskes, Thornton, Perry, & Feldman, 1989). Girotti et al. (Girotti et al., 1987) compared the nursing medication administration record with physician’s orders in the patients charts for a period of two weeks. The error rate per patient was 1.7 ± 2.4 among the sample of 60 patients. Ninety-percent of the errors captured in these data were IV-related. In an observation-based study at a university hospital in France, Tissot et al. (E. Tissot et al., 1999) detected a medication administration error rate of 6.6%. Observational data were collected during the six heaviest medication administration hours of the day and excluded weekends and nights. A study of two Dutch ICUs
identified an administration error rate of 33.0% when excluding wrong time errors. This percentage is likely higher than other studies due to lack of hospital processes for parenteral drug preparation and lack of specialized intensive care physicians (van den Bemt, PM. et al., 2002).

An observational study of adult patients in five ICUs in the United States used pharmacists (who were already in place as members of the healthcare team at the respective institution) to gather medication administration data on certain error-prone medications. From the 5,744 observations in 851 patients over a three-month period, a medication administration error rate of 3.3% was determined (Calabrese et al., 2001). Kopp et al. (Kopp et al., 2006) conducted an observation-based study of medication errors and ADEs in the ICU at an academic medical center. During the 33 12-hour shifts that were observed, 132 of the 172 medication errors were judged clinically important, 110 were associated with potential ADEs, and 22 were associated with actual, preventable ADEs. Additionally, one error occurred for every five doses administered to the patient. Finally, Herout and Erstad (Herout & Erstad, 2004) conducted a once daily evaluation of continuous infusions in the surgical ICU of a tertiary care teaching hospital and identified errors occurring at a rate of 105.9 per 1000 patient days.

Using data from incident reports from the NICU and PICU at University of Illinois Hospital, an error rate of 14.7% was determined using the error definition set forth by American Society of Health-System Pharmacists, which was equivalent to one error per 6.8 ICU admissions. Errors were most frequent during the day shift, and 60% of the errors were attributed to nurses (Raju et al., 1989). A second study used observation-based data collected over 26 12-hour shifts at the PICU of an academic medical center. In
this study, the most common type of error was wrong dose. Fifty-two medication errors were identified from 58 incidents, which is an error rate of 19.8 per dose. The error rate for clinically important errors was 16% per dose (Buckley et al., 2007).

How does pharmacist presence in an ICU affect the rate of preventable ADEs? According to Leape et al. (L. L. Leape et al., 1999), preventable prescribing ADE rates decreased significantly from 10.4 per 1000 patient-days to 3.5 per 1000 patient-days. During the same time period, a control unit that did not have pharmacist presence on physician rounds maintained its rate of preventable prescribing ADEs.

2.1.3 Medication Errors: Emergency Department

In 2000, ED utilization reached 108 million visits annually, an increase of 14% from 1997. Seventy-four percent of these visits resulted in the patient receiving medication, of which 32% was pain relief drugs (McCaig & Ly, 2002). EDs are known for being busy units of a hospital. At the same time, the ED is an error-prone environment, given the increases in acuity and volume along with emphasis on efficient and rapid care. “Barriers to patient safety” such as fatigue, stress, anxiety, fear of blame, distractions, noise, and location of critical supplies can have an effect on the risk for errors that is present within the system (Goldmann & Kaushal, 2002). A broad study of reported errors at a large academic ED identified 18 errors per 100 registered patients, and of these errors, 16% were categorized as related to pharmacotherapy. Nurses reported 40% of the errors in total, and 24% of the errors reported by nurses were related to pharmacotherapy (Fordyce et al., 2003). Patients themselves reported experiencing at least one concern during their ED stay, with the most common being misdiagnosis (22%) followed by physical mistake (16%) and medication errors (16%) (Burroughs et al.,
Patient misidentification is also a concern reported by 8% of the ED patients (Burroughs et al., 2005), and it is currently a primary concern within the ED and Joint Commission patient safety initiatives (O'Neill, Shinn, Starr, & Kelley, 2004).

Medication errors in the ED occur at all stages of the medication use system (Croskerry et al., 2004). One common practice in the ED that should be minimized to reduce the potential for medication errors is verbal orders (Paparella, 2004). Prescribing medication errors were identified in 10.7% of the charts reviewed from randomly selected days at a pediatric hospital ED (E. Kozer et al., 2002). In an effort to reduce the occurrence of these prescribing errors, Kozer et al. (E. Kozer, Scolnik, MacPherson, Rauchwerger, & Koren, 2005) experimented with a new pre-printed, formatted, ordering sheet that they found to reduce the risk for an error compared to the standard blank form.

Of the 2,063 ED errors reported in the 2001 MEDMARX report, 52.4% were attributed to the administration node of the medication use system and 24.6% were attributed to prescribing. Twenty-four percent of the errors were classified as improper dose/quantity. Finally, 7.6% of the total ED errors resulted in patient harm (United States Pharmacopeia, 2002).

A prospective, observational study of simulated ED scenarios was conducted to determine the incidence and nature of medication errors during pediatric resuscitations. Among the eight scenarios in which medical staff participated, 125 medications were ordered. Some doses and routes of administration were not specified within the orders. Several errors were caught by other medical staff during the scenario before reaching the patient (E. Kozer et al., 2004). A review of medical records from critically ill children
who presented at four rural EDs in California uncovered 84 medication errors among 69 patients. The overall error incidence was 39% (Marcin et al., 2007).

How can we reduce medication errors in the ED? Increasing pharmacist presence in EDs through patient contact and clinical activities is one way. Pharmacist presence in EDs has many benefits to patient safety (Case & Paparella, 2007). One specific role in which pharmacists have value over other ED providers is in gathering more complete medication histories from patients compared to others (Carter, Allin, Scott, & Grauer, 2006). Finally, pharmacist interventions were shown to avoid over one million dollars in costs over a four-month period. Interventions included providing drug information, recommending dosage adjustments, answering questions for nurses, making changes to fit formulary requirements, and suggesting drug therapy (Lada & Delgado, 2007).

2.1.4 Nursing Perceptions of Medication Errors

Research is beginning to show that the care provided by nurses affects patient health as their actions (such as monitoring patient status or assessing and evaluating the patient) are related to patient outcomes. While nurses may make errors, nursing vigilance is extremely important in preventing errors from reaching the patient. Nursing workspaces and processes should be organized in a way so that work is more efficient, the space is less conducive to the commission of errors, and the space allows nurses to detect and remedy errors when they happen. Nurses are necessary for keeping patients safe (Page & Institute of Medicine, 2004).

In general, healthcare professionals know that medications need to be given appropriately to a patient in order to avoid harm. When considering physicians, pharmacists, and nurses, the three largest groups of healthcare providers in an inpatient
setting, nurses scored the lowest on a test of knowledge of “hazards of medication” (Markowitz, Pearson, Kay, & Loewenstein, 1981). This study was conducted at a large, tertiary care teaching hospital in metropolitan New York. The examination assessed knowledge of hazards related to prescribing, dispensing, and administering medications to patients. In a similar study of healthcare workers’ responses to medication errors (Z. Wolf, Serembus, Smetzer, Cohen, & Cohen, 2000), a systematic sample of physicians, pharmacists, and nurses was taken from the State Boards of the Bureau of Professional Affairs of the Commonwealth of Pennsylvania. Drug administration was the phase of medication administration in which respondents believed the most errors occurred. In response to making errors, nurses were more guilty, worried, or embarrassed than physicians or pharmacists. When looking at concern of the healthcare provider, nurses were more fearful for patients, feared disciplinary action, and feared punishment more then physicians or pharmacists.

Researchers have considered the effect of drug administration errors on nurses and nursing perceptions of these errors. Canadian nurses reported “personal factors” such as lack of medication knowledge, failure to double check patient identification, failure to check for new medication orders, incorrect reading of labels, and calculation problems as the contributing factors for 39% of medication errors (Conklin, MacFarland, Kinnie-Steeves, & Chenger, 1990). In interviews of Norwegian nurses who were the primary persons involved with a medication error incident, nurses described feeling “shock and dread” when they realized that an error was made. They considered the error incident as deeply traumatic from both a professional and personal perspective and felt guilty and shameful for having committed such an error (Schelbred & Nord, 2007).
Taiwanese nurses were asked to choose categories that contribute to errors, personal neglect, heavy workload, and new staff were the three most commonly selected. The conditions most commonly identified as factors contributing to errors were the following: need to solve other problems while administering drugs, advanced drug preparation without rechecking, and new graduate. Thirty-three percent of the errors identified by nurses in this study occurred in the ICU (Tang, Sheu, Yu, Wei, & Chen, 2007).

Three studies used a similar instrument to investigate nurses’ perceptions of medication errors and the main causes of them. In the sample of medical-surgical nurses in a large community hospital in Florida, 35.1% of respondents believed that the main cause of errors was failure of the nurse to check the patient’s nameband with the medication administration record (MAR). Twenty-five percent responded that drug errors occur when nurses are tired and exhausted (Osborne, Blais, & Hayes, 1999). A sample of union nurses in Southern California responded that the top cause of medication errors was physician handwriting that is difficult to read or illegible, followed by nurses being distracted by other patient, coworkers or unit events and nurses being tired or exhausted. Ninety-three percent of these nurses were “usually sure what constitutes a medication error,” which is important when considering 45.6% of them believed that all drug errors were reported to nurse manager using an incident report (Mayo & Duncan, 2004). If nurses can recognize an error, why is the rate of reporting so low? Finally, the third study used a convenience sample of nurses at a Veterans Affairs medical center in Northern California. Similar to the first study, 46% of nurses identified “nurse fails to check nameband with MAR” as the number one cause of medication errors. Thirty-three percent of nurses identified “nurse is tired and exhausted” as the perceived cause of
medication errors. All of these nurses agreed that implementation of technological systems such as computer-prescriber order entry (CPOE) and barcode medication administration (BCMA) has resulted in a decrease in medication errors (Ulanimo, O'Leary-Kelley, & Connolly, 2007).

2.2 Nursing Components

2.2.1 Nursing Work Conditions

The IOM identifies nurses’ work hours as a potentially serious threat to patient safety, and it lists effects of fatigue that may inhibit patient safety: slow reaction time, less attention to detail, errors of omission, difficulty solving problems, lack of motivation, and decrease in energy (Page & Institute of Medicine, 2004). Both O'Shea (O'Shea, 1999) and Armitage and Knapman (Armitage & Knapman, 2003) conducted reviews of the factors contributing to medication errors and identified a multitude of reasons that errors occur, many of which were related to nurses and the conditions in which they work (heavy workload, many interruptions, staffing, etc.). A concept related to fatigue and work schedules is that of “need for recovery:” the need to recuperate from work-induced fatigue, primarily experienced after a day of work (N. Jansen, Kant, van Amelsvoort, Nijhuis, & van den Brandt, P., 2003). Higher work hours per day and greater work hours per week generally lead to more need for recovery from work. Both males and females had greater need for recovery when working overtime or shift work. When considering work hours within the medical community, the effect of long hours on medical errors was found in a study of medical interns (Landrigan et al., 2004). The interns worked traditional hours during part of the study and intervention hours in which their schedule eliminated extended work shifts and consisted of shorter hours in general during the other
part. The traditional schedule group made 36% more serious medical errors than their colleagues working shorter shifts.

An ICU study looked at various nurse working conditions (staffing, ratio of overtime to regular time hours, and average nurse wage) in relation to patient safety outcomes (30-day mortality, central line associated bloodstream infection, ventilator-associated pneumonia, catheter-associated urinary tract infection, and decubitus ulcer). Greater registered nurse (RN) hours per day had lower incidence of central line infections, pneumonia, mortality, and decubiti. Overtime was associated with higher odds of acquiring urinary tract infections and decubiti. Wages were not associated with any of the patient outcomes (Stone et al., 2007). Overall, these results show that nurse working conditions do affect patient outcomes in an ICU setting. Along with long work hours, nurses tend to take few breaks over the course of a shift. They reported having a break or meal period that was free of patient care duties in less than half of shifts worked, but no differences were seen in risk for error in nurses who took breaks compared to those who did not take breaks (A. Rogers, Hwang, & Scott, 2004). Other work conditions that may lead to errors are workload and lack of experience at the current unit, and lack of fatigue and long experience may enable nurses to detect more errors before they occur (Seki & Yamazaki, 2006).

2.2.2 Work Hours and Shift Work

“How long and how much are nurses now working?” is the question Trinkoff et al. (Trinkoff, Geiger-Brown, Brady, Lipscomb, & Muntaner, 2006) asked. The answer causes concern because nurses are working in excess of the IOM recommendation that suggests they work no more than 12 hours in a 24-hour period and no more than 60 hours
in a 7-day period. The study found that almost 20% of hospital nurses are working greater than 12 hours per day, with an even greater percentage of critical care (36%) and emergency (26%) nurses doing so. Half of the nurses cared for children at home while 12% cared for another dependent. Among other things, overtime and long hours are potential factors for increased risk of occupational injuries (Dembe, Erickson, Delbos, & Banks, 2005).

Do 12-hour shifts negatively affect nursing performance? According to an Irish study in which the MONITOR instrument was used, quality of nursing care was lower overall under 12-hour shifts compared to 8-hour shifts (Todd, Reid, & Robinson, 1989). On the contrary, other data indicate that nursing job performance and patient care delivered were the same between 12-hour and 8-hour work shifts (Mills, Arnold, & Wood, 1983; Palmer, 1991).

Two studies have used log books to gather error data from nurses in order to consider the effect of work hours on patient safety (A. E. Rogers, Hwang, Scott, Aiken, & Dinges, 2004; L. D. Scott, Rogers, Hwang, & Zhang, 2006). The broader sample of nurses for the Rogers et al. (A. E. Rogers et al., 2004) study were all members of the ANA and generally worked more than 40 hours per week. While 30% of shifts were scheduled for 12.5 or more hours, 39% of the shifts were actually 12.5 hours or more in length. Fifty-eight percent of the errors captured through the log books were related to medication administration. Working longer hours increased the likelihood of making an error, and nurses working 12.5 or more hours were three times as likely to make an error. Working more than 40 hours per week and working more than 50 hours per week also increased the odds of making an error. Scott et al. (L. D. Scott et al., 2006) used a sample
of members of the AACN in their study. Of these critical-care nurses, 44% were scheduled for shifts of 12.5 hours or more, and 62% worked actual shifts of 12.5 hours or more. Again, the majority of the errors reported involved administration of medications. When a nurse worked 12.5 hours or more in a shift, the risk for making an error almost doubled. Working more than 40 hours per week increased the odds of an error or near error occurring. In summary, both of these studies indicate that occurrence of errors is a concern when nurses work long hours.

In a national study of AACN nurses’ job satisfaction, 65% of the nurses met criteria to qualify as poor sleepers (Ruggiero, 2005). When shift work disrupts the relationship between the body’s internal clock and the environment, problems with sleep, increased accidents and injuries, and social isolation often occur (Berger & Hobbs, 2006). Nurses who rotate between day/night shifts were found to have 2.8 times the odds of reporting poor quality sleep when compared to day/evening nurses. The percentages of nurses who experiences fatigue during the day varied from 28% (night shift) to 46% (rotators) (Gold et al., 1992). Nursing home nurses in the Netherlands who worked 9-hour shifts were more fatigued, had more health complaints, and were less satisfied with their working hours than their colleagues who worked 8-hour shifts, indicating that this extended shift has similar negative characteristics to the 12-hour shift (Josten, Ng-A-Tham, & Thierry, 2003).

In general, 12-hour shifts are associated with more fatigue than 8-hour shifts (Bendak, 2003). Why do hospitals schedule 12-hour shifts? A random sample of North Carolina hospitals responded that the objectives of scheduling 12-hour shifts were the following: reduced turnover, pre-established schedule, provision of every other weekend
off, and provision of two consecutive days off at a time. The latter of these objectives appeal broadly to nurses as evidenced in the “benefits” of 12-hour shifts noted in the same study: increase in leisure time and more opportunities to travel, savings in work-related costs, and more productive weekends (Jones & Brown, 1986).

What are the perceptions of 12-hour shifts among critical care nurses? Nurses at a National Health Service hospital responded positively that patient care improved with 12-hour shifts because of continuity of care with patients and families and greater time to plan care. Nurses also liked the shift patterns that they were able to arrange. While the overall responses about fatigue and performance were positive, they were not perceived as the more positive aspects of 12-hour shifts. Nurses reported feeling too tired (McGettrick & O'Neill, 2006). In a quasi-experimental study, nurses were tested during their first and last hours of either an eight or 12-hour shift for fatigue and critical thinking skills. Fatigue was higher in both groups at the end of the shift compared to the beginning of it, but no difference was found in the two shift lengths. Shift rotation also played a role in fatigue levels. Critical thinking did not differ between the two shift-length groups of nurses (Fields & Loveridge, 1988).

2.2.3 Fatigue and Sleep

Medline Plus defines fatigue as “a feeling of weariness, tiredness, or lack of energy” (Hurd, 2007). Community-based studies of fatigue indicate fatigue prevalence ranging from approximately 10% to 45% (Lewis & Wessely, 1992). NHANES I data reported that 14.3% of male respondents suffer from fatigue while 20.4% of female respondents suffer from fatigue. Women have 1.5 times the risk of males for fatigue (Chen, 1986). Given the large percentage of women who work in nursing, this increased
risk is important to consider. Finally, a study of the United States working population reported two week fatigue prevalence of 38% among respondents to this random telephone survey. This high percentage of fatigue resulted in 9.2% workers reporting lost productive work time due to fatigue (Ricci, Chee, Lorandeau, & Berger, 2007).

“Our culture, especially in the military, holds that somehow training, habit, motivation, or attitude can overcome fatigue,” said Capt. Nick Davenport of the Naval Aviation Schools Command (Davenport, 2007). He continues by saying that mishaps or accidents suggest the contrary. When looking at aviation, flight safety is looking to improve by limiting fatigue causing factors which produce loss of concentration, slow reaction time, and misinterpretation of flight instrument information (Sparaco, 1996).

These ideas of fatigue translate into the healthcare arena as well. Sexton, Thomas, and Helmrich (Sexton, Thomas, & Helmreich, 2000) conducted a study of operating room and ICU staff in order to compare errors, stress, and teamwork attitudes of healthcare workers with aviation cockpit crews. Sixty-percent of medical respondents agreed that “even when fatigued, I perform effectively during critical phases of operations/patient care” compared to 26% of pilots. One-third of the ICU respondents did not acknowledge that they make errors at all. Multiple reasons for not discussing or acknowledging mistakes in the ICU were identified: personal reputation, threat of malpractice suits, high expectations of the patient’s family or society, possible disciplinary actions by licensing boards, threat to job security, and expectations of other team members. Overall, medical staff “played down” the effects of stress and fatigue on their performance. This view shows us where healthcare is compared to aviation in terms of a culture of safety. When healthcare team members participate in aviation-based Crew
Resource Management training (fatigue management, team building, communication, recognizing adverse events, team decision making, and performance feedback), they agree that this type of training will reduce errors and improve patient safety (Grogan et al., 2004).

Gaba points out that in the United States, medical professionals are “working far beyond the limits that society deems acceptable in other sectors” and that “this practice is incompatible with a safe, high-quality healthcare system” (Gaba & Howard, 2002). Medical personnel, like other workers, probably function at a suboptimal level when fatigued, and efforts to reduce fatigue are important within healthcare. While fatigue may not be eliminated, healthcare organizations should focus on systems-based approaches to limiting the potential for human errors and intercepting errors throughout the process (Jha, Duncan, & Bates, 2001).

The ANA holds the position that the individual registered nurse should be provided with the following: “a work schedule that provides for adequate rest and recuperation between scheduled work; and sufficient compensation and appropriate staffing systems that foster a safe and healthful environment in which the registered nurse does not feel compelled to seek supplemental income through overtime, extra shifts, and other practices that contribute to worker fatigue” (American Nurses Association, 2008a). At the same time, the ANA takes an additional position that, “regardless of the number of hours worked, each registered nurse has an ethical responsibility to carefully consider his/her level of fatigue when deciding whether to accept any assignment extending beyond the regularly scheduled work day or week, including a mandatory or volunteer overtime assignment” (American Nurses Association, 2008b). This position was enacted
out of concern for safety of both the nurse and patient, and the ANA directly mentions fatigue in both statements. How do individual nursing factors such as fatigue affect patient safety?

In their study of fatigue and sleep quality in day and night-shift nurses, Kunert, King, and Kolkhorst (Kunert, King, & Kolkhorst, 2007) found that fatigue and poor sleep quality are common among both day and night-shift nurses. They suggest implementing interventions to decrease fatigue and improve sleep quality in order to enable nurses to provide safe and competent care for their patients. An Australian pilot study of 23 nurses at a metropolitan hospital collected error data with logbooks and determined that sleep duration was a significant predictor of error occurrence. Twenty-two errors were reported, and nurses reported struggling to stay awake during one-third of their shifts (Dorrian et al., 2006). A general study of shift work from the Maastricht Cohort Study of fatigue in the Netherlands found that fatigue was prevalent in approximately 20% of shift workers (N. Jansen, van Amelsvoort, Kristensen, van den Brandt, PA., & Kant, 2003).

In a case study of six NICU nurses over 28 days, six errors (three procedural and three medication administration) were self-reported. The reported cases listed decreased alertness and lack of sleep as factors associated with both nurses. Also, the authors mention that nurses need to “be alert enough to provide safe care for their patients…and alert enough to detect and correct the errors made by others” (Dean, Scott, & Rogers, 2006). Scott and colleagues (L. Scott, Hwang, & Rogers, 2006) found that high fatigue and stress was associated with caring for both children and elders at home in a sample of registered nurses from the ANA and that nurses providing elder care at home were more fatigued and more likely to make errors at work than other nurses.
2.2.4 Interruptions

According to the *Summary of Information Submitted to MEDMARX in the Year 2001: A Human Factors Approach to Understanding Medication Errors*, distractions were reported as the contributing factor for medication errors in 47% of the records (United States Pharmacopeia, 2002). Nurses’ work patterns and activities are complicated, and human factors engineers have begun to investigate them through observation. When calculating interruptions for observed nurses, researchers detected an average of 3.4 interruptions per nurse per hour. Nurses who prepared medications for each patient individually had twice as many interruptions (1.3 interruptions / hour) as nurses who prepared medications for all of their patients at once (L. D. Wolf et al., 2006). When looking at operational failures within nurses’ work system, Tucker and Spear found that for an average 8-hour shift, nurses were interrupted mid-task (average task time was 3.1 minutes) an average of eight times per shift (Tucker & Spear, 2006). A study of health information technology captured interruptions among nurses that were equivalent to one interruption every 49 minutes. This same study reported that 25% of the interruptions occurred during nurse preparation or administration of medications (Westbrook, Ampt, Williamson, Nguyen, & Kearney, 2007). Both Australian and British studies of medication errors attributed interruptions and distractions during medication administration as potential environmental factors that contribute to errors (Deans, 2005; Fry & Dacey, 2007).

In an effort to improve nurses’ focus during medication administration, Pape et al. (Pape et al., 2005) designed a medication administration checklist that they found to improve focus among nurses. The group also implemented signage in areas related to
medication administration that reduced the number of distractions reported by nurses. A decentralized pharmacy system reduced nursing interruptions during medication administration by 64% in a study on two general medical units at Canadian hospitals (Bennett, Harper-Femson, Tone, & Rajmohamed, 2006). When looking at nurses’ ability to assimilate and use clinical information for medication administration, an average of six interruptions occurred while the nurse was assessing information (Hullin, Nelson, Dalrymple, & Hart, 2005).

The communication behaviors among clinicians at hospitals may contribute to interruptions through the use of telephones and pagers (E. Coiera & Tombs, 1998). With an interruption, there are two categories of roles in which the clinician may fall: initiator or recipient. A study looking into the interruption roles of physicians and nurses found that doctors initiated 2.1 interruptions per hour and had 25% of their activities interrupted. Nurses were interrupted at a much higher rate of 11.7 interruptions per hour, while only 16.5% of their activities were interrupted. They were also more likely to initiate an interruption, which may be a function of their responsibilities within the healthcare team. While some interruptions are necessary, the initiator of the interruption should be aware of the best way to deliver the interruption (Brixey, Robinson, Turley, & Zhang, 2007). Studies of communication loads in EDs found overall interruption rates of 11.2 and 15 per person per hour, respectively (E. Coiera, Jayasuriya, Hardy, Bannan, & Thorpe, 2002; Spencer, Coiera, & Logan, 2004).
2.3 References


CHAPTER 3

METHODS

This chapter details all aspects of the methods used for this study. It begins with information pertaining to Institutional Review Board (IRB) approval, recruitment, and the pre-sessions that were conducted. The pilot study design and data are provided, followed by a description of the design of the full study. Observation methodology is described fully along with the reconciliation process. Other sources of data collection are discussed. Finally, the analysis used to analyze the data is provided.
3.1 IRB Approval

The Biomedical IRB at the Ohio State University approved the protocol for this project (#2007H0200) in October 2007 (Appendix A). Amendments to the data collection forms were approved under the same protocol number in December 2007.

3.2 Recruitment

Volunteer ED nurses were recruited for the pre-sessions and pilot study with the help of the nurse manager and shift charge nurses. In the MICU, volunteer nurses were recruited for the pre-sessions with the help of the nurse manager. For the pilot and full study, the principal investigator (PI) visited three MICU Staff Meetings held during the week of February 25. Appendix B contains the recruitment script and consent form. In addition to this recruitment technique, the Clinical Nurse Scientist and nurse manager helped the PI to arrange short study-introduction sessions to recruit nurses who were unable to attend a staff meeting. Nurses were given a description of the study, were told that data collection would entail observation over given time periods and questionnaire completion, were advised that participation was completely voluntary, and were asked if they had any questions for the PI. No incentive was used to recruit the nurses. Eligibility criteria for participation included the following: primary employment in the ED or MICU, a registered nursing degree, and not working straight night shifts. Straight night shift nurses were excluded for two reasons: fewer medications given during the night shift and lack of observer availability to cover the night shifts. None of the observers work night shifts at all; having them suddenly change their schedule in order to observe night shift nurses would lead to poor accuracy in data collection as they are not at all used
to these hours. Aside from the 12-hour day shift on which the nurses were observed, nurses’ work schedules varied.

3.3 Pre-sessions

Two pre-sessions were held in both the ED and MICU. The purpose of the first session was to observe the work patterns of the unit’s nurses in order to determine if the unit presented any complications for the study and if the data collection form needed to be altered for the specific unit. A research group meeting was held after the first session to discuss the key information gathered and data collection instrument changes. Usability testing of the amended data collection instruments by the three observers occurred during the second pre-session in each setting.

For the ED, the PI, two other observers, and the PI’s advisor attended the first pre-session. The output of this session was the following: medication administration is unpredictable for a given time period, a 30 minute medication standard exists, patients have no Pyxis profile, verbal orders are common, and interruptions are common and a primary concern of nurses. In general, the data collection instrument was based on one in which ASHP safe medication practices (Schneider et al., 2006) were adapted into a column/checklist format for use in studies of Medical/Surgical units (Pedersen & Schneider, 2007). From this first pre-session, the ED data collection instrument was amended from the previously used Medical/Surgical tool in the following ways: the time standard was adjusted to 30 minutes, “check armband” was narrowed to “check armband before administration”, “not borrow from other patients” was eliminated because it is not applicable in the ED, and “wash hands” was added. Also, the interruption data collection instrument was created. During six hours of observation of three nurses in the second pre-
session, five total medications were administered. The observers believed the revised data collection instrument was appropriate for the setting.

For the MICU, the PI, the PI’s advisor, and a research team member attended the first pre-session. The output of this session was the following: nurses average one to two patients per shift, the nurse transcribes the medication orders from the CPOE system into the electronic MAR (eMAR), a 60 minute medication standard exists, other safe practices such as hand washing and turning the patient are observable, verbal orders are uncommon, the nurse has two ways in which to double check the medication before administering it (Pyxis profile and eMAR), and acuity of the shift is important. Also, a nurse sought out the PI to show her issues associated with the Pyxis process. Her primary concern was the added time it takes for a nurse to select the reason for overriding the system; many of the obvious/work process reasons are not available for selection, leading the nurse to spend extra time away from the patient in order to type a reason. Based on this pre-session, the MICU data collection instrument was amended in the following ways from the already amended ED tool: the time standard was adjusted to 60 minutes; a Pyxis override column was added because it is a common occurrence in the MICU; “transcription from CAPI to eMAR” was added; “not borrow from other patient” was added; a second double check option was added to allow the nurse to double check a medication against either the Pyxis profile or the eMAR; and vitals, patient turning, and patient weight were added. During six hours of observation of three nurses in the second MICU pre-session, 14 total medications were administered. The observers believed the revised data collection instrument was appropriate for the setting.
Based on the pre-sessions, the interruption component of the study was added for the MICU and ED pilot studies. Nurses felt these data were extremely valuable, and witnessing interruptions during medication administration was added to the duties of the observers. Through an amendment, IRB approved the revised data collection tools to include interruptions. No changes were required for the consent form, but nurses were informed in the recruitment script that interruptions during medication administration were of interest in this study.

In addition to the pre-sessions on each unit, a meeting was held with the ED and MICU pharmacists. The study objectives and design were described to the pharmacists. They provided input on additional data that would be of interest to them. For example, the MICU pharmacists were interested in insulin pen injection technique and IV dose adjustments.

3.4 Pilot Study

The objectives of the pilot study were the following: 1) to confirm the inter-rater agreement of the three observers (two hired and PI), 2) to determine if enough medications are administered at the proposed time periods of observation in the study in either the ICU or ED, and 3) to determine which setting (ICU or ED) is better to study medication administration errors and to determine issues with observing in these unique settings (The research team had experience observing nurses in medical-surgical units but not in ICU or ED settings.). Study observers were trained on specific procedures followed in this study.

The three observers varied in their backgrounds. The PI, who served as an observer, is a graduate student in pharmaceutical administration and is new to the practice
of observing. Observers Two and Three are pharmacy technicians who were hired in three previous studies of medication administration to observe nurses; this study is their fourth. Both administered drugs to patients at the Ohio State University Medical Center (OSUMC) under the former drug administration pharmacy technician program, which was directed by Phil Schneider, a member of the research team.

The pilot study examined three nurses who work the 12-hour shift in the ICU and three nurses who work the 12-hour shift in the ED. Each nurse was observed for one 4-hour interval, as shown in Figure 3.1. The observers monitored these nurses in groups of two in order to confirm inter-rater agreement. More specifically, Observer One and Observer Two were paired for observation of two nurses, Observer Two and Observer Three were paired for observation of two nurses, and Observer One and Observer Three were paired for observation of two nurses. The PI served as one of the three observers. The inter-rater agreement provided valuable input into the overall study design in determining if the same observer needs to monitor a given nurse for the entire shift of observation.

![Figure 3.1: The three observation periods for the pilot study design](image-url)
3.4.1 Inter-rater Agreement

Percent agreement and Cohen’s kappa (κ) statistic (Landis & Koch, 1977) were used to assess inter-rater agreement among the study observers. Each pair of observers (three pairs in total given three observers) was together two times during the pilot study: once in the MICU and once in the ED. Table 3.1 contains the percent agreement among the observers in each setting and on average along with the κ statistic for each pair and on average.

<table>
<thead>
<tr>
<th>Observer Pair</th>
<th>Percent (%) Agreement</th>
<th>Cohen’s κ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ED</td>
<td>MICU</td>
</tr>
<tr>
<td>One and Two</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Two and Three</td>
<td>95.2</td>
<td>100</td>
</tr>
<tr>
<td>One and Three</td>
<td>96.7</td>
<td>94.8</td>
</tr>
<tr>
<td>AVERAGE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3.1: Inter-rater agreement among the three observers

The average percent agreement among the observers was 97.8%. The average κ value was 0.844, which classifies as “almost perfect” (Landis & Koch, 1977). Based on these measures, single observers were able to observe the same nurse at the various observation points in the study. For example, at times Observer One observed the morning period while Observer Two observed the two afternoon/evening periods.

3.4.2 Setting

This project was conducted at The Ohio State University Medical Center, an academic medical center in the Midwest. The pilot study was completed in both the ED and MICU. These two units were chosen because of the lack of observational medication
error research that exists in the literature for them. These two units also have the highest number of nurses who work shifts longer than 12 hours (Trinkoff, Geiger-Brown, Brady, Lipscomb, & Muntaner, 2006). In a patient perception study, 16% of ED patients were concerned about medication errors (Burroughs et al., 2005). General medical surgical units were considered, but preliminary data indicated a small number of medication orders at the end of both 8-hour and 12-hour day shifts, which did not make it a feasible unit for this study, given the interest in observing errors at both early and late periods in a nurse’s work shift.

The pilot study informed the researchers of which unit administers adequate numbers of medications for observation to be feasible at the three proposed time periods of observation. Observing for the pilot time periods (Figure 3.1) informed the researchers of the number of medications administered over an entire 12-hour day shift (Table 3.2). A greater number of medications were observed in the MICU over the 12-hour shift, and the ratio of observed medications/patient was generally higher in the MICU. Based on these two findings in the pilot study, the MICU is the more feasible setting for a time-depended observation-based study.
<table>
<thead>
<tr>
<th>Setting</th>
<th>Time Period</th>
<th>Number of Observed Medication Administrations</th>
<th>Number of Patients Observed</th>
<th>Ratio of Observed Medications/Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED</td>
<td>7a-11a</td>
<td>6</td>
<td>2</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>11a-3p</td>
<td>7</td>
<td>2</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>3p-7p</td>
<td>5</td>
<td>3</td>
<td>1.7</td>
</tr>
<tr>
<td>MICU</td>
<td>7a-11a</td>
<td>12</td>
<td>1</td>
<td>12.0</td>
</tr>
<tr>
<td></td>
<td>11a-3p</td>
<td>3</td>
<td>1</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>3p-7p</td>
<td>9</td>
<td>2</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Table 3.2: Observed medication administration counts from the pilot study by setting

Some additional ED characteristics were identified and factored into the setting decision for the full study. First, for a study such as this one where observations happen at specific time points rather than a large block of time, the ED is not practical because it is too unpredictable in terms of when medications are given to patients. The busiest ED time periods (i.e. Monday afternoons) are still no guarantee that observers will witness medication passes. Interruptions are rampant in the ED, as nurses respond at all moments to the cell phones they carry. Different nurses often obtain, administer, and chart a medication for a single patient. Finally, the ED has many verbal orders so the nurse has no double check in the MAR before administering.

As in the ED, additional MICU characteristics were identified as important when considering an observation-based study of medication administration. In the MICU, patient medications are more scheduled than in the ED but less scheduled than on a typical medical-surgical unit. MICU nurses give more as-needed medications in comparison to the ED, which means the nurses has greater discretion in medicating the
patient. Based on the pre-session and pilot study data, the MICU was selected as the setting for this project.

3.4.3 Sample

The final sample for this study consisted of 30 MICU nurses and 3 ED nurses (pilot study only). Table 3.3 provides the errors observed during the pilot study in both the MICU and ED. During the pilot study, no order-based errors were observed in the MICU; thus, a sample size calculation based on a pilot medication error rate for this setting was not performed. Instead, previous nurse-focused, observation-bases studies were reviewed for the number of nurses included. A study of the impact of dedicated medication nurses on error rates had a sample of 28 nurses for the experimental and control groups combined (Greengold et al., 2003). A study that investigated the use of an interactive CD-ROM for improving rates of medication administration errors included 30 nurses (Schneider et al., 2006), and a study of the impact of BCMA on medication administration errors also included 30 nurses (Pedersen & Schneider, 2007). Based on these three studies, a sample size of 30 was decided for the full study setting. Also, this sample size of 30 nurses fell within the resource budget for the study and the timeline for completion.
### Table 3.3: Tally of errors identified in the pilot study in both the MICU and ED

*24 medication administrations were observed during the MICU pilot.  
**18 medication administrations were observed during the ED pilot.  
***Time standard in the MICU is 60 minutes; time standard in the ED is 30 minutes.

#### 3.5 Study Design

Upon recruitment, each nurse completed the written consent form and had the opportunity to ask questions about the study. The PI scheduled nurses for the day of observation based on their schedule information published on the unit. Observation of nurses did not occur on days when the nurse was precepting a student, orienting a new
nurse, serving as the charge nurse, or working an overtime shift. On the scheduled day of observation, the observer would arrive at the beginning of the 7am to 7pm shift and ask the nurse “if today is an okay day for observation.” The nurse would notify the PI when she or he was ready to obtain and administer medications to the patient. The day was divided into three observation periods- 7-9 am, 1pm-3pm, and 5pm-7pm. These time points were selected in order to have data collected at the beginning of the nurse’s work shift, the eight-hour point of the shift, and the end of the shift. Figure 3.2 depicts the observations sequence over the nurse’s work shift.

<table>
<thead>
<tr>
<th>Hours</th>
<th>0-2</th>
<th>6-8</th>
<th>10-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>7AM</td>
<td></td>
<td></td>
<td>7PM</td>
</tr>
</tbody>
</table>

Figure 3.2: Full study observation sequence for a single nursing shift

### 3.6 Observation Methodology

The observation technique of researching medication administration errors dates back to the early 1960s with research by Barker (K. N. Barker & McConnell, 1962). In using observation as a scientific methodology, an observer is essentially assigning numbers to a human behavior (K. N. Barker, 1980). For this project, the behavior is nurses’ administering medications to patients.
Observation methodology has advantages over other methods of data collection. The subject’s physical ability to report and the selective perception of the subject are irrelevant. Most importantly, observation is independent of the subject’s knowledge of the given situation, and the subject’s willingness to report is eliminated as an obstacle to data collection (K. N. Barker, 1980). The subject does not need to remember to report the situation, no communication is required of the subject, observer inference is involved, and the effect of the observer on the observed is not significant (K. N. Barker, Flynn, & Pepper, 2002).

Barker’s years of experience with the observation methodology also reveals more general, practical advantages over other methods of collecting data (K. N. Barker et al., 2002). Observation is an easily understood method, producing data that are easy to use for identifying trends in medication safety. Data are timely in availability. Overall, the method adopts a systems approach to medication use, thus viewing a dose error as a problem with the system and not assigning blame. Within the hospitals where observation methodology is used, problem-based continuing education places the focus on “our errors, with the facility having a sense of ownership/responsibility for them.

In addition to the advantages of observation that were discussed, some disadvantages are associated with this methodology. The occurrence of the behavior must be predictable in nature so that the observer is able to be there to watch it, and the behavior must be a visible one. The event must be of limited duration so it can be observed in entirety, which medication administration is. Finally, observation may be
physically and mentally difficult for the observer, and it is usually expensive to conduct (K. N. Barker, 1980).

One other “major problem of observation is the observer himself” (K. N. Barker, 1980). The observer is responsible for absorbing the observed information and making inferences from it. Also, the observer may affect the observee by his presence. Critics of the observation methodology believe that the major issue is people acting differently when observed. This problem, however, is not as severe as critics may think. According to Kerlinger (Kerlinger, 1973), observers actually have little effect on what they are observing when the observer is unobtrusive and nonjudgmental and when the observee is doing a familiar activity such as work that is the normal responsibility of his job. When considering whether individuals being observed behave in an exceptional manner, they are only able to do what their abilities permit (K. N. Barker, 1980). If someone cannot tie his shoes on Wednesday when not being observed, that same individual is unable to tie his shoes on Thursday when an observer is present. While subjects may try to impress an observer early during the observation period, they soon return to their normal behavior, as shown in Barker’s study of pharmacists’ counting techniques (K. Barker, Smith, & Winter, 1972). Remaining nonjudgmental and unobtrusive is especially important for the observer when the observed activity is one in which errors could be embarrassing to the observee. In general, Barker has found that people get used to an observer if “his behavior convinces the group that he is no threat” (K. N. Barker, 1980).

In order to address some validity and reliability concerns about the observation method, Dean and Barber (Dean & Barber, 2001) conducted a study to explore potential effects of observation on medication administration errors, impact of observer
intervention, and impact of observer reliability. Inter-rater agreement contributed to the reliability of the method. They also found that omitted drug error documentation reasons were proportionally the same in observed and unobserved periods, and repeated observations had no effect on the omitted drug error rate.

A medication error is defined as “a deviation from the physician’s medication order as written on the patient’s chart” (K. N. Barker, Kimbrough, & Heller, 1966). Here, a defined medication error also incorporated variation from safe medication practices and institutional policy. On the assigned shifts, observers accompanied each nurse as the nurse administers medication to patients; thus, the observer witnessed each dose. The following data were collected: drug name, dose, time of administration, route of administration, dosage form, patient name, code number of the nurse administering, and name of observer. Compliance with safe medication practices was also assessed based on monitoring by the observers. Key safe medication practices (Schneider et al., 2006) included the following: maintenance of package integrity until the dose is administered, checking the patient’s armband prior to administration, not borrowing a dose from another patient’s supply, confirming the dose in the MAR prior to administration, and witnessing the patient take the dose prior to documenting administration. Additional data included washing hands, overriding the Pyxis machine, and comparing the CAPI order to the transcribed eMAR.

No patient-specific information was available to the observer before the observation period and prior to medication administration in general. If the observer was aware of an administration error that would cause patient harm (i.e. a drug allergy), she alerted the nurse; none of these instances occurred while observing nurses in this study.
After documentation of the administration process through observation, these records were compared with physicians’ orders and the MAR. If a physician’s order was clarified by the pharmacist or nurse, the clarified order was used for comparison. The observer compared observed data with the eMAR and CAPI orders to determine if an error occurred. The observer recorded errors and variances from safe medication practices that occurred.

The specific medication administration errors that were monitored come from the defined list of the American Society of Health-Systems Pharmacists (ASHP guidelines on preventing medication errors in hospitals.1993). The error types include the following: omission (drug not administered by the time the next dose is due), unauthorized drug (physician did not write the order), wrong dose (greater or less than the amount ordered), wrong dosage form, wrong route, wrong rate of administration, wrong preparation of dose, wrong administration technique, and wrong time. Wrong time errors were defined by the policy of the setting in which the study was conducted.

When designing this study, a research team of members who have used the observation methodology in past research was assembled. This research advisory team had extensive previous experience with observation-based medication error studies. In three previous studies, over 11,000 medication administrations were observed on medical-surgical units. These studies are summarized in the remainder of this section in order to provide a brief overview of the team’s experience.

In a randomized controlled trial, Greengold et al. (Greengold et al., 2003) investigated the role of medication nurses who focused exclusively on medication administration. Medication errors and process variation errors were examined. The results
indicate that having medication nurses does not reduce medication error rates; however, subgroup analysis suggests benefits in some settings. Furthermore, the differences in medication use systems are believed to have contributed to the results in the study.

Schneider (PI), Pedersen, and Curran were part of a team (Schneider et al., 2006) that investigated the impact of an interactive CD-ROM program on rates of medication administration errors. The CD-ROM was designed to highlight safe medication administration practices. Having observed that some nurses were more compliant with policy and procedures than others, this study extended previous research by investigating additional safe medication administration practices (process variation errors) and most importantly introduced the nurse as a unit of analysis. All prior observation-based medication administration research used total opportunities for error as the unit of analysis and ignored the influence of the nurse. Results showed decreases in deviations from safe medication administration practices, at both the aggregate and nurse level.

Finally, Pedersen (PI) and Schneider (Pedersen & Schneider, 2007) were funded by Catholic Healthcare Partners (Cincinnati, OH) to examine the impact of a BCMA system on the rate of medication administration errors and process variation errors, to evaluate compliance with policy and procedures on the order of processes nurses use when administering medications, to evaluate the time nurses spend administering medications, to characterize interruptions, and to evaluate nurse satisfaction with the medication use system. Results showed a decrease in errors after implementation of BCMA system. From the nursing perspective, nurses did not spend a significantly different amount of time administering medications to patients after implementation, and
they failed to follow the set process order. After three months, nurses were not satisfied with the BCMA system, a finding that was likely due to its novelty, their resistance to change, and their lack of comfort with technology.

3.7 Reconciliation issues

In order to reconcile the observed medicines that were given to patients with the ordered medications, the observers needed access to the electronic charting systems within the ED and MICU. For the ED, access was granted for the Ibex system on December 14, 2007 with the help of the nursing director, manager, and clinical information systems manager. For the MICU, attempts of the individual PI to gain access were met with resistance beginning in November 2007. The Clinical Nurse Scientist for the OSUMC was contacted and helped the PI with attempts to navigate various routes of permission from December 2007 to February 2008, when an alternative was discussed and accepted. Rather than each observer having system access, the presence of a MICU nurse manager was required for logging into the CAPI and eMAR systems. Also, only the PI worked with these individuals after the day of observation to reconcile all observations from the previous day. The other observers contacted the PI at the end of a day’s data collection and informed her of any questions or complicating factors that needed to be considered in reconciliation.

3.8 Data Collection

Data for this project were collected in two ways: observation and questionnaires. The observation data were generated from observation of the nurse administering medications to patients in accord with the methodology discussed above. For this structured observation, three checklist instruments (K. N. Barker, 1980) were used for
data collection: an ED data form, an MICU data form, and an interruption form. The forms specific to medication administration were developed from ones used previously by Pedersen and Schneider and changes were made based on the pre-sessions (see Section 3.3). The PI, PI’s advisor, and research team member developed the interruption form for this study. The interruption data that were collected answered three questions: who or what interrupted, why did the interruption occur, and how did the nurse respond to the interruption. The final forms are presented in Appendix C.

On the MICU form, the following items were included: observer initials, nurse id number, date, patient id number, patient room number, page number, drug, dose, dosage form, route, rate if iv, time of administration, scheduled time, dose preparation, administration technique, Pyxis override, wash hands, maintain package integrity, check armband before administration, not borrowing medication from another patient, double checking the medication in the Pyxis, double checking the medication in the eMAR, documenting after administering the dose, transcription from orders to eMAR, comments, omitted medications, patient weight, patient restraints, time of vitals, and time of turning. The following items were included on the final ED form: observer initials, nurse id number, date, patient id number, patient room number, page number, drug, dose, dosage form, route, rate if iv, time of administration, scheduled time, dose preparation, administration technique, maintain package integrity, wash hands, check armband before administration, double checking the medication in the eMAR, documenting after administering the dose, comments, and omitted medications.

The data collected on the interruption form were the following: nurse id number, patient id number, patient room number, corresponding observation form page number,
administered medication corresponding to the interruption, who/what interrupted, reason for interruption, action/response of the nurse to the interruption, and description of the interruption.

Over the course of the observation shift, each nurse completed three questionnaires (Appendix D). Questionnaire A contained 10 demographic and home life items, three work schedule items, one sleep item, and one medication error item. It was distributed to the nurse during the morning observation period. Questionnaire B contained the 20-item Checklist Individual Strength (CIS) chronic fatigue instrument. Questionnaire C contained the 11-item Need for Recovery acute fatigue instrument along with four week-specific work schedule items, one sleep item, one medication error item, and three patient-related items. These two fatigue instruments were selected because they have been used in working populations, and the validity and reliability of them is established. Also, the research team was unsure whether chronic or acute fatigue was a possible factor in nurses’ making medication administration errors. Thus, both instruments were included in the study in order to examine it among this sample of MICU nurses.

Questionnaires B and C were distributed to the nurse during the second and third observation periods, respectively. Nurses were randomly assigned to receive Questionnaire B from 1:00 to 3:00pm or Questionnaire C from 1:00 to 3:00pm. The other respective questionnaire was assigned to the 5:00 to 7:00pm period. The decision was made to randomize these two questionnaires so that a comparison between nurses’ fatigue responses on the two instruments at the given time periods was possible. While neither instrument measures fatigue at a specific moment in time, nurses may respond to fatigue
questions differently at times in their shift when they are more tired or closer to going home.

The CIS chronic fatigue instrument was developed by the University Hospital of Amsterdam and the University Hospital of Rotterdam (Vercoulen et al., 1994). Each of 20 items is scored on a seven-point scale, and the items are summed for a total score. The four interpretable factors are subjective experience of fatigue (8 items), concentration (5 items), motivation (4 items), and physical activity level (3 items). These factors explain 67.7% of the variance in the principal components analyses. The psychometric characteristics of the instrument are the following: Cronbach’s alpha for reliability of the entire instrument was 0.90, Gutman split-half reliability coefficient was 0.92, and subscale Cronbach’s alphas were 0.88, 0.92, 0.83, and 0.87, respectively. Bültmann et al. (Bültmann et al., 2000) worked with six samples of patients in order to determine the appropriate cutoff point in CIS score at which a working individual is at risk for sick leave or disability due to fatigue. The CIS total score cutoff point was >76. Validity of the CIS and its ability to distinguish between fatigued and non-fatigued working people was established in a study of 219 workers in the Netherlands (Beurskens, Anna J H M. et al., 2000).

The need for recovery concept incorporates the need for recuperation from work-related fatigue that a worker experiences after a day of work. When looking at data from the Maastricht Cohort Study, need for recovery was found in almost all employees, and it was associated with high psychological job demands, which would be something that nurses experience during their work (Jansen, Kant, & van den Brandt, Piet A., 2002). The instrument contains 11 items and is scored dichotomously as “yes” or “no”. In a study of
68,775 Dutch workers, van Veldhoven and Boersen (van Veldhoven & Broersen, 2003) found Cronbach’s alpha to be 0.88, with subgroups of workers ranging from 0.81 to 0.92 when looking at age, sex, and education level. Nurses and truck drivers were used in a study that considered the test-retest reliability of the need for recovery instrument. In a stable work environment, the two year intra class correlation (ICC) of the instrument was 0.68 for truckers and 0.80 for nurses (de Croon, Sluiter, & Frings-Dresen, 2006).

Need for Recovery was used as a short-term fatigue measure in a study of Greek nursing staff. Among these nurses, the mean Need for Recovery score was 66.2, and it was significantly higher in women and lower educated nurses (Alexopoulos, Burdorf, & Kalokerinou, 2003). Studies of the effects of work shift rotation have also used this measure. Backward rotation schedule was related to increased need for recovery (van Amelsvoort, Jansen, Swaen, van den Brandt, PA., & Kant, 2004).

How do the CIS and Need for Recovery instruments compare to each other? Two identified studies compared these fatigue measures and determined their reliability. The first used a random sample of the working population in the Netherlands. Cronbach’s alpha for the CIS was 0.96 while it was 0.91 for the Need for Recovery. The correlation between the two instruments was 0.66 (De Vries, Michielsen, & Van Heck, 2003). The second study used data from the Maastricht Cohort Study of fatigue in the working population in the Netherlands. In this cohort, Cronbach’s alpha for the CIS was 0.93 while it was 0.78 for the Need for Recovery. The correlation between the two instruments was 0.633 (Kant et al., 2003). These data support the use of the CIS and Need for Recovery as reliable and valid instruments for measuring fatigue in a working population.
Fulfilling a complete shift of data collection for a scheduled nurse in the MICU was difficult at times. Here are some situations explaining why. In the first situation, the observer completes morning data collection for a nurse with one patient. At the beginning of the second data collection period, the patient dies and the nurse has no new admission for the remainder of the shift. In the second situation, the scheduled nurse is assigned to a single, critical patient, but the patient only has morning medications. Thus, there is no data to collect for both the second and third time points. A third situation is when the nurse takes the patient to another floor for a procedure, is delayed, and does not return until the end of the shift. In order to try to avoid some of these situations, the PI would often look at the assignment board upon her arrival for morning data collection and make last minute changes if the nurse scheduled for observation that day was assigned to a single patient whom the PI knew had no meds in the afternoon. Another study volunteer was substituted for the scheduled nurse. If no other study volunteers were working, the day was canceled and the nurse was rescheduled for a later day. With the rescheduling that occurred, the nurses and the hired observers were very patient.

3.9 Data Analysis

The results for this study were considered in two ways: opportunity for error as the unit of analysis and the nurse as the unit of analysis. Historically, Barker established “opportunity for error” as the unit of data in observational medication error studies (K. N. Barker, Kimbrough, & Heller, 1966). This term includes all doses that are prepared and given by a nurse who is observed in the study (Barker, 1969). Schneider et al. implemented use of the nurse as the unit of analysis because variations in practice may differ among nurses who are observed in a study; thus, this difference is accounted for in
the nurse-based error rates (Schneider et al., 2006). The results in Chapter Four are divided into sections based on which unit of analysis is used.

From the observation data, medication errors and process variations errors were determined. For the nurse-based error rates, the unit of analysis for this study was the medication administration error rate (number of errors / number of opportunities for error) per individual nurse. Thus, a nurse served as his/her own control. Three error rates were calculated for each nurse for each period of observation: order-based error (drug, dose, route, dosage form, and iv rate), preparation/administration-based error (administration time, dose preparation, and administration technique), and error of process variation (did not wash hands, did not maintain package integrity, did not check patient armband, borrowed med from other patient, did not double check Pyxis and/or did not double check MAR, pre-charted, and did not chart). Using the same nurse for the 8-hour (1pm-3pm) and 12-hour (5pm-7pm) shift error rates eliminated a potential source of error since fatigue was measured within the same individual.

The analytical dataset included data for each variable as collected through the questionnaires and observation. Categorization of the following continuous variables occurred: age, first year licensed, and working overtime during the week of the observation day. Two summary measures were created for fatigue: a score for Need for Recovery (acute) and a score for CIS (chronic). Using the Need for Recovery instrument, a score for each nurse, ranging from 0-100, was determined. With the CIS, items 2, 5, 6, 7, 8, 11, 12, 15, and 20 were scored according to the number circled by the respondent. Items 1, 3, 4, 9, 10, 13, 14, 16, 17, 18, and 19 were reverse scored. The four subscales were determined through the following summation method: subjective feelings of
fatigue- items 1, 4, 6, 9, 12, 14, 16, 20; concentration- items 3, 8, 11, 13, 19; motivation- items 2, 5, 15, 18; and physical activity- items 7, 10, 17. The overall CIS score was the sum of the subscale scores.

The data analysis for each study objective was the following:

1. Determine the relationship between nurses’ work hours and the occurrence of medication administration errors.

This relationship was examined for each type of medication error: order-based, preparation/administration-based, and process variation. Univariate and multivariate linear regression models were used to examine this relationship. The respective error rate was the outcome variable. The primary independent variable of interest was the total actual hours worked during the week of the observation day. Covariates included in the analysis were personal factors and work-related factors.

1.1 Observe nurses’ administering medications to patients.

The observation data collection tool, along with observer comments, were examined for instances of inconsistencies and error. Qualitative review of the completed tool and comments provided insight into the process followed by the nurse in administering medications and was completed during the pre-sessions and pilot study. As part of the pilot study, the observers watched the same nurse so that inter-rater agreement was established using the kappa statistic and percent agreement.

1.2 Examine the relationship between demographic/personal characteristics of the nurses and the occurrence of medication administration errors.

Frequencies of responses and mean values of the characteristics of the nurses gathered through the questionnaires were produced. A series of univariate linear
regression models were used to examine this relationship. The medication administration error rate was the continuous outcome variable. The independent variables of interest were the personal (demographic, work-practice, and work-schedule) factors of the nurses.

1.3 **Classify the types of medication errors that occur during nurses’ administration of medications to patients.**

The three types of medication errors (order-based, preparation/administration-based, and process variation) observed through data collection were counted and reported through frequency of occurrence as a percentage of the medications observed. Rates were established for each type of error for each nurse overall and at each time period of observation.

2. **Determine the relationship between fatigue and the occurrence of medication administration errors.**

This relationship was examined for each type of medication error: order-based, preparation/administration-based, and process variation. Univariate and multivariate linear regression models were used to examine this relationship. The respective error rate was the outcome variable. The primary independent variable of interest was the nurse fatigue score. Separate models considered the Need for Recovery score and the CIS score. Covariates included in the analysis were personal factors and work-related factors.

2.1 **Using reliable and valid instruments, assess the chronic and acute fatigue of nurses.**

The overall fatigue of nurses was assessed through the Need for Recovery and CIS instruments described previously. CIS total and subset scores were assessed once for each nurse. Need for Recovery total score was assessed once for each nurse as well.
Frequency of responses, mean scores, and Cronbach’s alpha for both the Need for Recovery and CIS were produced.

2.2 Examine the relationship between work hours and fatigue.

The relationship between actual work hours and the two fatigue measures was determined through the Pearson correlation coefficient.

3. Determine the progression of errors over a nurse’s work shift based on observations during three time periods.

Repeated measures ANOVA was used to examine the progression of errors at each time point of observation via each type of error rate over the nurse’s work shift. Sphericity was assumed and tested in the models. When the main effects were significant, the Bonferroni correction was used for multiple comparisons among the mean error rates at the three periods of observation.

3.1 Determine if a relationship exists between fatigue and error progression over the work shift.

Repeated measures ANOVA was used to examine the progression of errors at each time point of observation via each type of error rate over the nurse’s work shift while the covariate was Need for Recovery score, CIS score, or actual hours worked during the week of the observation day, respectively.

4. Explore the quantity and type of interruptions that nurses experience while administering medications to their patients along with the nurse’s response to the interruption.

Frequencies of interruption occurrence, nurse response to interruptions, and interrupters were produced.
3.10 References


CHAPTER 4

RESULTS

Results for this study are divided into three sections. The first section presents results with opportunity for error as the unit of analysis. The second section transitions into results in which the nurse was the unit of analysis. Finally, results for the interruption component of the study are presented in the third section.
4.1 Results: Opportunity for Error as Unit of Analysis

A total of 548 medication administrations were observed among the 30 MICU nurses who volunteered for this study. Fourteen medications were held (10) or omitted (four) during the observation periods. Held medications were consciously not given to the patient for a clinical reason and were not included in the analysis. Pyxis overrides for medications not in the patient’s profile occurred for 4.1% of the observed medications. Transcription between the CAPI ordering system and the eMAR was incorrect in 1.6% of the observed medications. The total percentage of medications with an associated error is located in Table 4.1.
<table>
<thead>
<tr>
<th>Errors</th>
<th>n</th>
<th>% (of total medications observed)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Order-based</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Dose</td>
<td>33</td>
<td>6.0</td>
</tr>
<tr>
<td>Dosage form</td>
<td>2</td>
<td>0.4</td>
</tr>
<tr>
<td>Route</td>
<td>2</td>
<td>0.4</td>
</tr>
<tr>
<td>IV-rate</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Preparation &amp; Administration-based</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Admin time</td>
<td>31</td>
<td>5.7</td>
</tr>
<tr>
<td>Dose prep</td>
<td>6</td>
<td>1.1</td>
</tr>
<tr>
<td>Admin technique</td>
<td>58</td>
<td>10.7</td>
</tr>
<tr>
<td><strong>Process variation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not wash hands</td>
<td>68</td>
<td>12.5</td>
</tr>
<tr>
<td>Did not maintain package</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>integrity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not check patient</td>
<td>433</td>
<td>79.6</td>
</tr>
<tr>
<td>armband</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borrowed med from other</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not double check Pyxis</td>
<td>1</td>
<td>0.6</td>
</tr>
<tr>
<td>Did not double check MAR</td>
<td>76</td>
<td>16.6</td>
</tr>
<tr>
<td>Pre-charted</td>
<td>18</td>
<td>3.4</td>
</tr>
<tr>
<td>Not charted</td>
<td>15</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Table 4.1: Medication administration errors identified in the study

Six percent of the order-based administration errors were dose errors. Thirteen total nurses made these errors. Eight of the errors were attributed to one nurse who spilled approximately 75% of these eight medications while administering them. The remaining 25% was administered to the patient, and the medications were charted as given in full. Of the dose errors, 19 were considered “underdosed” while 13 were “overdosed”. The drugs and dosage forms varied. Table 4.2 provides details on these dose errors.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Magnitude of dose error (% less than or more than ordered dose)</th>
<th>Dosage form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbidopa/levodopa (x2)</td>
<td>33%, -33%</td>
<td>Tablet</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>1mg vs. 1 drop</td>
<td>N/A</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>14%</td>
<td>Injection</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>-25%</td>
<td>Injection</td>
</tr>
<tr>
<td>Fibercon</td>
<td>-20%</td>
<td>Tablet</td>
</tr>
<tr>
<td>Fleet</td>
<td>25%</td>
<td>Liquid</td>
</tr>
<tr>
<td>Hydrcortisone (x2)</td>
<td>300%, 100%</td>
<td>Injection</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>-50%</td>
<td>Injection</td>
</tr>
<tr>
<td>Insulin</td>
<td>-50%</td>
<td>Injection</td>
</tr>
<tr>
<td>Lactulose (x2)</td>
<td>100%, 100%</td>
<td>Liquid</td>
</tr>
<tr>
<td>Methylprednisolone (x2)</td>
<td>108%, -50%</td>
<td>Injection</td>
</tr>
<tr>
<td>Metoclopramide</td>
<td>100%</td>
<td>Injection</td>
</tr>
<tr>
<td>Metoprolol (x2)</td>
<td>50%, 100%</td>
<td>Tablet</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>-60%</td>
<td>IV</td>
</tr>
<tr>
<td>Morphine</td>
<td>-50%</td>
<td>Injection</td>
</tr>
<tr>
<td>Nicotine</td>
<td>125%</td>
<td>Patch</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>20%</td>
<td>Liquid</td>
</tr>
<tr>
<td>Propofol (x2)</td>
<td>-90%</td>
<td>IV</td>
</tr>
<tr>
<td>Risperidone</td>
<td>-50%</td>
<td>Tablet</td>
</tr>
</tbody>
</table>

Table 4.2: Drugs with dose errors, magnitude of dose error, and dosage form

Given the three observation time points over the course of a nurse’s work shift, the percentage of medications with an error per time point are given in Table 4.3 (order-based errors), Table 4.4 (preparation/administration-based errors), and Table 4.5 (errors of process variation). The bottom row of each of these tables summarizes the percentage of medications that were categorized as having one error affiliated with them, the percentage of medications that were categorized as having two errors affiliated with them, and the percentage of medications that were categorized as having three errors affiliated with them. Based on ANOVA results, categories of errors for which the three time periods were found to differ significantly are noted.
### Table 4.3: Percentage of observed medications with an order-based error within each time point of observation

<table>
<thead>
<tr>
<th></th>
<th>7am-9am (n=304)</th>
<th>1pm-3pm (n=126)</th>
<th>5pm-7pm (n=114)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>0</td>
<td>0.8</td>
<td>0</td>
<td>0.188</td>
</tr>
<tr>
<td>Dose</td>
<td>7.8</td>
<td>5.6</td>
<td>1.8</td>
<td>0.067</td>
</tr>
<tr>
<td>Dosage form</td>
<td>0.3</td>
<td>0.8</td>
<td>0</td>
<td>0.584</td>
</tr>
<tr>
<td>Route</td>
<td>0.3</td>
<td>0.8</td>
<td>0</td>
<td>0.584</td>
</tr>
<tr>
<td>IV-rate</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Medications with one or more order-based errors</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 order-based error</td>
<td>7.8</td>
<td>5.6</td>
<td>1.8</td>
<td>0.086</td>
</tr>
<tr>
<td>2 order-based errors</td>
<td>0.3</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>3 order-based errors</td>
<td>0</td>
<td>0.8</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*p-value for significance at $\alpha = 0.05$

### Table 4.4: Percentage of observed medications with a preparation/administration-based error within each time point of observation

<table>
<thead>
<tr>
<th></th>
<th>7am-9am (n=304)</th>
<th>1pm-3pm (n=126)</th>
<th>5pm-7pm (n=114)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administration time</td>
<td>8.1</td>
<td>4.8</td>
<td>0</td>
<td>0.005*</td>
</tr>
<tr>
<td>Dose preparation</td>
<td>1.6</td>
<td>0.8</td>
<td>0</td>
<td>0.334</td>
</tr>
<tr>
<td>Administration technique</td>
<td>8.9</td>
<td>14.3</td>
<td>11.4</td>
<td>0.246</td>
</tr>
<tr>
<td>Medications with one or more preparation/administration-based errors</td>
<td></td>
<td></td>
<td></td>
<td>0.183</td>
</tr>
<tr>
<td>1 prep/admin-based error</td>
<td>16.1</td>
<td>19.8</td>
<td>11.4</td>
<td></td>
</tr>
<tr>
<td>2 prep/admin-based errors</td>
<td>1.3</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

*p-value for significance at $\alpha = 0.05$
Within administration time, the mean error rate at 7am-9am was significantly different from the mean error rate at 5pm-7pm (p=0.004). No other preparation/administration-based errors were significantly different over time.

<table>
<thead>
<tr>
<th>Error Type</th>
<th>7am-9am (n=308)</th>
<th>1pm-3pm (n=126)</th>
<th>5pm-7pm (n=114)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not wash hands</td>
<td>5.6</td>
<td>17.5</td>
<td>25.4</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Did not maintain package integrity</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Did not check patient armband</td>
<td>71.1</td>
<td>84.9</td>
<td>96.5</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Borrowed med from another patient</td>
<td>0</td>
<td>0</td>
<td>0.9</td>
<td>0.152</td>
</tr>
<tr>
<td>Did not double-check Pyxis</td>
<td>3.6</td>
<td>0</td>
<td>0</td>
<td>0.081</td>
</tr>
<tr>
<td>Did not double-check MAR</td>
<td>17.0</td>
<td>17.5</td>
<td>14.1</td>
<td>0.779</td>
</tr>
<tr>
<td>Pre-charted</td>
<td>1.7</td>
<td>4.0</td>
<td>7.3</td>
<td>0.017*</td>
</tr>
<tr>
<td>Not charted</td>
<td>2.6</td>
<td>1.6</td>
<td>4.4</td>
<td>0.405</td>
</tr>
<tr>
<td>Medications with one or more errors of process variation</td>
<td>54.7</td>
<td>53.2</td>
<td>57.0</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>1 process variation</td>
<td>16.9</td>
<td>31.7</td>
<td>32.5</td>
<td></td>
</tr>
<tr>
<td>2 process variation</td>
<td>2.3</td>
<td>1.6</td>
<td>7.9</td>
<td></td>
</tr>
</tbody>
</table>

*p-value for significance at α = 0.05

Table 4.5: Percentage of observed medications with an error of process variation within each time point of observation

Within “did not wash hands,” the mean error rate at 7am-9am differed significantly from both the mean error rate at 1pm-3pm (p=0.002) and the mean error rate at 5pm-7pm (p<0.001). Within “did not check patient armband,” the mean error rate at 7am-9am differed significantly from both the mean error rate at 1pm-3pm (p=0.003) and
the mean error rate at 5pm-7pm (p<0.001). Pre-charting differed significantly between 7am-9am and 5pm-7pm (p=0.015). When considering the significant differences among the medications with one or more errors of process variation, the following differences were identified: mean error rates at 7am-9am differed from both the mean error rate at 1pm-3pm (p=0.002) and the mean error rate at 5pm-7pm (p<0.001), and mean error rates at 1pm-3pm differed from rates at 5pm-7pm (p=0.025).

4.2 Results: Nurse as Unit of Analysis

A total of 30 nurses volunteered for this study. On average, each nurse was observed administering 18 medications. Rates of medication errors were determined for each nurse. The average order-based error, preparation/administration-based error, and error of process variation rates for the nurses at the three time points of observation and overall are presented in Table 4.6.

<table>
<thead>
<tr>
<th>Errors</th>
<th>7am-9am (SD)</th>
<th>1pm-3pm (SD)</th>
<th>5pm-7pm (SD)</th>
<th>Overall (SD)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order-based (n=14 nurses)</td>
<td>1.8% (3.9)</td>
<td>2.3% (4.7)</td>
<td>0.2% (1.2)</td>
<td>1.5% (2.5)</td>
<td>0.104</td>
</tr>
<tr>
<td>Preparation/administration-based (n=26 nurses)</td>
<td>7.4% (7.7)</td>
<td>5.7% (7.1)</td>
<td>4.0% (7.2)</td>
<td>5.6% (5.0)</td>
<td>0.259</td>
</tr>
<tr>
<td>Process variation (n=29 nurses)</td>
<td>14.6% Δ (7.6)</td>
<td>17.8% (8.2)</td>
<td>20.1% Δ (7.7)</td>
<td>15.9% (6.7)</td>
<td>0.006*</td>
</tr>
</tbody>
</table>

* p-value for significance at α = 0.05 for differences among the time points
Δ p=0.003 for pairwise comparison of groups where α = 0.05

Table 4.6: Medication administration error rates by nurse for each time period of observation and overall
In addition to the error data that were collected through observation, data were collected from each nurse through questionnaires. Table 4.7 and Table 4.8 contain results for general characteristics of the nurses while Table 4.9 and Table 4.10 contain results for characteristics of the nurse that are specific to the shift on which the nurse was observed. Sixty-one percent of nurses checked the patient’s tube placement while an observer was present during an observation period.

Four nurses reported making a medication administration error during the day on which they were observed. Three of the reported errors were dose errors while one was an administration time error. Two of the reported errors were captured in the observation data while two were not captured. The administration time error was captured because the nurse gave the medication an hour early to the patient. One of the dose errors in which 20mg was given rather than 10mg was captured as well. The situations for the other two reported errors were the following: one involved a nurse not restarting an IV medication after stopping it to draw blood and then getting called away, an event which happened outside of the observation periods, and the second was a potential dose error that did not reach the patient because the nurse spilled the medication prior to administering. She recognized the error after going back to Pyxis to re-retrieve the medication for the patient.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>33.2 years</td>
<td>10.9</td>
<td>23</td>
<td>55</td>
</tr>
<tr>
<td>Years employed by current employer</td>
<td>7.8 years</td>
<td>8.0</td>
<td>.75</td>
<td>30</td>
</tr>
<tr>
<td>Years in current position</td>
<td>6.3 years</td>
<td>6.9</td>
<td>0.5</td>
<td>29</td>
</tr>
<tr>
<td>Total work hours (general)</td>
<td>38.4 hours</td>
<td>4.8</td>
<td>24</td>
<td>44</td>
</tr>
<tr>
<td>Regular hours (general)</td>
<td>34.6 hours</td>
<td>3.8</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Sleep per night (general)</td>
<td>6.5 hours</td>
<td>1.2</td>
<td>4</td>
<td>9</td>
</tr>
</tbody>
</table>

Table 4.7: Descriptive statistics for continuous demographic variables for the MICU nurses (n=30)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>23</td>
<td>76.7</td>
</tr>
<tr>
<td>Basic nursing degree</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diploma- nursing</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Associate degree nursing</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Bachelor’s degree nursing</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>First year licensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before 1980</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>1980-1984</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>1985-1989</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>1990-1994</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>1995-1999</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>2000-2004</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>2005 and later</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 25</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>25-29</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>35-39</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>40-44</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>45-49</td>
<td>6</td>
<td>20.0</td>
</tr>
<tr>
<td>50-54</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>55 and over</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single, never married</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Married</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Number of dependent children</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>23</td>
<td>76.7</td>
</tr>
<tr>
<td>1</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>3</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Number of dependent adults</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Typical rotation schedule</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7a-7p only</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>7a-7p and 7p-7a</td>
<td>21</td>
<td>70.0</td>
</tr>
<tr>
<td>Control over work schedule</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A little bit of control</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>Some control</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>Quite a bit of control</td>
<td>7</td>
<td>23.3</td>
</tr>
<tr>
<td>Secondary employment</td>
<td>1</td>
<td>3.4</td>
</tr>
<tr>
<td>Ever made a medication error</td>
<td>26</td>
<td>86.7</td>
</tr>
</tbody>
</table>

Table 4.8: Frequencies for categorical demographic variables for the MICU nurses (n=30)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation pattern this week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7a-7p only</td>
<td>28</td>
<td>93.3</td>
</tr>
<tr>
<td>7a-7p and 7p-7a</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Consecutive days worked (up through and including day of observation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Working overtime during the week when observation occurred</td>
<td>22</td>
<td>73.3</td>
</tr>
<tr>
<td>Made a medication error today</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Number of patients today</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>2</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>Acuity of patients today</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>2</td>
<td>6.9</td>
</tr>
<tr>
<td>Medium</td>
<td>14</td>
<td>48.2</td>
</tr>
<tr>
<td>High</td>
<td>13</td>
<td>44.8</td>
</tr>
<tr>
<td>How did today compare to all other days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 = really easy</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>4 = same</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>6.6</td>
</tr>
<tr>
<td>7 = really hard</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 4.9: Frequencies for categorical variables for the MICU nurses specific to the week of observation
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Std. deviation</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual work hours this week</td>
<td>39.3 hours</td>
<td>10.6</td>
<td>12</td>
<td>68</td>
</tr>
<tr>
<td>Regularly-scheduled hours</td>
<td>33.8 hours</td>
<td>6.5</td>
<td>12</td>
<td>48</td>
</tr>
<tr>
<td>Consecutive days worked</td>
<td>2.4 days</td>
<td>1.8</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Sleep in the last 24-hour period</td>
<td>6.3 hours</td>
<td>1.2</td>
<td>3.5</td>
<td>9.0</td>
</tr>
</tbody>
</table>

Table 4.10: Descriptive statistics for continuous demographic variables for the MICU nurses specific to the week of observation (n=30)

Data were collected in order to evaluate the fatigue levels at both an acute and a chronic level among the nurses. Nurse responses per item for the Need for Recovery acute fatigue measure are presented in Table 4.11. Table 4.12 provides the nurse responses per item for the CIS-20 chronic fatigue measure. Overall fatigue scores for both instruments are presented in Table 4.13. Based on the CIS score cutoff of scores > 76 established by Bültmann et al. (see Section 3.8), 33.3% of the MICU nurses are at risk for sick leave and disability due to fatigue.
<table>
<thead>
<tr>
<th>Need for Recovery Items</th>
<th>n</th>
<th>Percent “Yes” Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I find it difficult to relax at the end of a working day.</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>2. By the end of the working day, I feel really worn out.</td>
<td>29</td>
<td>96.7</td>
</tr>
<tr>
<td>3. Because of my job, at the end of the working day I feel rather exhausted.</td>
<td>26</td>
<td>86.7</td>
</tr>
<tr>
<td>4. After my evening meal, I generally feel in good shape.</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>5. In general, I only start to feel relaxed on my second non-working day.</td>
<td>10</td>
<td>33.3</td>
</tr>
<tr>
<td>6. I find it difficult to concentrate in my free time after work.</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>7. I cannot really show any interest in other people when I have just come home myself.</td>
<td>17</td>
<td>56.7</td>
</tr>
<tr>
<td>8. Generally, I need more than an hour before I feel completely recuperated after work.</td>
<td>21</td>
<td>70.0</td>
</tr>
<tr>
<td>9. When I get home from work, I need to be left in peace for a while.</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>10. Often, after a day’s work, I feel so tired that I cannot get involved in other activities.</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>11. A feeling of tiredness prevents me from doing my work as well as I normally would during the last part of the working day.</td>
<td>15</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Table 4.11: Nurse responses to items on the Need for Recovery fatigue instrument
<table>
<thead>
<tr>
<th>CIS-20 Items</th>
<th>Percent Responses (n=30)</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel tired.</td>
<td>26.7 23.3 16.7 6.7 16.7 6.7 3.3</td>
<td>3.0 (1.8)</td>
</tr>
<tr>
<td>2. I feel very active.</td>
<td>6.7 16.7 13.3 30.0 16.7 10.0 6.7</td>
<td>3.9 (1.6)</td>
</tr>
<tr>
<td>3. Thinking requires effort.</td>
<td>10.0 16.7 33.3 3.3 16.7 13.3 6.7</td>
<td>3.7 (1.8)</td>
</tr>
<tr>
<td>4. Physically, I feel exhausted.</td>
<td>10.0 16.7 26.7 6.7 10.0 23.3 6.7</td>
<td>3.9 (1.8)</td>
</tr>
<tr>
<td>5. I feel like doing all kinds of nice things.</td>
<td>10.0 16.7 16.7 30.0 16.7 10.0 0</td>
<td>3.6 (1.9)</td>
</tr>
<tr>
<td>6. I feel fit.</td>
<td>6.7 13.3 16.7 20.0 23.3 10.0 10.0</td>
<td>4.1 (1.7)</td>
</tr>
<tr>
<td>7. I do quite a lot within a day.</td>
<td>33.3 36.7 13.3 10.0 3.3 3.3 0</td>
<td>2.2 (1.3)</td>
</tr>
<tr>
<td>8. When I am doing something, I can concentrate quite well.</td>
<td>10.0 43.3 20.0 16.7 6.7 3.3 0</td>
<td>2.8 (1.3)</td>
</tr>
<tr>
<td>9. I feel weak.</td>
<td>0 0 13.3 6.7 16.7 46.7 16.7</td>
<td>5.5 (1.3)</td>
</tr>
<tr>
<td>10. I don’t do much during the day.</td>
<td>0 6.7 0 3.3 6.7 30.0 53.3</td>
<td>6.1 (1.4)</td>
</tr>
<tr>
<td>11. I can concentrate well.</td>
<td>10.0 30.0 43.3 6.7 10.0 0 0</td>
<td>2.8 (1.1)</td>
</tr>
<tr>
<td>12. I feel rested.</td>
<td>3.3 6.7 10.0 20.0 20.0 30.0 10.0</td>
<td>4.8 (1.6)</td>
</tr>
<tr>
<td>13. I have trouble concentrating.</td>
<td>3.3 10.0 20.0 20.0 13.3 20.0 13.3</td>
<td>4.4 (1.7)</td>
</tr>
<tr>
<td>14. Physically, I feel I am in poor condition.</td>
<td>6.7 6.7 10.0 6.7 20.0 33.3 16.7</td>
<td>4.9 (1.8)</td>
</tr>
<tr>
<td>15. I am full of plans.</td>
<td>23.3 36.7 20.0 13.3 0 6.7 0</td>
<td>2.5 (1.4)</td>
</tr>
<tr>
<td>16. I get tired very quickly.</td>
<td>0 10.0 16.7 16.7 20.0 26.7 10.0</td>
<td>4.7 (1.5)</td>
</tr>
<tr>
<td>17. I have a low output (productivity).</td>
<td>0 3.3 3.3 10.0 13.3 50.0 20.0</td>
<td>5.6 (1.2)</td>
</tr>
<tr>
<td>18. I feel no desire to do anything.</td>
<td>0 3.3 0 6.7 23.3 30.0 36.7</td>
<td>5.9 (1.2)</td>
</tr>
<tr>
<td>19. My thoughts easily wander.</td>
<td>0 23.3 10.0 13.3 20.0 26.7 6.7</td>
<td>4.4 (1.7)</td>
</tr>
<tr>
<td>20. Physically, I feel in good shape.</td>
<td>10.0 20.0 23.3 13.3 10.0 13.3 10.0</td>
<td>3.7 (1.9)</td>
</tr>
</tbody>
</table>

Table 4.12: Nurse responses to items on the CIS-20 fatigue instrument
Table 4.13: Nursing fatigue- descriptive statistics for scores on fatigue instruments

The CIS fatigue instrument was randomly assigned to be given to a single nurse at either the 1:00-3:00pm (n=16) observation or the 5:00-7:00pm (n=14) observation period, respectively. The Need for Recovery instrument was given at the other respective time period. Average fatigue scores between the two time periods differed on the CIS but did not differ on the Need for Recovery (Table 4.14). Also, the CIS and Need for Recovery are significantly correlated with each other (r=0.622, p<0.001).

Table 4.14: Fatigue instrument scores per time period given

*p-value for significance at $\alpha = 0.05$
Correlations between hours worked and fatigue scores were investigated. No significant correlation was found between CIS and average work hours, CIS and total hours worked during week of the observation day, and Need for Recovery and total hours worked during week of the observation day. The correlation between Need for Recovery and average work hours was significant ($r=0.446$, $p=0.014$). No significant correlation existed between the fatigue scores and average compensated overtime hours and scheduled overtime hours for the week of the observation day. Finally, independent t-tests revealed no significant differences between the fatigue scores of 1) nurses who worked overtime for the week of the observation day and those who did not and 2) nurses who worked only days and those who rotated between days and nights.

Two of the main objectives of this study were to determine relationships between work hours and medication administration errors and fatigue and medication administration errors. Based on univariate linear regression models and attempted multivariate models, neither work hours nor the two measures of fatigue is associated with order-based, preparation/administration-based, and process variation medication administration errors. Two nurse variables that were associated with order-based errors included being female and working overtime during the week of the observation day. Nurse variables associated with preparation/administration errors included making a previous medication error, rotating shifts, number of patients on the day observed, and years in current position. No nurse variables were associated with errors of process variation. Table 4.15 provides the significant results from the regression analysis for the error categories and the non-significant results for the primary study objectives.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Model R²</th>
<th>β</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse order-based error rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIS</td>
<td>0.055</td>
<td>0</td>
<td>0.212</td>
</tr>
<tr>
<td>Need for Recovery</td>
<td>0.011</td>
<td>0</td>
<td>0.588</td>
</tr>
<tr>
<td>Actual work hours this week</td>
<td>0.041</td>
<td>0</td>
<td>0.283</td>
</tr>
<tr>
<td>Average work hours</td>
<td>0.002</td>
<td>0</td>
<td>0.796</td>
</tr>
<tr>
<td>Female</td>
<td>0.176</td>
<td>-0.024</td>
<td>0.021*</td>
</tr>
<tr>
<td>Worked overtime this week</td>
<td>0.189</td>
<td>-0.024</td>
<td>0.016*</td>
</tr>
<tr>
<td>Nurse preparation/administration-based error rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIS</td>
<td>0.028</td>
<td>0.001</td>
<td>0.378</td>
</tr>
<tr>
<td>Need for Recovery</td>
<td>0.062</td>
<td>0.001</td>
<td>0.184</td>
</tr>
<tr>
<td>Actual work hours this week</td>
<td>0.002</td>
<td>0</td>
<td>0.838</td>
</tr>
<tr>
<td>Average work hours</td>
<td>0.009</td>
<td>0</td>
<td>0.618</td>
</tr>
<tr>
<td>Ever made a med error</td>
<td>0.134</td>
<td>0.053</td>
<td>0.047*</td>
</tr>
<tr>
<td>Rotates days/ nights</td>
<td>0.149</td>
<td>0.042</td>
<td>0.035*</td>
</tr>
<tr>
<td>Number of patients</td>
<td>0.156</td>
<td>0.041</td>
<td>0.031*</td>
</tr>
<tr>
<td>Years in current position</td>
<td>0.141</td>
<td>-0.003</td>
<td>0.041*</td>
</tr>
<tr>
<td>Nurse process variation error rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CIS</td>
<td>0.051</td>
<td>0.001</td>
<td>0.230</td>
</tr>
<tr>
<td>Need for Recovery</td>
<td>0</td>
<td>0</td>
<td>0.939</td>
</tr>
<tr>
<td>Actual work hours this week</td>
<td>0</td>
<td>0</td>
<td>0.950</td>
</tr>
<tr>
<td>Average work hours</td>
<td>0.005</td>
<td>0</td>
<td>0.698</td>
</tr>
</tbody>
</table>

*p-value for significance at α = 0.05

**Table 4.15: Results of regression analysis for primary objectives**

Several nurse variables were associated with the CIS fatigue score: being female, years in current position, caring for dependent adults, and having ever made a medication error. Basic nursing degree, years in current position, caring for dependent children and caring for dependent adults, control over schedule, and having ever made a medication error were associated significantly with the Need for Recovery score. Table 4.16 provides these results.
Table 4.16: Results of regression analysis for fatigue instruments

In addition to the linear regression models, repeated measures ANOVA was used to determine whether fatigue or work hours were associated with the error rates at each time point in a work shift. Work hours and fatigue were not associated with the order-based, preparation/administration-based, and process variation error rates. In the repeated measure models (see Table 4.6), order-based and preparation/administration-based errors had no significant effects and thus no differences in error rates over the progression of the work shift. Errors of process variation, however, did have significant effects (p=0.006), and pairwise comparisons indicated that the error rate (14.6%) during the 7am-9am time period was significantly different from the error rate (20.1%) during the 5pm-7pm time period (p=0.003).

4.3 Interruptions

Along with error and nursing-specific data, information was collected on the interruptions that nurses experienced while administering medications to their patients.
While data were recorded only for interruptions that occurred during medication administration, interruptions seemed prevalent during all of the nurses’ patient care activities. Among all of the observed administrations, 16.6% (n=91) of the medications given to patients had an interruption associated with them. The frequency of interrupters is presented in Table 4.17. Additionally, the nurses’ responses to the interrupters were the following: 1.1% of nurses ignored the interruption, 4.4% deferred the reason for the interruption until after she/he finished administering the medication(s) to the patients, and 94.5% of the nurses attended to the interruption when it occurred.

<table>
<thead>
<tr>
<th>Interrupter</th>
<th>n</th>
<th>Percentage of total interruptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Another nurse</td>
<td>10</td>
<td>11.0</td>
</tr>
<tr>
<td>Physician</td>
<td>1</td>
<td>1.1</td>
</tr>
<tr>
<td>Other healthcare worker</td>
<td>31</td>
<td>34.1</td>
</tr>
<tr>
<td>Family member</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>Page or telephone</td>
<td>12</td>
<td>13.2</td>
</tr>
<tr>
<td>Other patient-related</td>
<td>20</td>
<td>22.0</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>Physician and other patient-related</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>Other healthcare worker and family member</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>Other healthcare worker and other patient-related</td>
<td>9</td>
<td>9.9</td>
</tr>
</tbody>
</table>

Table 4.17: Frequency of interrupters of nurses during medication administration
CHAPTER 5

DISCUSSION

This chapter begins with a discussion of the important findings of this research study. Next, limitations of this study are presented. Implications of this research and a brief conclusion complete the chapter.
5.1 Discussion of Research Findings

5.1.1 Order-based Errors

Of the medications observed during this study, 6% were administered to the patient with an incorrect dose. The medications that had dosing errors varied. The majority of the dosage forms for these dose errors were injection (eight) and tablet (six). Given these findings, the dose errors occurred in medications for which the drug was unavailable to the nurse in the specific dose required for that patient. Previous ICU studies reported dose error rates of 7.2% (Tissot et al., 1999), 12.7% (Girotti et al., 1987), and 20% (Kopp et al., 2006). Wrong dose error rate in the PICU was 26.2% in Buckley et al. (2007). The dose error rate in settings other than the ICU is higher: 10% in accredited hospitals (excluding wrong time errors) in Barker et al. (2002). Dose errors represented the greatest percentage of errors within the order-based category, followed by dosage form and route with 0.4% each and one wrong drug error. No order-based errors differed in percentage over the three time periods of observation within the nurse’s shift.

5.1.2 Preparation/Administration-based Errors

Almost 6% of the observed medication administrations occurred with a wrong-time error. This wrong time rate is lower than in other studies: 9% in the ICU (Kopp et al., 2006), 16.7% in the PICU (Buckley et al., 2007), 7.2% on a medical-surgical unit in Pedersen & Schneider (2007), and 43% in the mixed setting sample of Barker et al. (2002). While the significance of wrong-time errors is debated, the occurrence of them represents a stray from MICU guidelines that were established to improve patient safety within the unit. Wrong-time errors differed significantly over the nurse’s shift, with 8.1% of medications being administered at the incorrect time during 7am-9am, 4.8% of
medications being administered at the incorrect time during 1pm-3pm, and no wrong-time errors from 5pm-7pm. Other studies in the ICU reported wrong time error rates ranging from 3.7% (Tissot et al., 1999) to 41.2% (Girotti et al., 1987). Administration technique errors were observed in 10.7% of the medications. The majority of these errors were the result of nurses pushing intravenous medications too quickly when administering them to patients. Pharmacy guidelines and Micromedex information were used to determine if the medication was administered in too short of a time period.

5.1.3 Errors of Process Variation

The largest percentages of medications with an associated error were observed in the process variation error category. In nearly 80% of the medication administrations, the nurse neglected to check the patient’s identification armband prior to administering the medication. Checking a patient’s identification is a key safe practice of medication use. This practice became progressively neglected over the course of the nurse’s shift, ranging from 71% during 7am-9am to 97% during the 5pm-7pm. One potential reason why nurses did not check the patient’s armband prior to each administration is the small number of patients for which each nurse cares in this particular MICU. Thirty-seven percent of nurses had only one patient during the observed shift while 60% had two patients. These nurses often check the patient’s identification during the morning assessment and then assume the role of “knowing their patient.” While the concept of “knowing their patient” may hold true for these nurses, the practice of checking patient identification prior to administering medications is held as a key safe medication practice. If nurses fail to check armbands as part of their daily routine with their own patients, do they check the armband of another nurse’s patient when covering for that nurse over
lunch? This practice also extends beyond medication use to the broad area of patient safety. Mix-ups among patients occur; checking armbands for all patient care activities is a practice that can prevent these mix-ups.

Seventeen percent of medications were not checked against the patient’s MAR or Pyxis profile prior to administration. Again, double checking the medication in hand versus the ordered drug is a key safe medication practice. Nurses are busy workers with many different tasks on their minds, and the possibility of getting a dose mixed up due to not double checking exists, especially due to the large number of medications that nurses may administer at one given time. Also, nurses would check the drug name against the MAR, but the exact dose may have been skipped over as evidenced by the percentage of dose errors observed.

Thirteen percent of medications were administered without the nurses’ washing their hands prior to administration, and this percentage increased over the course of the shift from 5.6% from 7am-9am to 25.4% from 5pm-7pm. With the current concern for hospital-acquired infections, hand washing is a key practice for patient safety and infection prevention. Almost 3% of medications observed were not charted. Lack of charting can lead to patient harm in the form of under-treatment of a condition or an overdose if either the same nurse or another one believes that a medication was not given because it is not charted in the MAR. Finally, 3.4% of medications were charted prior to the nurses’ administering them. This practice violates the key safe medication practices to which nurses should adhere, and it increased in occurrence over the course of the shift (7am-9am: 1.7%, 1pm-3pm: 4.0%, and 5pm-7pm: 7.3%). A major concern with pre-
charting a medication is that the nurse will get distracted, forget to give the medication, check the MAR and see it documented, and neglect to give the medication to the patient.

In addition to the overall errors of process variation just discussed, the percentage of medications having two or three errors of process variation associated with them increased from the 7am-9am shift to the shifts later in the day. From 7am-9am, 16.9% of medications had two errors of process variation, and 2.3% had three errors of process variation. From 1pm-3pm, 31.7% of medications had two errors of process variation, and 1.6% had three errors of process variation. From 5pm-7pm, 32.5% of medications had two errors of process variation, and 7.9% had three errors of process variation. What is the reason for these increases in errors of process variation? Two primary culprits, fatigue and work hours, were not associated with errors of process variation so the answer is still unknown.

The MICU in which this study occurred requires nurses to transcribe orders from the CAPI ordering system into the eMAR. In the observed medications, the transcription error rate was 1.6%. While this percentage is lower than expected, likely due to the double checks in place when orders are entered for a new patient on the unit, it could potentially be zero if an integrated system were in place.

5.1.4 Error Rates per Nurse and Nursing Characteristics

Overall rates of medication administration errors per nurse were the following: 1.5% order-based, 5.6% preparation/administration-based, and 15.9% process variation. This process variation error rate is lower than individual nurse rates reported in previous studies from medical surgical units (Schneider et al., 2006; Pedersen & Schneider, 2007). Four nurses reported making a medication administration error during the day of
observation. These nurses had an average age of 41 years, had worked in their current position for over eight years, and were all female. An additional medication administration-related practice that was recorded was whether or not the nurse checked the patient’s tube placement if the patient was given medications through a tube. Sixty-one percent of nurses checked the tube placement during any observation period when an observer was present. This percentage, however, cannot be interpreted as 39% of nurses did not check tube placement at all because the process on the unit allows the nurse to check placement during the morning assessment of the patient.

When examining this sample of 30 nurses, the following characteristics were identified: 77% were female, 93% held a Bachelor’s degree in nursing, 47% were first licensed in 2005 or later, 60% were younger than 30 years of age, 70% rotated between 12-hour day shifts and 12-hour night shifts, 47% felt they had some control over their work schedule, and 87% said they had made a medication administration error in the past. The nurses had worked in their current position for an average of six years, worked an average of 38 hours per week (regular plus overtime), and slept an average of 6.5 hours per night. Seventy-three percent of nurses worked overtime during the week when observation occurred, and 93% of patients were rated as medium or high acuity for the day on which the nurse was observed. This sample of nurses differs from the general population of nurses and other descriptions of critical care nurses (Trinkoff et al., 2006; L.D. Scott et al., 2006). It consists of nurses who are younger, less experienced, and more highly educated. Fewer are married, and they have fewer dependent children.

On both fatigue instruments, a higher score represents a higher level of fatigue. For the CIS, the mean nurse fatigue score was 66.3 out of 100. Based on the cutoff score
of 76 established previously (Bültmann et al., 2000), 33.3% of the nurses observed are at risk for sick leave and disability due to fatigue, which is unhealthy from both individual worker and management perspectives. Among a diverse group of Dutch workers, the mean CIS score was 57.2 (Kant et al., 2003). For the Need for Recovery, the mean fatigue score was 57.0. Some unpublished research of nurses from five Ohio hospitals found a mean score of 59, which is similar to our study (Chipps, Buck, Boyd, & Young, 2005). Research from nurses in the Netherlands identified a mean score of 43 among those workers (Sluiter, de Croon, Meijman, & Frings-Dresen, 2003), and Greek nurses’ mean score was 66 (Alexopoulos, Burdorf, & Kalokerinou, 2003). Overall, the chronic and acute fatigue measures had some correlation, indicating that some of the components of fatigue overlap.

The nurses’ fatigue levels as measured by both the CIS and Need for Recovery increased when comparing scores from 1:00-3:00pm completers to 5:00-7:00 completers. Within the CIS, scores increased significantly from 61.0 in the 1:00-3:00pm completers to 72.4 in the 5:00-7:00 completers (p=0.049). The CIS measured chronic fatigue; the Need for Recovery measured acute fatigue. Supposedly, neither fatigue instrument measures fatigue at a specific point in time; however, the results here suggest otherwise. Nurses appeared to have higher fatigue levels on both instruments when completing fatigue items later in their shifts. This finding suggests that both instruments measured fatigue more specifically than anticipated when selecting these fatigue instruments.

No relationship was found between nurses’ work hours and the occurrence of medication administration errors, and no relationship was found between nurses’ fatigue and occurrence of medication administration errors. Something other than work hours
and fatigue explains the errors that were observed in this study. When considering the error rates per nurse at the three periods within the shift, order-based and preparation/administration-based errors did not differ among the early, 8-hour, and 12-hour points. Process variation error rates per nurse did differ between the early (14.6%) and 12-hour points (20.1%). The error rate at the 8-hour point (17.8%) did not differ from the early point. In general, nurses make more errors of process variation while administering medications at the 12-hour time point in the shift compared to the 8-hour time point in the shift.

5.1.5 Intermittent

Nurses experience many interruptions while engaging in patient care activities, and medication administration is no exception. Seventeen percent of the observed medications in this study had an interruption occur during the process of administration. Another healthcare worker (i.e. respiratory therapist, speech therapist, etc.) was responsible for 34% of the interruptions, and 22% of the interruptions were concerning a patient other than the patient for which the nurse was administering medications at the time. Thirteen percent of the interruptions were in response to a telephone call or page. More than nine times out of 10, the nurse attended to the interruption when it occurred. The amount of interruptions and the willingness of the nurse to attend to the interruption are cause for concern from a medication safety standpoint. Once engaged in medication administration, the nurse should focus on that task in order to limit the potential for making errors.
5.2 Study Limitations

The potential for selection bias exists within this project. Nurses were approached directly and asked if they would like to volunteer to participate. If nurses were busy with a patient at the time recruitment occurred, they were not approached during that particular recruitment session; however, they were likely to have been approached during subsequent recruiting. Also, night-only nurses were excluded from the sample for a couple of reasons. First, none of the observers worked night shifts, and thus the quality of data collection during an overnight period would be limited. More importantly, fewer medications are administered overnight, and the time-based component of this study would have made data collection extremely difficult to complete.

The second and most common potential bias mentioned when an observation-based study is conducted is the Hawthorne effect, which is an improvement in a subject’s performance when being observed. Kerlinger found that observers have little effect on what they are observing when the observer is unobtrusive and nonjudgmental and when the observee is doing a familiar activity such as work that is the normal responsibility of his job (Kerlinger, 1973). Barker notes that individuals are only able to perform up to their abilities (K. N. Barker, 1980), and he found that subjects soon return to their normal behavior even after trying to impress an observer early during the observation period (K. Barker, Smith, & Winter, 1972).

During this study, nurses commented that they “forgot I was even watching them” and that “they felt like they were in school again.” At times, nurses viewed us as working with them rather than “monitors” of behavior and performance. Considering the mean order-based, preparation/administration-based, and process variation error rates per nurse
over the periods of observation, nurses’ behaviors did not seem to differ, indicating that they were doing their work in a normal manner without an in-tuned awareness of the observation. Even if we consider the possibility that all of the nurses were on their best behavior while observed, the error rates indicate room for improvement.

The number of nurses from whom we were able to collect data was limited due to the tight timeframe of the study once the systems-access issues were resolved. On numerous occasions, the nurses being observed had relatively few medications for their patients, which limited the number of data opportunities. At the same time, this observation-based study had a real-world focus, and in the real world, nurses’ patients vary in terms of their conditions and need for medication. Nurses were observed for three 2-hour time periods over the course of a shift, which is not ideal. With unlimited resources, nurses would have been observed for an entire shift so that data collection could have been maximized.

If repeating this study, several changes would be made to data collection: 1) medications would have been classified as “Pyxis, medication bin, or override” rather than “Pyxis override” in order to gather data to support efficiency improvements of this system, 2) “checked tube placement” would have been collected for each medication rather than recorded as a comment for each nurse, and 3) Pyxis or MAR double checks would have been recorded differently. With respect to the latter, the unit process was to check the medication against either the Pyxis profile or eMAR. From a medication safety standpoint, however, checking that the patient Pyxis profile (populated by the ordering system) matches the eMAR (populated by the nurse) is a potential way for nurses to catch transcription errors, and thus a practice that is important. Nine transcription errors were
uncovered by the observers during the reconciliation process of this observation-based study.

5.3 Study Implications

Overall, the findings of this observation-based study indicate a need for improvement in medication administration. Dose errors can be corrected by nurses’ checking the dose more closely in the eMAR prior to administering a drug to a patient. Rates of administration technique errors and errors of process variation can be lowered through nurse education. A list of the most common IV-push medications and the rate at which they should be administered to the patient would provide nurses with an easy reference, and hopefully, it would help lower the rate of administration technique errors. A seminar in which medication administration processes are addressed may help lower the process variation error rate. Emphasis on the patient safety reasons behind the various processes is important and may help reinforce the importance of following processes for the nurse. While no differences in nurse error rates were found between the 8-hour and 12-hour time points within the shift, a difference in errors of process variation existed between the morning observation period and the 10-12-hour observation period. Thus, processes are followed more closely early in the shift compared to the end of the shift, and nurses should be aware of this finding.

While fatigue was not related to errors, it is a concern given the high fatigue scores of the nurses. Limiting the amount of overtime a nurse works, while not ideal for staffing a unit, may help lower the fatigue among the staff. Nursing managers should be aware of staff fatigue levels as high fatigue may affect a nurse’s overall health and ability to work.
Using observation for this study provided data on aspects of the medication administration process that otherwise would have been undetected. This study produced findings on process variation in an ICU setting. Previous error studies in the ICU were unable to collect these types of data. In the pilot study, the ED was explored for the first time using observation, and based on the findings, it is a setting in which observation-based studies of medication administration are needed. The benefits and challenges of a time-based observational study design were illuminated and are useful to other researchers interested in this type of work. Collecting data in two-hour time periods was complicated because nurses did not always have medications to administer at those specific times. In these situations, the nurse was rescheduled for observation at a later date, which extended the time required for data collection within the study. From an institutional perspective, data such as these are important for quality improvement and medication safety committees. From the perspective of other institutions, these data shed light on areas for possible research and topics to address with nurses in order to maximize medication use and patient safety.

5.4 Conclusion

In conclusion, this study did not find a relationship between nurse fatigue and the occurrence of medication administration errors. No relationship existed between nurses’ total work hours and occurrence of medication administration errors. When looking within a nurse’s 12-hour work shift, the process variation error rate from the 7am-9am period was significantly lower than the rate at the 12-hour point in the shift, but it did not differ from the rate at the 8-hour point in the shift.
Nursing leadership should apply the findings of this study to develop nurse education programs on processes that nurses should follow when administering medications to patients. Overall, nurses’ performance of administering medications was satisfactory, but room for improvement exists, especially in some of the process variation error categories that are designed to prevent medication errors.
5.5 References


APPENDIX A

IRB APPROVAL LETTER AND GRANT AWARD NOTICE
September 28, 2007

Protocol Number: 2007H0200
Protocol Title: THE RELATIONSHIP BETWEEN NURSES’ WORK HOURS, FATIGUE, AND OCCURRENCE OF MEDICATION ADMINISTRATION ERRORS, Craig A. Pedersen, Pamela J. Sibberz, Katherine L. Bellebaum, Philip J. Schneider, Pharmacy

Type of Review: Initial Submission
IRB Staff Contact: Jennifer Hart
614-292-9804
Hart.191@osu.edu

Dear Dr. Schwartz,

The Biomedical IRB APPROVED BY EXPEDITED REVIEW the above referenced protocol. The Board was able to provide expedited approval under 45 CFR 46.110(b)(1) because the research presents minimal risk to subjects and qualifies under the expedited review category(s) listed below.

Date of IRB Approval: September 28, 2007
Date of IRB Expiration: September 25, 2008
Expedited Review Category: 7

If applicable, informed consent (and HIPAA research authorization) must be obtained from subjects or their legally authorized representatives and documented prior to research involvement. The IRB-approved consent form and process must be used. Changes in the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before they are implemented (except where necessary to eliminate apparent immediate hazards to subjects).

This approval is valid for one year from the date of IRB review when approval is granted or modifications are required. The approval will no longer be in effect on the date listed above as the IRB expiration date. A Continuing Review application must be approved within this interval to avoid expiration of IRB approval and cessation of all research activities. A final report must be provided to the IRB and all records relating to the research (including signed consent forms) must be retained and available for audit for at least 3 years after the research has ended.

It is the responsibility of the investigator to promptly report to the IRB any serious, unexpected and related adverse events or potential unanticipated problems involving risks to subjects or others.

This approval is issued under The Ohio State University’s OHRP Federally Assured #00005378.

All forms and procedures can be found on the ORR website – www.orr.osu.edu. Please feel free to contact the IRB staff contact listed above with any questions or concerns.

Karla Zadnik, OD, PhD, Chair
Biomedical Institutional Review Board
NOTICE OF AWARD

DISSERTATION AWARD
Department of Health and Human Services
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Grant Number: 1R36HS017381-01

Principal Investigator:
KATHERINE LOUISE BELLEBAUM, MS

Project Title: The Relationship between Nurses Work Hours, Fatigue, and Medication Administration

ERIN SCOTT
Sponsored Program Officer
Health Sciences Office
8030 Graves Hall
333 W. 10th Avenue
Columbus, OH 43210

Award e-mailed to: NIHaward@osu.edu

Budget Period: 01/04/2007 – 09/03/2008
Project Period: 01/04/2007 – 09/03/2008

Dear Business Official:

The Agency for Healthcare Research and Quality hereby awards a grant in the amount of $37,124 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Ohio State University Foundation in support of the above referenced project. This award is pursuant to the authority of 42 USC 241, 42 CFR 52, 42 CFR 67 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

All investigators and directors of research projects supported by grants from the Agency for Healthcare Research and Quality are expected to make their research results promptly and widely available to the health professions, public administrators, and the scientific community. All published reports, both formal and informal, should acknowledge grant support with the following footnote: "This project was supported by grant number R36HS017381 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality." When a manuscript resulting from this grant is accepted for publication, the principal investigator must promptly notify the project officer of its acceptance and the date it is scheduled to be published.

Award recipients are also responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. For additional information, please visit http://www.iedison.gov.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely,

Joan Metcalfe
Grants Management Officer
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Additional information follows.
APPENDIX B

NURSING STAFF RECRUITMENT SCRIPT AND CONSENT FORM
Good morning,

My name is Katie Bellebaum and I am a grad student in the College of Pharmacy. I’m here because we need your help!

We are getting ready to begin an exciting research study here in the MICU. We have two things we’re interested in: 1. fatigue in nurses, which we’ll assess through short questionnaires and observing you while you administer medications and care for your patients and 2. interruptions that you experience while you give work giving meds to patients.

We’ll work with your nurse manager to schedule your participation in the study on one of your regularly- scheduled work days.

Essentially, we’ll watch you work. At the same time, none of this is reported to your nurse managers, etc. All of your data are identified by a number, and your name and number appear nowhere together.

I would like to get everyone to complete the consent form today so that we can start scheduling some of you for next week. You can sign and print your name on the last page. While you’re reading over the form, I would like to answer any questions you may have about the study.
The Ohio State University Consent to Participate in Research

Study Title: The Relationship between Nurses’ Work Hours, Fatigue, and Occurrence of Medication Administration Errors
Principal Investigator: Craig A. Pedersen (for IRB purposes; Katherine Bellebaum is PI for entire study)
Sponsor: Agency for Healthcare Research and Quality

• This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

• Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

• You may or may not benefit as a result of participating in this study. Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

• You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being done to determine if nurses’ work hours or fatigue affect the occurrence of medication administration errors. You are being asked to participate because you are a nurse who works at The Ohio State University Medical Center University Hospital.

2. How many people will take part in this study?

A total of 66 nurses who work in the ICU or ED at Ohio State University Medical Center University Hospital will take part in the study.
3. What will happen if I take part in this study?

You will be observed in your normal patient care activities administering medications to your patients on one day for up to 6 hours. These observations will occur for two-hour intervals at three points over the course of your work shift: 0-2 hour point, 6-8 hour point, and 10-12 hour point. If you choose to participate in this study, you will not be asked to do anything differently than you would normally do when administering medications to your patients. You will complete three questionnaires that will determine characteristics of your home life, work life, acute fatigue, and chronic fatigue. The first questionnaire will be completed upon signing this consent form and enrolling in the study. It will take approximately ten minutes to complete. The second questionnaire will be completed immediately prior to the 6-8 shift-hour observation period. It will take approximately five minutes to complete. The third questionnaire will be completed immediately prior to the 10-12 shift-hour observation period. It will take approximately five minutes to complete. The questionnaires will be completed at a location of your choice, such as your work station or lounge area.

4. How long will I be in the study?

You will be enrolled in the study for 4 months and observed for one day.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University or The Ohio State University Medical Center.

6. What risks, side effects or discomforts can I expect from being in the study?

You may feel self-conscious about being observed administering medications. Because errors that do not lead to patient harm will be recorded for study purposes only, you should not feel any increased risk of administrative, legal, or punitive action that might not otherwise normally occur. Any error that leads to patient harm will be reported in the usual manner for your hospital.

You will be assigned an identification number that will be recorded on your respective questionnaires and observation form. Your name will not be recorded on any of these documents in order to protect your privacy. Thus, your data will be anonymous. The data collected from you will be stored in a locked cabinet in the office of the principal investigator and in a database to which only the co-investigators will have access.
7. What benefits can I expect from being in the study?

While you will not benefit directly from participating in the study, this study fills a significant gap because it is the first in-depth examination of nurses’ work hours and medication administration error occurrence. Knowing the relationship between work hours and medication error occurrence will provide insight into the scheduling policies of inpatient hospitals. The overall goal of this research is to improve patient safety. Process changes for medication administration can occur with the input of data such as these. Fatigue is also a prominent topic in healthcare research. This study will provide results that demonstrate the relationship between fatigue and medication administration error occurrence.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following group:

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices

10. What are the costs of taking part in this study?

There will be no costs to you for participating in this study. You will be observed administering medications on a regularly scheduled day of work.

11. Will I be paid for taking part in this study?

You will not be paid to participate in the study.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher immediately, who will determine if you should obtain medical treatment. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of healthcare expenses for this study.
13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Katie Bellebaum (614-292-5989).

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Katie Bellebaum (614-292-5989).
Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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APPENDIX C

DATA COLLECTION FORMS
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<th>Dose (if tab broken)</th>
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<th>IV, Rate</th>
<th>Time of Administration / MAR sched.</th>
<th>Time (w/h 30 min)</th>
<th>Dose Prepared</th>
<th>Admin Technique</th>
<th>Maintain Packaging Integrit</th>
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</tbody>
</table>

Omitted Drugs

Comments

Omitted

Revised 10/29/07
The Ohio State University College of Pharmacy
DATA COLLECTION FORM
Medical Intensive Care Unit

<table>
<thead>
<tr>
<th>Observer</th>
<th>RN ID#</th>
<th>Date</th>
<th>Patient ID#</th>
<th>Room #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Drug (concentration in mg/dL)</th>
<th>Dose (ml in 30 mls/infusion)</th>
<th>Dosage Form (tablet/capsule/vial/liquid)</th>
<th>Route</th>
<th>IV, Rate</th>
<th>Time of Administration (School/Time of 60 min)</th>
<th>Dose Preparation</th>
<th>Admin. Technique</th>
<th>Pyridine Exceeds</th>
<th>Wash Hands</th>
<th>Maintain Medication Integrity</th>
<th>Check Arm Band Before Admin</th>
<th>Net Borrowed From Other Patient</th>
<th>Med In Profile</th>
<th>MARR Compliance</th>
<th>Transcription From CAPI to Chart(s)</th>
<th>Comments</th>
</tr>
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</table>

**Omitted Drugs**

**Was the patient turned?**

**Time visits were taken**

**Time period of observation:**
- Yes
- No

**Patient weight:**

**Is patient in restraints?**
- Yes
- No

**Related to:**
## Tally of Interruptions

<table>
<thead>
<tr>
<th>Corresponding</th>
<th>Who/What Interrupted</th>
<th>Reason for Interruption</th>
<th>Action/Response</th>
<th>Describe the situation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 2 3 4 5</td>
<td>Patient</td>
<td>Family member</td>
<td>Ignore</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>Pager/telephone</td>
<td>Defer</td>
<td></td>
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<tr>
<td></td>
<td>Physician</td>
<td>Other patient related</td>
<td></td>
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<td></td>
<td>Other HOW</td>
<td>Other</td>
<td>Attend to</td>
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<td>1 2 3 4 5</td>
<td>Patient</td>
<td>Family member</td>
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<td>Family member</td>
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<td>Pager/telephone</td>
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<td>Physician</td>
<td>Other patient related</td>
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<td>1 2 3 4 5</td>
<td>Patient</td>
<td>Family member</td>
<td>Ignore</td>
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<td>Physician</td>
<td>Other patient related</td>
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<td>1 2 3 4 5</td>
<td>Patient</td>
<td>Family member</td>
<td>Ignore</td>
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<td>Nurse</td>
<td>Pager/telephone</td>
<td>Defer</td>
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<td></td>
<td>Physician</td>
<td>Other patient related</td>
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<td></td>
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<tr>
<td></td>
<td>Other HOW</td>
<td>Other</td>
<td>Attend to</td>
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</tbody>
</table>

Revised 01/28/08
APPENDIX D

FINAL STUDY QUESTIONNAIRES
Questionnaire A

Please respond to the following questions related to your demographics and your work experiences.

1. Age: ______ years

2. Gender: _____ Male _____ Female

3. Basic nursing degree:
   ____ Diploma - nursing
   ____ Associate Degree - nursing
   ____ Bachelor of Science

4. Highest degree earned (if applicable):
   ____ Master of Science
   ____ PhD
   ____ Other: please specify ____________________________

5. In what year were you first licensed as a nurse? ______

6. Number of years employed by your current employer: ______

7. Number of years employed in your current position by your present employer: ______

8. What is your marital status?
   ____ single, never married
   ____ single, separated or divorced
   ____ married
   ____ widowed

9. Number of dependent children: ______

Do your dependent children have any extenuating circumstances that affect your care for them?
__________________________________________________________________________________

10. Number of dependent adults for whom you provide care: ______

Do your dependent adults have any extenuating circumstances that affect your care for them?
__________________________________________________________________________________
11. Please report your AVERAGE work schedule for your PRIMARY employment position. On average, in a typical or normal work week,
   a. How many total actual hours do you work? ______
   b. Of this total, how many are: i. regularly scheduled hours? ______
      ii. compensated overtime? ______
      iii. uncompensated overtime? ______
   c. In a given month what is your typical rotation pattern?
      ___ day/evning
      ___ day/night
      ___ straight days
      ___ straight evenings
      ___ straight nights
      ___ other, please specify: ____________________________

12. How much control do you have in determining your work schedule?
   ___ no control
   ___ a little bit of control
   ___ some control
   ___ quite a bit of control
   ___ complete control

13. Please select one of the following:
   ___ I do not have secondary employment.
   ___ I do have secondary employment.

If you have secondary employment that contributes to your earnings, please provide information about your secondary job(s). If the activity is within nursing, please indicate the type of unit.

<table>
<thead>
<tr>
<th>In Nursing?</th>
<th>Describe the activity</th>
<th>Hours/week</th>
<th>Weeks/year</th>
<th>Type of unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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<td>Yes</td>
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<tr>
<td>Yes</td>
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</tbody>
</table>

14. On average, how many hours of sleep did you get each 24-hour period over the past week? ______

15. Have you ever made a medication administration error?
   ___ Yes
   ___ No
**Questionnaire B**

**DIRECTIONS**

We wish to get an impression of how you have felt during the past two weeks. Please circle your response. For example,

If you feel that this statement is **completely true**, circle the number "1".

<table>
<thead>
<tr>
<th>Yes, that is true.</th>
<th>No, that is not true.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
</tbody>
</table>

If you feel that this statement is **not true at all**, circle the number "7".

<table>
<thead>
<tr>
<th>Yes, that is true.</th>
<th>No, that is not true.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
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</tbody>
</table>

If you feel that this statement is not **"yes, that is true." but also not "no, that is not true."** circle the number in accordance with how you have felt.

<table>
<thead>
<tr>
<th>Yes, that is true.</th>
<th>No, that is not true.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
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</tbody>
</table>

**RESPONSES**

Please respond to ALL items and circle only one response for each item.

<table>
<thead>
<tr>
<th>Yes, that is true.</th>
<th>No, that is not true.</th>
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</thead>
<tbody>
<tr>
<td>1 2 3 4 5 6 7</td>
<td></td>
</tr>
</tbody>
</table>

1. I feel tired.
   1 2 3 4 5 6 7
2. I feel very active.
   1 2 3 4 5 6 7
3. Thinking requires effort.
   1 2 3 4 5 6 7
4. Physically, I feel exhausted.
   1 2 3 4 5 6 7
5. I feel like doing all kinds of nice things.
   1 2 3 4 5 6 7
6. I feel fit.
   1 2 3 4 5 6 7
7. I do quite a lot within a day.
   1 2 3 4 5 6 7
8. When I am doing something, I can concentrate quite well.
   1 2 3 4 5 6 7
9. I feel weak.
   1 2 3 4 5 6 7
10. I don't do much during the day.
    Yes, that is true. No, that is not true.
<table>
<thead>
<tr>
<th></th>
<th>Yes, that is true.</th>
<th>No, that is not true.</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. I can concentrate well.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12. I feel rested.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>13. I have trouble concentrating.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>14. Physically, I feel I am in poor condition.</td>
<td>1</td>
<td>2</td>
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<tr>
<td>15. I am full of plans.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>16. I get tired very quickly.</td>
<td>1</td>
<td>2</td>
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<tr>
<td>17. I have a low output (productivity).</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>18. I feel no desire to do anything.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>19. My thoughts easily wander.</td>
<td>1</td>
<td>2</td>
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<tr>
<td>20. Physically, I feel in good shape.</td>
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Questionnaire C

Please answer the following items based on your work schedule for THIS WORK WEEK for your primary employment position.

1. During this work week,
   a. How many total actual hours do you work? _____
   b. Of your total hours, how many are:
      i. regularly scheduled hours? _____
      ii. compensated overtime? _____
      iii. uncompensated overtime? _____
      iv. mandatory overtime? _____
      v. scheduled overtime? _____
      vi. non-scheduled overtime? _____

2. During this work week, what is your rotation pattern?
   ___ day/evening
   ___ day/night
   ___ straight days
   ___ straight evenings
   ___ straight nights
   ___ other, please specify: ___________________________

3. Please enter all hours worked over the past week for ALL of your employment. Indicate whether the hours were worked at your primary place of employment (circle "1") or at a secondary place of employment (circle "2").

<table>
<thead>
<tr>
<th>Day of the week</th>
<th>Hours worked</th>
<th>Primary (1)</th>
<th>Secondary (2)</th>
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<td>1</td>
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<td>2</td>
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<td>Day Two</td>
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<td>2</td>
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<td>Day Three</td>
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<td>2</td>
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<td>Day Four</td>
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<td>Day Five</td>
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<td>Day Six</td>
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<td>2</td>
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<tr>
<td>Day Seven</td>
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<td>2</td>
<td>1</td>
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</table>

Current Information

4. How many days have you worked consecutively, counting today? If today is your first day, put a number 1 for the response. _____

5. How many hours of sleep did you get in the last 24-hour period? _____

6. Are you aware of making any medication administration errors during your shift today?
   ___ Yes
   ___ No
If yes, please describe the error and situation:

____________________________________________________________________________________

7. Number of patients you cared for today: ____

8. Overall acuity of patients during your shift today (circle most appropriate):
   1=low
   2=medium
   3=high

9. How does today compare to all of your other workdays? (circle the number)
   Really easy  Same  Really hard
   1  2  3  4  5  6  7

10. Please answer yes or no to each of the following items:
    I find it difficult to relax at the end of a working day.
    ____ Yes
    ____ No

    By the end of the working day, I feel really worn out.
    ____ Yes
    ____ No

    Because of my job, at the end of the working day I feel rather exhausted.
    ____ Yes
    ____ No

    After my evening meal, I generally feel in good shape.
    ____ Yes
    ____ No

    In general, I only start to feel relaxed on my second non-working day.
    ____ Yes
    ____ No

    I find it difficult to concentrate in my free time after work.
    ____ Yes
    ____ No

    I cannot really show any interest in other people when I have just come home myself.
    ____ Yes
    ____ No

    Generally, I need more than an hour before I feel completely recuperated after work.
    ____ Yes
    ____ No

    When I get home from work, I need to be left in peace for a while.
    ____ Yes
    ____ No

    Often, after a day's work, I feel so tired that I cannot get involved in other activities.
    ____ Yes
    ____ No

    A feeling of tiredness prevents me from doing my work as well as I normally would during the last part of
    the working day.
    ____ Yes
    ____ No
BIBLIOGRAPHY


