Medication Administration Complexity, Work Interruptions, and Nurses' Workload as predictors of Medication Administration Errors

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June, 2009

A thesis submitted to McGill University in partial fulfilment of the requirements of the degree of Doctor of Philosophy (Nursing)

Abstract

Background: The evidence to date in support of system related factors to account for medication administration errors (MAE) remains scant and inconclusive.

Objective: To examine the predictive power of medication administration complexity (component and coordinative), work interruptions and nurses' workload as potential contributing factors to MAE.

Design: A prospective correlational design.

Setting: A medical patient care unit in a university teaching hospital

Sample: A convenience sample of medication administration rounds performed by registered nurses with at least six months of professional experience.

Method: Data were collected using direct observation (MAE and work interruptions), self-report measures (subjective workload, nurses' characteristics) and the Medication Administration Complexity (MAC) coding scale (component and coordinative medication complexity).

Results: One hundred and two rounds were observed, during which 965 doses were administered and performed by 18 nurses. When wrong administration time errors were included, MAE rate was 28.4% whereas it decreased to 11.1% when wrong time errors were excluded. An interruption during the medication preparation phase (OR 1.596; 1.044 - 2.441) significantly increased the odds of MAE. Two significant interaction effects were found (patient demand for nursing care X overtime and patient demand for nursing care X professional experience). These interactions pointed to more negative effects of overtime and professional experience among nurses who rated the demand for nursing care as above average. Contrary to expectations, coordinative medication administration complexity significantly *decreased* the odds of MAE (OR 0.558; .322-.967). Including wrong administration time errors changed the cluster of predictors with component medication administration complexity (1.039; 1.016 - 1.062), and nurses' workload (1.221; 1.061 - 1.405) were significant predictors of MAE while controlling for education and time of administration. Results support the role of nurses' workload as a mediator in the relationship between work interruptions and MAE when wrong administration time errors were included in the analysis.

Conclusion: Based on the evidence gathered herein, work interruptions, demand for nursing care, overtime, and professional experience constitute significant factors to be considered to reduce medication administration errors. The potential protective effect of medication administration coordinative complexity protective effect against MAE also should be further explored.

Abrégé

Introduction: Les résultats probants relatifs aux facteurs prédictifs des erreurs d'administration des médicaments (EAM) sont peu nombreux et non-concluants.
Objectif: Examiner la complexité de l'administration (composante et coordination), les interruptions dans le processus d'administration des médicaments et la charge de travail infirmière subjective comme facteurs prédictifs des EAM.
Devis: Un devis corrélationnel prospectif.
Milieu: Une unité de médecine dans un centre hospitalier universitaire.
Échantillon: Un échantillon de convenance formé de 102 cycles d'administration des médicaments effectués par 18 infirmières avec un minimum de six mois d'expérience professionnelle.
Méthode: Les données ont été colligées par observation directe (EAM et interruptions), mesures auto-rapportées (charge de travail subjective, caractéristiques sociodémographiques) ainsi qu'avec l'échelle de la complexité de l'administration médicamenteuse (MAC coding scale).
Résultats: 102 observations ont été effectuées au cours desquelles 965 doses ont été administrées par 18 infirmières. En incluant les erreurs de temps d'administration, le taux d'EAM était de 28.4% et diminua à 11.1% lorsque les erreurs de temps d'administration étaient exclues. Une interruption lors de la préparation des médicaments (OR 1.596; 1.044 - 2.441) augmente significativement le risque d'EAM. Deux interactions significatives ont été trouvées (charge de travail X temps supplémentaire et charge de travail X expérience professionnelle). Ces interactions indiquent un effet plus négatif du temps supplémentaire et de l'expérience professionnelle parmi les infirmières ayant une charge de travail supérieure à la moyenne. La complexité de coordination de l'administration de médicament, contrairement aux attentes, diminue significativement les risques d'EAM (OR 0.558; .322-.967). L'inclusion des erreurs de temps d'administration produit un groupe différent de prédicteurs avec la complexité de composante (1.039; 1.016 - 1.062), et la charge de travail (1.221; 1.061 - 1.405) comme prédicteurs significatifs d'EAM en contrôlant pour l'éducation et le temps d'administration. De plus, les résultats appuient le rôle de la charge de travail comme médiateur de la relation entre

les interruptions et les EAM lorsque les erreurs de temps d'administration sont incluses dans l'analyse.

Conclusion: L'interruption d'une infirmière lors dans la préparation des médicaments, la charge de travail, le temps supplémentaire et l'expérience professionnelle constituent des facteurs importants à considérer pour prévenir les erreurs d'administration des médicaments. Les mécanismes par lesquels la complexité de coordination de l'administration de médicaments protège contre les EAM devraient être étudiés plus à fond.

Acknowledgments

First and foremost, I would like to thank Dr Loiselle and Dr Lavoie- Tremblay for having accepted to share this journey with me. Many lessons have been learnt from you over the years. Your scientific rigour, dedication, and guidance have had a profound influence on me which goes beyond the realm of academic. You taught me to focus on what is important without compromise but always with humanism. In that sense, you were much more than advisors, you were real mentors. Thank you.

This journey has also been blessed with the presence of exceptional dissertation committee members: Dr Sean Clarke, Patricia Lefebvre, and Linda Ward. Your constant guidance and constructive criticism helped me achieve a deeper understanding of key issues in patient safety research. If I only could accomplish a small fraction of your contribution to the profession and to our healthcare system, it would already be extraordinary.

This dissertation would not have been possible without the excellent collaboration of people from the McGill University Health Centre (MUHC). I am sincerely grateful to nurses who agreed to participate in the different phases of this dissertation and nursing leaders who believed in the project. Among the great nursing leaders of this institution, I wish to especially thank Sharon Mooney, Joan Legair, Marie Dias, Joan Robins, Marcia Ryan, and Ann Lynch.

The McGill University Health Centre has been an outstanding milieu for my research residency. A number of persons have contributed to make this residency an exceptional learning experience. Sincere appreciation to Dr Judith Ritchie for her wealth

of knowledge she so willingly shared, Madeleine Boulay-Bolduc for her passion, and Diem Vo for her enthusiasm in working collaboratively.

Many collaborators have contributed in different phases of this dissertation. Many thanks to Balbir Sandhu N. M.Sc. for her dedicated work with data collection. I felt confident that together we would succeed through this period. Intelligence, dedication, work ethic. Dr Ginette Pepper, Associate Dean for Research and PhD Programs University of Utah, who so readily accepted to share her methodological expertise. Francoise Picard with who was tested a computerized version of the observation grid. A number of statisticians have also made essential contribution: Louise Fortier, Dr James Hanley, and Dr Jose Correra.

Many colleagues in the doctoral program have been of invaluable support. Marie-Claire Richer, Marilyn Aita, and Sylvie Dubois. It is so much important to feel that someone understands all the concerns involved in pursuing doctoral education when others do not.

I am very grateful for the funding that supported my doctoral studies. The Centre Ferasi (Training and Expertise in Nursing Administration Research), Fond de recherche en santé du Québec (FRSQ), Ministère de l'Education et des Loisirs (MELS), the MUHC Research Institute (Molson and Barbara Tiffin Bourne awards).

Finally, to my family for which the nursing profession is essential. To my parents, who have always encouraged me to pursue my dreams. Nancy and Stéphane for your incredible support throughout the years. Both of you are great exemplars of the nursing contribution to our society. Laurence and Mathis, two wonderful sunshines, who bring so much joy. To my in-laws, who have played a pivotal influence in my professional career

without probably knowing it. Last but not least, my partner, Marco, for the many sacrifices he made and for the incredible support provided over this journey. This dissertation would have never been possible without you.

Preface

Thesis Format

According to the guidelines set forth by the Faculty of Graduate Studies and Research, McGill University, the candidate has the option to submit a dissertation composed of one or more manuscripts submitted or to be submitted for publication or the duplicate text of one or more published manuscripts in the dissertation. Such option was selected by the candidate. This dissertation contains four original manuscripts and found throughout the dissertation work.

The first chapter provides a general introduction to the dissertation along with the research objectives pursued. The second chapter presents the literature review and includes manuscript #1 of this dissertation entitled: “Work interruptions and their contribution to medication administration errors: An evidence review”. This second chapter concludes with a presentation of the study framework and the study objectives.

Chapter three pertains to the method employed to meet the dissertation study objectives. This dissertation study unfolded into two phases. The first phase was a pilot study, which has set the stage for the main study. The development and the evaluation of the psychometric properties of the Medication Administration Complexity (MAC) scale, reported in manuscript #2, was among the objectives pursued in this pilot study. Another objective of the pilot study was to ensure that the coding schemes of instruments used in the main study were optimal. The method used to meet this second objective of the pilot study is presented following manuscripts #2. The objectives of pilot study met, the main dissertation study which examined the predictors of medication administration errors

could be undertaken. The overview of the method employed in the main dissertation study concludes the chapter on the method.

Chapter four presents the findings through two distincts manuscripts to fully depict the evidence generated from this dissertation work. Manuscript #3 is entitled: "Medication Administration Complexity, Work Interruptions, and Nurses' Workload as Predictors of Medication Administration Errors". This manuscript presents evidence on the contribution of the main predictors to medication administration errors. Manuscript #4 entitled: "Characteristics of work interruptions during medication administration", is a finer grained analysis of work interruptions during medication administration. This analysis was undertaken to guide the selection of possible interventions to reduce the number of work interruptions experienced by nurses.

Chapter five provides an overall discussion and conclusion. The main research findings are highlighted and linked to current research evidence on predictors of medication administration errors. The potential implications of these findings for practice and research considering some of the inherent limitations are then identified.

Contribution of Authors

This dissertation is the original work of the candidate. Drs Loiselle and Lavoie-Tremblay, the candidate's advisors, are recognized for their constant conceptual and methodological support in the process of the dissertation. Together, the candidate, Dr Loiselle and Dr Lavoie-Tremblay made significant intellectual contribution to each manuscript included in this dissertation. Specifically, the candidate was involved in the conceptualization and design of the study, participant recruitment, data collection, data analysis, and interpretation and manuscripts preparation. Dr Loiselle and Dr Lavoie-

Tremblay contributed to the conceptualization, design, data interpretation, and critical review of manuscripts.

Original Contribution

This doctoral research contains a number of original clinical, theoretical, and methodological contributions. First and foremost, the evidence produced contributes to a better understanding of the potential underlying causes of medication administration errors (MAE) occurrences. A better understanding of these causes is a prerequisite to intervene efficiently to maximize medication administration safety in nursing. To achieve this better understanding, a theoretical framework is proposed to depict the predictors of MAE, which is a significant departure from previous studies that were mostly atheoretical (Hoff et al., 2004). The hypotheses stemming from the proposed theoretical model were tested through a micro-level approach moving away from traditional secondary data analysis and their inherent limitations found in research on medication administration errors. A new measure of medication administration complexity applicable to the context of medication administration also is proposed. This measure offers the opportunity to better understand how medication characteristics might contribute to the risk of medication administration errors.

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Chapter 1 Introduction

The incidence worldwide of medication administration errors (MAE) varies between 10.5 to 44.6% of all doses administered by nurses (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Greengold et al., 2003; Lisby, Nielsen, & Mainz, 2005; Schneider, Cotting, & Pannatier, 1998; Tissot et al., 2003; van den Bemt et al., 2002; van Gijssel-Wiersma, van den Bemt, & Walenbergh-van Veen, 2005). The proportion of these MAE with the potential to harm patients such as permanent disability and death is estimated at 7% (Barker, Flynn, Pepper, Bates, & Mikeal, 2002). The incidence of MAE and their consequences implies that significant gains in patient safety within healthcare organisations can only be achieved if the issue of MAE is tackled effectively.

Little evidence is currently available on the predictors of MAE to guide practitioners, administrators, and policy makers in their efforts to reduce the incidence of MAE. Most of the existing studies focus on the incidence of medication errors, their perceived causes, and reasons for reporting deficiencies (Dennison, 2005), but few have yet empirically examined the predictors. Primarily, these predictors are found to be embedded within the system rather than being solely related to individual nurses. Although individuals can make errors, the characteristics of a system makes them more likely. Moreover, interactions among these diverse characteristics create a potential for MAE to occur (Wilson, 2000).

Medication administration complexity (Nolan, 2000), work interruptions, and nurses' workload (Balas, Scott, & Rogers, 2004; Fry & Dacey, 2007; Stratton, Blegen, Pepper, & Vaughn, 2004; Tang, Sheu, Yu, Wei, & Chen, 2007) have been proposed as key predictors of MAE. Because attempts to examine these predictors are based almost

exclusively on secondary data analysis of administrative databases, this constitutes an important limitation (White & McGillis Hall, 2003). Administrative databases of incident reporting systems as a data source are described as unreliable, erratic, and therefore cannot qualify as a sound measure of MAE (Vincent, 2006). Systematic underreporting of MAE partially explains these observations (Flynn, Barker, Pepper, Bates, & Mikeal, 2002; Wakefield et al., 1999).

Direct observation of MAE, described as the method of choice for its reliability (Barker, Flynn, & Pepper, 2002), can overcome the aforementioned limitations. Direct observation also can provide data on work interruptions not available within these databases (Vincent, 2006). As for nurses' workload, a micro level approach to measurement has been proposed (Carayon & Gurses, 2005). This measurement is specific to a situation such as during the medication administration cycle, which corresponds to the period of time spanning when a nurse begins and ends the administration of all assigned patient medications due at specific times (Pape, 2003).

An additional limitation of prior studies is the absence of a theoretical basis for predicting MAE (White & McGillis Hall, 2003). Theoretical models depicting predictors are seldom found (Hoff, Jameson, Hannan, & Flink, 2004). This limitation is particularly important considering that both work interruptions (Speier, Vessey, & Valacich, 2003) and task complexity (Campbell, 1988) have been proposed as workload contributors. The predictive power of work interruptions and medication administration complexity could therefore be mediated by workload. This would be congruent with a system perspective (Wilson, 2000).

The examination of system-related predictors of MAE is at a crucial point (Perneger, 2006). A relative absence of evidence on predictors inhibits further

development of knowledge about the underlying causes of MAE. Until these causes are better understood, proposed interventions are at risk of being ineffective. Therefore, the study of medication administration complexity, work interruptions, and workload as predictors of MAE has the potential to expand the current knowledge base about underlying causes. The overall objective of this dissertation is to examine the predictive power of three potential contributing factors to MAE: work interruptions, medication administration complexity, and nurses' workload on a medical unit in a large university teaching hospital.

Chapter 2 Literature Review

The literature review first summarizes the evidence on the incidence and consequences of MAE. Next, the conceptual model guiding this dissertation is presented. This conceptual model is then used to organize the review of the literature of the main predictors of MAE under study. The review of the literature on the main predictors includes manuscript #1 of this dissertation entitled: "Work interruptions and their contribution to medication administration errors: An evidence review". The literature review concludes with a presentation of the study framework and objectives.

Medication administration errors: Definition, incidence, and consequences

Any attempt to evaluate the magnitude of a problem is pre-empted by knowing what to look for (Vincent, 2006). Medication safety research is characterized by a multiplicity of terms related to diverse aspects of the medication use process (Yu, Nation, & Dooley, 2005). Taxonomies have been offered in an attempt to promote consistency of use, but despite their existence, confusion prevails (Pronovost, Thompson, Holzmueller, Lubomski, & Morlock, 2005). A *medication error* is "the failure to complete a planned action as it was intended, or when an incorrect plan is used, at any point in the process of providing medications to patients" (Canadian Patient Safety Institute, 2003). This definition is based on James Reason's work (1990).

Reason (1990) also introduces the concept of violation of practice standards conceptually different from medication administration errors. These violation of practice standards can also adversely affect patients. *Violation of practice standards* are "the *deliberate* deviation in practices deemed necessary to maintain safe operation" (Reason,

1990, 2005). Violation of practice standards takes into consideration the fact that most humans do not plan and execute their actions in isolation, but within a regulated social context in which behaviour is governed by operating procedures, codes of practice, rules, and the like (Reason, 1990). Deliberately injecting an intravenous medication in three minutes instead of the recommended five-minute time frame, to save time, illustrates violation of practice standards. It is not considered a mistake because the nurse knows the correct practice but chooses not to follow it. Together, medication administration errors and violation of practice standards constitute the two dimensions of unsafe medication administration practices (UMAP) (Reason, 1990).

The presence of multiple definitions of MAE partially explains why a wide range of incidence rates are reported. The incidence of MAE based on direct observation, the most reliable data collection method (Barker, Flynn, Pepper et al., 2002), varies between 10.5% (van Gijssel-Wiersma, van den Bemt, & Walenbergh-van Veen, 2005) and 44.6% of all doses administered (van den Bemt et al., 2002). The majority of reported incidence rates is between 15 and 20 % (Barker, Flynn, Pepper et al., 2002; Bruce & Wong, 2001; Greengold et al., 2003; Schneider, Cotting, & Pannatier, 1998; Tissot et al., 2003). This means that approximately 1 in 5 medications administered by a nurse in a hospital falls below an agreed standard for safe medication administration.

The incidence of violation of practice standards in relation to medication administration practices has been less extensively studied although interest in growing (Carayon et al., 2007). Taxis and Barber (2003) report that 67% of all unsafe medication administration practices (UMAP) are violation of practice standards, with a faster than recommended injection of IV boluses as the most frequently observed violation. According to these authors, nurses are knowledgeable about the required procedure but

deliberately choose not to follow it for reasons not reported. This proportion of violation of practices standards is based on direct observation. Accordingly, these results should be interpreted with caution because distinguishing between errors and violations necessitates the determination of nurses' intentions, which are not easily observable (Vincent, 2006). Furthermore, these categories might not even be mutually exclusive, as both can be present in a sequence of events (Reason, 1990). Nevertheless, this distinction is conceptually important for analyzing predictors to understand the origins of MAE, and therefore, the associated solutions to their occurrences.

Incidence rates using the administrative incident reports found in health care organizations also have been reported. Incident reports are standard forms that contain basic clinical information and a brief narrative of the incident (Vincent, 2006). Incidence rates based on administrative incident reports are believed to be largely underestimated (Stetina, Groves, & Pafford, 2005). Direct observation yields incidence rates 300 times higher than incidence rates based on incident reports (Flynn, Barker, Pepper, Bates, & Mikeal, 2002). For this reason, direct observation is believed to represent the method of choice in studies of MAE. Moreover, direct observation gives access to data otherwise not available in incident reports, such as work interruptions (Zhan & Miller, 2003).

Barker and colleagues (2002) estimated that 7% of MAE may result in adverse drug events (ADE). An ADE has been defined as "an injury resulting from a medical intervention related to a drug" (Bates et al., 1995). The rate of ADEs in health care organizations varies between 6.6 to 35.9 per 1000 patient-days (one patient day = one patient using one hospital bed for 24 hours) (Baker et al., 2004; Blais, Tamblyn, Bartlett, Tré, & St-Germain, 2004; Classen, Pestotnik, Evans, & Burke, 1991; Hardmeier et al., 2004; Kaushal et al., 2001; Neale, Woloshynowych, & Vincent, 2001), although Nebeker

et al. (2005) found an incidence rate of 70 ADEs per 1000 patient-days, twice the rate compared to that found by other researchers. According to Nebeker et al. (2005), the highly computerized environment within which their study was performed— facilitated the identification of ADE through the use of triggers like specific lab results.

Studies on ADEs usually exclude emotional consequences associated to MAE (Vincent, 2006). Feelings of anger, frustration, belittlement, and lost of relationship and trust toward clinicians are often experienced by patients and their families following MAE (Kuzel et al., 2004). Dealing with the emotional aftermaths of MAE has been identified as a fundamental need by patients and their families (Duclos et al., 2005). This need for emotional support expressed by patients and families victim of medication errors has often been, however, neglected (Crigger, 2005). Moreover, the long-term emotional consequences of MAE for patients and their families, on the other hand, are mostly unknown but undeniably present (Vincent, 2006). These consequences are preventable and justify the need for further research on predictors of MAE.

MAE-related injuries have not only consequences for patients and their families but for health care organizations as well. Adverse drug events, compared to other adverse events, are among the most costly to healthcare organisations (Hoonhout et al., 2009). These direct costs have been estimated at 5 857 $ US per ADE (Classen, Pestotnik, Evans, Lloyd, & Burke, 1997). In France, 6.6% of admissions to intensive care units are judged to be related to ADE, which partly explains the observed added cost (Darchy, Le Miere, Figueredo, Bavoux, & Domart, 1999).

The consequences of MAE underscore the importance of addressing the issue. Part of the process towards resolution may reside in a better understanding of predictors of MAE, which would allow the development of effective MAE reduction interventions.

The next section presents the UMAP System Model used in this dissertation to organize the current evidence on predictors of MAE.

Unsafe Medication Administration Practice System Model

Theoretical propositions that support the various factors related to MAE are rarely found, although a number of conceptual models have been proposed for safe or quality patient care (Affonso, Jeffs, Doran, & Ferguson-Pare, 2003; Donabedian & Bashshur, 2003; Mitchell, Ferketich, & Jennings, 1998; O'Brien-Pallas et al., 2004) However, these models—with the exception of Reason's Human Error Model—do not specifically address errors and violation occurrences within organizations (Reason, 1990, 2000, 2001, 2005). The Human Error Model was first adopted by high reliability industries such as the aviation or nuclear power plants that generally have fewer accidents. Healthcare and nursing interest in the Human Error model mostly developed within the past decade (Page, 2004) in an effort to better understand errors and violation occurrences within health care organizations.

Reason's work triggered a paradigm shift in the study of errors moving from a "person model" to a system perspective to accident and incident causation. In the person model, errors are explained by personal characteristics of professionals and, if properly trained, no errors should occur (Crigger, 2005). The basic premise of the system approach is that humans are fallible and errors are bound to happen. Within this perspective, a system is "a set of interdependent elements, both human and non-human (equipment, technologies, etc.), interacting to achieve a common aim" (Reason, 1990). Moreover, although individuals can make errors, characteristics of a system make them more likely to do so. Further, the system approach takes the position that although individuals must be

responsible for the quality of their work, more MAE can be eliminated by focusing on the system rather than on individuals. Consequently, if the system approach is correct, one of the first steps in a MAE reduction program is the identification of system-related predictors of MAE.

Reason's model of errors and violation occurrences was adapted (Figure 1) by using a terminology specific to the context of MAE, so to allow for a deeper understanding of MAE. The model starts with managerial decisions which generate two kinds of effects: error and violation producing conditions within the local workplace, and longstanding "holes" or weaknesses in the defence barriers. Error and violation producing conditions are the most immediate predictors of MAE are found. As such, any attempts to study predictors of MAE should target these error- and violation-producing conditions.

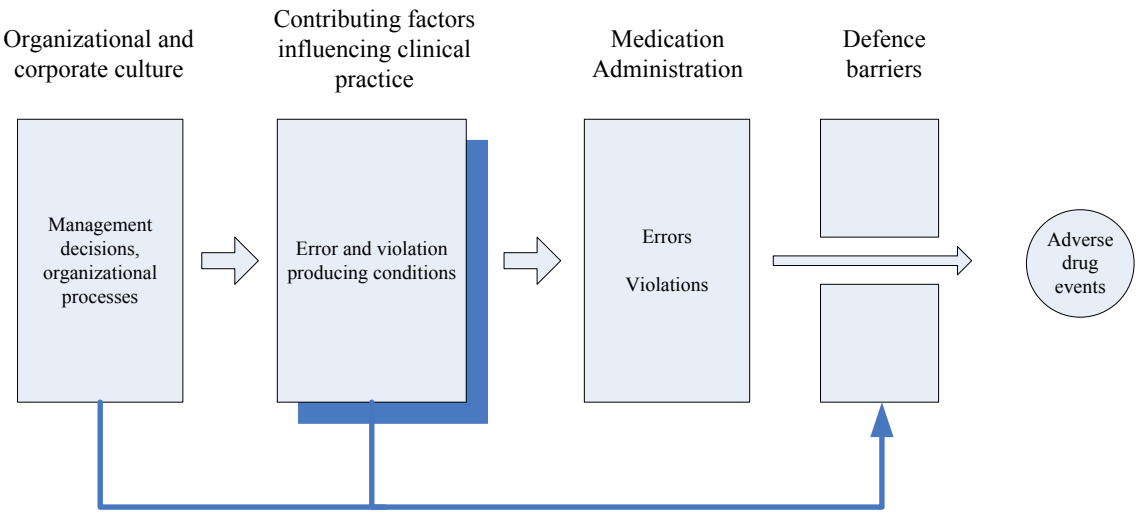

Figure 1: Unsafe Medication Administration Practices System Model.
Note. Adapted from Reason (2001). Understanding adverse events: The human error factor. In C. Vincent (Ed.), *Clinical risk management: Enhancing patient safety*. (2nd ed.). London, UK: BMJ Publishing Group. Adapted with permission.

Unsafe medication administration practices are made of medication administration errors and violations of practices standards. Reason (1990) further subdivides errors into

two categories: slips/lapses and mistakes. *Slips* and *lapses* are "failures in the process of executing and / or storage of an action sequence, regardless of whether or not the plan which guided them was adequate to achieve its objective" (Reason, 1990, p. 9). The nurse has an adequate plan, but her actions do not proceed as intended. *Mistakes*, on the other hand, are "failures in the judgmental and / or inferential process involved in the selection of an objective or in the specification of the means to achieve it" (Reason, 1990, p. 9). For instance, a wrong dose calculation is considered a mistake. Whether or not these errors and violations result in an adverse drug event depends partially on the effectiveness of the implemented defence barriers.

These defence barriers can take many forms: some are engineered (alarms, physical barriers, automatic shutdowns, etc.), others rely on people (nurses, pharmacists, control room operators), and yet others depend on procedures and administrative controls (Reason, 1990). An example is the double-check recommended for the administration of insulin. A nurse may prepare the wrong dosage, but the error would be intercepted by another nurse through a double-checking procedure prior to its administration. Studies on defence barriers mostly focus on technology such as bar-code assisted medication administration (Cummings, Bush, Smith, & Matuszewski, 2005), computerized physician order entry (CPOE) (Handler et al., 2004), and smart pumps which prevent entering an administration rate beyond a specific range (Larsen, Parker, Cash, O'Connell, & Grant, 2005). Defence barriers do not prevent errors and violations from occurring, but they prevent development into adverse drug events by intercepting errors and violations before reaching the patient.

The efficacy of defence barriers in preventing MAE is influenced by the organizational culture (Reason, 2001) and also, but not depicted in the initial model, the errors and violation-producing conditions. For example, in situation of high workload, an error and violation-producing condition, nurses have developed workaround strategies to bypass the bar code medication administration technology implemented (that ascertains the identity of patients and prevent medications to be administered to the wrong patient) (Patterson, Rogers, Chapman, & Render, 2006). Consequently, error and violation producing conditions are essential to consider for ensuring optimal functioning of defence barriers.

The study of defence barriers brings to the forefront one of the limitations of the model, the implied linearity. Defence barriers are depicted as distinct from errors and violation producing conditions. Inefficient defence barriers can create potential for error and violation of practice standards to occur such as for engineered alerts. Inefficient alerts have low specificity and sensitivity requiring the clinician to constantly override them which, in itself, results in workflow disruptions with increased risk of MAE (van der Sijs, Aarts, Vulto, & Berg, 2006). Despite certain limitations, the model, through its focus on the system, brings a necessary shift in the studies of MAE in which defence barriers play an important role, but it might even be more important to prevent these MAE from occurring in the first place. Such a perspective requires an understanding of the significant predictors of MAE.

Predictors of MAE

According to the UMAP System Model, the most immediate predictors of MAE are to be found in error and violation producing conditions. Medication administration

complexity, work interruptions, and nurses' workload have been identified as representative of these error and violation producing conditions, and as potential key predictors of MAE. First, the literature review addresses them, followed by a review of the potential control variables to be considered. The overall objective is to specify the important gaps in current knowledge about predictors of MAE and to identify how research can address these gaps.

Medication Administration Complexity

Medication administration complexity, based on Campbell's definition of task complexity (Campbell, 1988), refers to intrinsic characteristics of medication that place high cognitive demands on nurses for its administration. These demands result from the nature of the task to be performed and not from the individual performing the task (Campbell & Gingrich, 1986). Therefore, *medication administration complexity* is conceptualized as "a function of objective task characteristics as opposed to being conceptualized as primarily a psychological experience" (Campbell, 1988) or an interaction between medication characteristics and person characteristics. The selection of a conceptualization of complexity as an objective task characteristic is adopted because it has been reported to be a stronger predictor of task performance (Chinburapa et al., 1993).

According to Wood (1986), medication administration complexity includes three dimensions: component, coordinative, and dynamic. Component complexity is a direct function of the number of required acts that need to be executed and the number of information cues processed to perform a given task (Wood, 1986). The required acts correspond to the different steps when administrating medications such as mixing the

medication and assembling the syringe. The number of required acts depends on a number of factors such as whether the medication is premixed or if it is a controlled substance. These required acts are based on information cues. The information cues used by the nurse originate from the patient (e.g. glucose level) as well as from patients' charts. The five "rights" (right patient, right medication, right dose, right time, right route) are the fundamental information cues used by the nurse to administer the medication.

The coordinative dimension refers to the nature of the relationship between task inputs and task products and particularly the sequencing of inputs (Wood, 1986). Certain required acts and information cues have to be processed in a given order bringing in the notion of coordination. A nurse who has to administer analgesics, needs to first assess the patient's pain level before she can move on with the administration. The coordinative complexity is intrinsically linked to the third and last dimension (i.e., the dynamic dimension). According to Wood (1986), total medication administration complexity is a function of component and coordination. However, each dimension of complexity does not contribute equally to total medication administration complexity: the coordinative dimension contributes to a greater extend than the component dimension. Further, greater complexity has been postulated to negatively affect task performance (Wickens & Hollands, 2000).

This concept of medication administration complexity has seldom been used to predict MAE, although a number of studies have attempted to document the predictive power of diverse medication characteristics—such the number of medications contained in a regimen, its form, and the number of steps—without any explicit conceptual underpinnings. The number of medications or doses was found to be a significant

predictor of MAE in some studies (Kopp, Erstad, Allen, Theodorou, & Priestley, 2006), but not in others (Han, Coombes, & Green, 2005; Prot et al., 2005; van den Bemt et al., 2002). The number of medications usually considered involves the number of medications prescribed to be administered within a 24-hour period (Prot et al., 2005). Usually, nurses have more than one patient, and only certain medications among those prescribed are administered for each medication administration cycle. Consequently, the number of medications to be administered at each medication administration cycle might be more pertinent for determining how medication administration complexity may predict MAE.

The form of medication is an additional medication characteristic that has been examined. The intravenous form seems to have the highest frequency of MAE (Kaushal et al., 2001) but two additional studies did not document such finding (Tissot et al., 2003; van den Bemt et al., 2002). If the number of steps required for medication administration rather than the form is the more important predictor, this may explain, in part, these mixed results. Usually, IV forms require more steps for medication administration, but some are prepared already, which decreases the complexity hence, these observed results. The latter hypothesis is supported by the findings of Taxis and Barber (2004) who collected data on the number of steps required to administer IV medication. In both studies, IV medications ready to be administered contained no error or violation occurrences, which was not the case for those medications requiring one or multiple steps (Taxis & Barber, 2003b, 2004). These findings support Wood's (1986) argument that the form has little to do with complexity; rather, complexity is influenced by the number of

steps to be accomplished and the number of information cues to be processed for the administration of medications.

Evidence concerning the coordinative dimension of complexity as a predictor of MAE is found in the literature that addresses medication classes. Medication classes are groups of medications that are characterized according to the organ or system on which they act and/or their therapeutic and chemical characteristics (World Health Organization Collaborating Center for Drug Statistics Methodology, 2006). In a review of studies, Kanjanarat et al. (2003) report that the following medication classes increase the risk of preventable adverse events: cardiovascular, central nervous, analgesics, and anticoagulants. Certain medications within these classes, such as warfarin, require adjustment of the dose prior to each administration. The complexity associated with adjusting medication might explain the increased frequency of errors for these medication classes. The possibility of this dimension of complexity predicting MAE is supported further by the Institute for Safe Medication Practices list of High Alert Medication (Institute for Safe Medication Practices, 2008), which does not only cite warfarin but also insulin as a medication often requiring dose adjustment prior to each administration. This list was created to focus attention of practitioners on certain medications and is based on surveys of experts and incidents reports; moreover, it is supported by a number of published case reports of MAE involving these two medications (Bates, 2002; Caudill-Slosberg & Weeks, 2005).

To move the development of evidence of medication characteristics beyond the consideration of their individual effects, a reliable and valid measure of medication administration complexity is required. A number of measures developed in the context of

patient adherence studies exists (Conn, Taylor, & Kelley, 1991; DiIorio et al., 2003; George, Phun, Bailey, Kong, & Stewart, 2004). However, these measures do not capture the full concept of medication administration complexity based on Wood's (1986) work on task complexity. A unidimensional subjective measure of task complexity also has been proposed (Maynard & Hakel, 1997), but complexity measures based on objective characteristics have been found to be stronger when compared to subjective measures (Chinburapa et al., 1993) and should be preferred.

In summary, medication administration complexity has seldom been considered empirically as a predictor of MAE, although attempts have been made to find medication characteristics that may predict MAE. In part, this limitation is the result of an absence of a valid measure of medication administration complexity that reflects a comprehensive conceptual definition. The development of such a measure, and subsequently the assessment of its predictive power in relation to MAE, is required to better understand predictors of MAE.

The review of evidence on predictors of MAE continues with the presentation of manuscript #1 in this dissertation. The manuscript presents an evidence-based literature review on work interruptions in nursing and their contribution to MAE. Following the presentation of manuscript #1, the literature review continues where evidence on the third main predictors examined in this dissertation, nurses' workload, is reviewed.

Manuscript #1: Work interruptions and their contribution to medication administration errors: an evidence review

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Accepted for publication in Worldviews on Evidence-based Nursing (Appendix A)

Preface

Manuscript #1 of this dissertation presents an evidence literature review on work interruptions in nursing and their contribution to medication administration errors. Work interruptions are one of the main predictors examined in this dissertation along with medication administration complexity previously reviewed and nurses' workload which follows this first manuscript. Last, the literature review concludes with a presentation a presentation of the study framework and objectives.

Abstract

Background: In many surveys, nurses cite work interruptions as a significant contributor to medication administration errors. **Objectives**: To review the evidence on (1) Nurses' interruption rates, (2) Characteristics of such work interruptions, and (3) Contribution of work interruptions to medication administration errors. **Search strategy**: CINHAL (1982-2008), MEDLINE (1980-2008), EMBASE (1980-2008), and PSYCINFO (1980-2008) were searched using a combination of keywords and reference lists. **Selection criteria**: Original studies published in English using nurse as participants and for which work interruptions frequencies are reported. **Data collection and analysis**: Studies were identified and selected by two reviewers. Once selected, a single reviewer extracted data and assessed quality based on established criteria. Data on nurses' work interruptions rate were synthesised to produce a pooled estimate. **Main results**: Twenty-three studies were considered for analysis. A rate of 6.7 work interruptions per hour was obtained by pooling data from 14 studies that reported both an observation time and work interruption frequency. Work interruptions were found to be primarily initiated by nurses themselves and other members of the nursing staff. They were characterized by face-to-face interactions of short duration. A lower proportion of interruptions resulted from work system failures such as missing medication. One nonexperimental study documented the contribution of work interruptions to medication administration errors with evidence of a significant association ($p = .01$) when errors related to time of administration are excluded from the analysis. Conceptual shortcomings were noted in the majority of reviewed studies, these included the absence of theoretical underpinnings and a diversity of definitions of work interruptions. **Conclusion**: Future studies should demonstrate improved methodological rigour through a precise definition of work interruptions and

reliability reporting to document work interruptions characteristics and their potential contribution to medication administration errors considering the limited evidence found. Meanwhile, efforts should be made to reduce the number of work interruptions experienced by nurses.

Background

The worldwide incidence of medication administration errors varies between 6.6 to 44.6% for all doses administered by nurses (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Greengold et al., 2003; Lisby, Nielsen, & Mainz, 2005; Tissot et al., 1999; van den Bemt et al., 2002). The proportion of these errors with the potential to harm patients, such as permanent disability and death, is estimated at 7% (Flynn et al., 2002). The importance of addressing this problem is recognized internationally (Kohn, Corrigan, Donaldson, & Institute of Medicine (U.S.). Committee on Quality of Health Care in America., 2000; Nicklin et al., 2004; World Health Organization, 2004)

Medication errors are found at every stage of the medication use process with a third of medication errors harming patients being associated to the medication administration stage (Leape et al., 1995). The medication administration stage differentiates itself from other stages from a medication safety perspective for two reasons. Nurses act as safeguards against errors intercepting up to 86 percent of all errors made by physicians, pharmacists, and others involved in providing medications for patients (Leape et al., 1995). At the same time, medication administration has very few safeguards against errors because it is located at the end of the medication use process (Aspden, 2007). For these reasons, improvements to the medication administration process could tremendously maximize medication use safety within healthcare organizations.

Medication errors have been defined as "the failure to complete a planned action as it was intended, or when an incorrect plan is used, at any point in the process of providing medications to patients" (Canadian Patient Safety Institute, 2003, p. 31). Medication administration errors have been divided into a number of categories such as

wrong time, unauthorized drug, extra dose, wrong dose, omission, wrong route, and wrong form (Flynn et al., 2002). Wrong time medication administration errors are the most frequent comprising 42.8% of all medication administration errors followed by omission with 30.2% (Barker, Flynn, Pepper et al., 2002). However, wrong time errors are often considered clinically unimportant although this perspective has been debated (Kopp et al., 2006). This incertitude about the clinical significance of wrong time errors explains why, at times, researchers studying contributing factors to medication administration errors are performing their analysis with and without the wrong time administration error category.

Studies on contributing factors promote an enhanced understanding of the underlying causes of medication administration errors. Such contribution is urgently needed to assist in the development of effective prevention strategies (Vincent, 2006). In line with this goal, James Reason's work (Reason, 1990) has played a pivotal role in shifting from a person-centred to a system perspective on potential contributing factors to medication errors (Page, 2004). A system approach posits that, although individuals are responsible for the quality of their work, more medication administration errors can be avoided by focusing on the system rather than solely on individuals. Consequently, if the system approach is correct, one of the first steps in a medication administration error reduction program is to systematically document system-related contributors to such errors.

When nurses are surveyed, work interruptions appear among the most prominent of the system-related factors (Armutlu, Foley, Surette, Belzile, & Jane, 2008; Balas, Scott, & Rogers, 2004; Cohen, Robinson, & Mandrack, 2003; Stratton, Blegen, Pepper, &

Vaughn, 2004). Work interruptions entail a halt of the activity being performed for monitoring purposes or to carry out a secondary task (Hopp, Smith, Clegg, & Heggestad, 2005). Distractions, on the other hand, are detected by a different sensory channel from those of the primary task, and may be ignored or processed concurrently with the primary task; this is not the case for work interruptions (Speier et al., 2003). However, both concepts are related. Distractions are the necessarily precursor of work interruptions (McFarlane & Latorella, 2002).

A number of hypotheses have been formulated to explain how work interruptions might results into human errors. The mechanisms underlying this contribution could depend of the task performance level (Reason, 1990). Three levels of task performance have been proposed: skill-based, rule-based, or knowledge-based (Rasmussen, 1986). Skill-based performance is mostly automatic as is found in routine actions. These routine actions require dispersed attentional checks to ensure proper task completion. Work interruptions during skill-based performance may interfere with these required attentional checks and lead to slips and lapses (Reason, 1990). At the other end of the spectrum, knowledge-base task performance, nurses must rely on conscious analytical processes and stored knowledge to solve problem. At this level of performance, work interruptions add to the amount of information being processed, and if the demands for cognitive resources are higher than those available, task performance is negatively be affected (Wickens & Hollands, 2000).

Interventions addressing the frequency of work interruptions in the interests of maximizing medication administration safety certainly represent a promising avenue considering work interruptions could lead to human errors (Potter et al., 2005). However,

before intervening, any evidence on the frequency, characteristics, and potential contribution of interruptions to medication administration errors—evidence that goes beyond the data obtained in the surveys—should be described and assessed systematically. A thorough review of the evidence is essential to ensuring that future actions by clinicians, administrators, policy-makers and researchers are informed by the best available information.

Objective

To review the evidence on the rates, characteristics and potential contribution of work interruptions to medication administration errors.

Method

This literature review is based on a systematic approach at every step that includes identification of the studies, their selection, critical appraisal, and data synthesis.

Study identification

Four databases were searched for relevant literature on work interruptions (Table 1). The search strategy used a combination of keywords and Medical Subject Headings (MeSH) terms (Table 2). The MeSH terms were slightly adapted to each database to reflect their specificities. Keywords were necessary, since work interruptions are not currently indexed. 'Distraction' was also employed as a related term. The search strategy involved combining interruptions and nursing care, interruptions and medication administration process related terms. The final step of the search strategy involved limiting the results to English language. Identified references in each database were then imported into Endnote® X1 to remove possible duplicates. The reference lists of articles meeting inclusion and exclusion criteria were also searched for relevant references.

Table 1 Yield from each database searched

Databases	Coverage	Yield
Embase Ovid	1980-2008 week 6	154
Medline Ovid	1980-2008 week 6	138
Psychinfo Ovid	1980-2008 week 6	33
CINHAL Ebsco	1980-2008 week 6	90
Total yield		415
All references imported to Endnote® XI. Duplicates removed.		380

Table 2 Medline search strategy

Concepts	**Search category**	**Search terms**
Work Interruption	MeSH	Nil
	Keywords	Distraction$[1], Interrupt$
Nursing care	MeSH	Task performance and analysis, nursing care, decision making, nursing process, system analysis, time and motion studies
	Keywords	Nil
Medication Administration process	MeSH	Medication systems, medication errors, safety management
	Keywords	Medication$ adj5 administrat$, drug$ adj5 administrat$,
Nurses	MeSH	Nursing staff exp, health personnel, nurses, personnel, hospital.
	Keywords	Nurs$, personnel$

[1]$ = truncation function

Study selection

The inclusion criteria were based on study design, participants, variables reported, and year of publication. Accordingly, published original studies that included nurse participants, reported work interruptions frequencies, and were published in English between 1980 and 2008 were selected for this review. Conference proceedings were excluded. The study selection was performed by two reviewers in a three-step process (primary author AB and a master prepared research assistant) (Higgins & Green, 2008). Titles and abstracts were first reviewed to identify potential studies for inclusion. The complete article was then reviewed to ensure that inclusion and exclusion criteria were met. The third step involved the identification of studies from reference lists of studies included for analysis (Figure 2).

Data extraction and appraisal

A standard data extraction form was developed by the primary author and used to extract data from relevant studies. The following data were extracted from included studies: author, location, objective, design, sample size and characteristics, sampling method, variables measured, theoretical background, data sources, reliability, validity, interruption definition, statistical analysis performed, findings, strength, and weaknesses. Data extracted, when possible, were specific to nursing and appraisal criteria were based on the *Cochrane Effective Practice and Organisation of Care Review Group Data Collection* (2002) for experimental studies, on the Agency for Hospital Research and Quality (AHRQ) criteria for observational research (2002), and Mays and Pope (2000) for qualitative research. Data were extracted by a single reviewer (AB).

Data synthesis

A pooled estimate of nurses' work interruption rate was calculated by using nurse-specific data from studies reporting both work interruption frequency and length of observation. Further, each study needed to meet a number of quality criteria to be part of this data synthesis. Only data from studies measuring multiple sources of work interruptions using minimally direct observation were used. These quality criteria ensured maximum homogeneity of the studies from which data synthesis was performed.

Results

The search strategy yielded 415 records. After importation into Endnote® X1, 35 duplicates were removed, leaving 380 records (Table 1). Titles and abstracts reviewed for inclusion and exclusion criteria led to 46 retrieved articles. The main reasons for exclusion based on reviewed titles and abstracts are described in Table 3. The full text of the retrieved articles was reviewed to ascertain inclusion and exclusion criteria, resulting in 20 included articles. Another five were identified from reference lists; three of these five were included, for a total of 23 articles to be critically analyzed (Figure 2). The main reason for exclusion among retrieved articles was the non-reporting of work interruptions frequencies (Table 4). The use of the truncated keywords **interrupt*** and **distraction*** resulted in the identification of interrupted time series studies and of studies on nurses' use of distraction as a pain management strategy. The other category (n=3) consists of methodological articles whose results appear in studies already included in the review.

Table 3 Reasons for exclusion based on titles and abstracts

Reasons	n	%
Not original research	83	24.9
Nurses not participants	140	41.9
Distraction as an intervention	23	6.9
Distraction or interruptions not reported	56	16.8
Surveys	15	4.5
Conference proceedings	7	2.1
Duplicate not identified by Endnote® XI	9	2.7
Not published in English	1	0.3
Total	334	100

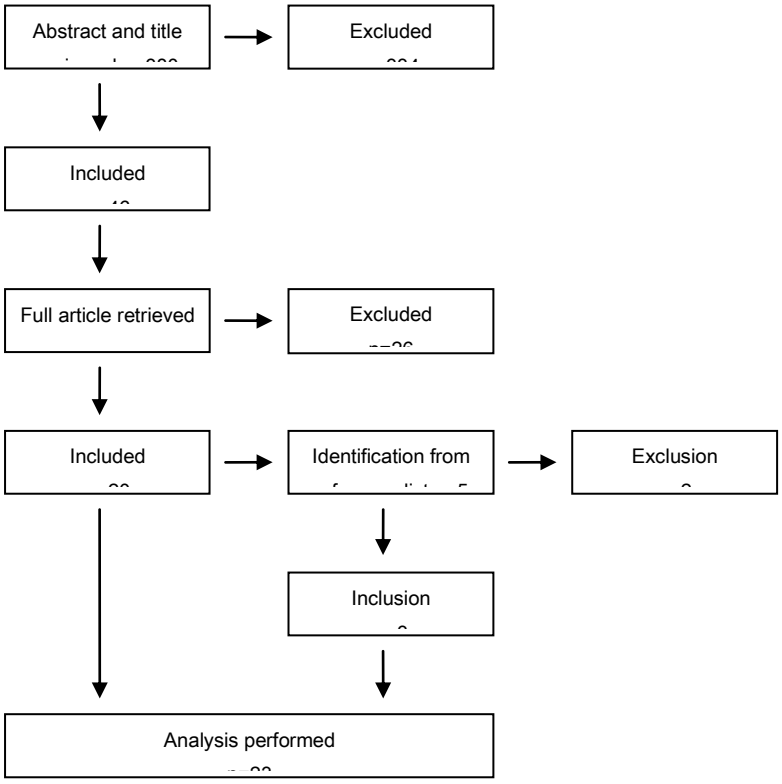

Figure 2 Yield from the search and selection strategy

Table 4 Reasons for exclusion among full retrieved articles

Reasons	n	%
Not original research	2	7.1
Distraction or interruptions not reported	17	60.7
Nurses not participants	4	14.3
Conference proceedings	2	7.1
Other (e.g. methodological)	3	10.7
Total	28	100

Study Characteristics

Approximately half of the 23 studies included (n=12) had been published in the past three years. The majority (n=10) had originated in the United States, followed by the United-Kingdom (n=7) and Australia (n=4). The studies were typically performed within hospital settings (n=21) and on different speciality units simultaneously (n=7). In this field of research, nonexperimental design predominated (n=14); quasi-experimental (n=3); mixed method (n=3); qualitative (n=2); and pre-experimental (n=1) designs were comparatively less present. Two of the experimental studies specifically targeted 'distraction' among nurses during medication administration (Pape, 2003; Pape et al., 2005). The first of the remaining two experimental studies documented the impact of a communication intervention designed to meet family information needs in the intensive care unit on the number of incoming calls interrupting nurses' work (Medland & Ferrans, 1998); the second, a change in surgical technology which required less unplanned and unscheduled interventions from operating room nurses (Luketich et al., 2002). Table 5 provides a summary of the main characteristics and findings of reviewed articles.

Table 5 Characteristics and Key Findings of Reviewed Studies

Authors **Country**	**Setting**	**Objective**	**Design**	**RN Sample** **Data Collection**	**Key Findings**
Alvarez & Coiera (2005) Australia	ICU[1]	An exploratory study to examine interruptive communication patterns of healthcare staff within an intensive care unit (ICU) during ward rounds.	Nonexperiemental	3 RN Direct structured observation and audio-recording	**Rate**: 145 WI[2] / 8h 40min = 16.7 WI / hr
Bennett et al. (2006) Canada	Inpatient	To compare a traditional unit dose medication cart system to a system using a locked medication cupboard in each patient's room.	Preexperimental	Not reported Direct structured observation	**Rate**: 14 WI / 63 min = 13.3 WI / hr
Coiera et al. (2002) Australia	ED[3]	To measure communication loads on clinical staff in an acute clinical setting, and to describe the pattern of informal and formal communication events.	Nonexperimental	6 RN Direct structured observation and audio-recording	**Rate**: 185 WI / 16h 37min = 11.1 WI / hr
Coiera and Tombs (1998) UK	NA	An exploratory study to identify patterns of communication behaviour among hospital based healthcare workers.	Nonexperimental	2 RN Direct structured observation and audio-recording	**Rate**: 8 WI / 5h 32min = 1.4 WI / hr (pages and telephone calls only)
Ebright et al. (2003) USA	Mixed[4]	To increase understanding of RN work complexity in an acute care setting using a human performance framework.	Mixed	8 RN Direct structured observation	**Rate**: 152 WI / 48 hrs = 3.2 interruptions / hr

[1] ICU : Intensive Care Unit
[2] WI : Work interruptions
[3] Emergency Department

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Fairbanks,. Bisantz,. & Sunm (2007) USA	ED	To characterize and describe the communication links and patterns between and within emergency department (ED) practitioner types.	Nonexperiemental	4 RN Direct structured observation and audio-recording	**Rate**: Bedside nurses: 2 WI / 4h 12min = 0.5 WI / hr Charge nurses: 15 WI / 4h 13min = 3.6 WI / hr
Hedberg & Larsson (2004) Sweden	Mixed	To explore environmental elements related to the decision-making process in nursing practice.	Qualitative	6 RN Direct unstructured observation	**Rate**: 85 WI / 30 hrs = 2.8 WI / hr **Source**: Nursing assistant: 27% Family: 25% **Primary activity**: Medication administration 29%
Luketich, Fernando, & Buenaventura (2002) USA	OR	To assess the impact of voice recognition technology during a surgical procedure on operating room efficiency and user satisfaction.	Quasiexperimental	Not reported 30 OR cases observed Direct structured observation	**Results**: Average WI to adjust surgical with and without new technology: Control: 15.3 WI per OR case Intervention: 0.33 per OR case Statistically different
Lyons, Brown, & Wears (2007) UK	ED	To objectively evaluate the organisation of triage and what issues may affect the effectiveness of the process.	Nonexperimental	15 RN Direct structured observation	**Rate**: 160 WI / 1870 min = 5.1 WI / hr **Sources**: Patient / family Local staff Interrupted by phone

[4] Mixed : Involves at least two different type of nursing units

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Manias, Botti, & Bucknall (2002) Australia	Surgical	To investigate the effectiveness of the observation method in exploring nurse–patient interactions for pain assessment and management in hospitalized postsurgical patients, and to identify barriers that surround nursing pain management decisions.	Qualitative	12 RN Direct unstructured observation	**Rate**: 247 WI / 24 hrs = 10.3 WI / hr **Sources:** Seeking items Assisting nurses with procedures Answering telephone calls Interrupting or being interrupted by others
McLean (2006) UK	Medical	To try reduce medication errors through a three-phased approach: 1. Reduce interruptions to the round 2. Introduce a system of double-checking 3. Introduce an additional level of drug expertise than may normally be found on a busy medical ward.	Nonexperimental	RN sample not reported Direct structured observation	**Rate**: 99 WI / 1261 min = 4.7 WI / hr
Medland & Estwing Ferrans (1998) USA	ICU	To test a structured communication program for family members to determine whether the program would … decrease disruption for the ICU nursing staff caused by incoming telephone calls from patient's family members.	Quasiexperimental	30 family members (15 per group) Self-report	**Source:** Single interruption source: incoming phone calls Control group: 3.26 phone calls per day Intervention group: 0.33 phone calls per day Difference statistically significant t (14)=5.88, p= <.0001

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Pape (2003) USA	Med-surg	To measure the effect of two targeted interventions based on airline industry measure for decreasing nurses' distraction during medication administration.	Quasiexperimental	24 RN Direct structured observation	**Rate**: Control group: 60,5 distraction per MAC[5] Focused protocol: 22.5 distractions / MAC Focused protocol + vest: 8 (SD= 4.5) / MAC Significant difference among experimental groups $F(2, 23)=68.229$ $p= <.0001$ **Source of interruptions for control group:** MD 2.9% Other person 31.8% Phone cal1 3.8% Other patient 4.8% Visitor 2.9% Missing medication 3.9% Wrong dose medication 0.0% Emergency situation 1.0% External talking 32.0% Loud noise 6.2%
Pape et al. (2005) USA	Mixed	To measure the effect of an intervention to reduce nurses' distraction.	Preexperimental	20 RN Self-report measure developed by author	Less perceived distractions post intervention ($t = -14.33$, $df = 19$, $p= <.0001$).
Paxton et al. (1996), UK	Primary care	Compare rate and perception of interruptions experienced by practice nurses before and after change in physician practice.	Nonexperimental	34 RN Self-report	**Rate =** Phone:15,7 WI / 100 consultations Person: 32,7 WI / 100 consultations

[5] MAC : Medication Administration Cycle.

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Potter et al. (2005) USA	Mixed	To analyze the nature of nurses' cognitive work and how environmental factors create disruptions that pose risks for medical errors.	Mixed	7 RN Direct structured observation	**Rate**: Human Factor definition: 261WI / 43 hrs = 6.1 WI / hr Nurse researcher definition: 151 WI/ 43 hrs = 3.5 WI / hr **Location**: Medication room: 22%.
Scott-Cawiezell et al. (2007) USA	Nursing home	To determine the impact of various levels of credentialing among nursing home staff who deliver medications (RN, LPN, or CMT/A[6]) on medication error.	Nonexperiemental	8 RN 12 LPN Direct structured observation	**RN medication administration error rate:** With wrong time errors: 34.6% Without wrong time: 7.4% **Distraction rate:** 2200 distractions / 4803 minutes = 27.5 distractions / hr[7] **Association between WI and MAE:** Increased interruptions are associated with increased medication error rates when wrong time errors are excluded (p □□.0348).

[6] CMT/A : Certified Medication Technician / Aides
[7] Sample constituted of RN, LPN, and CMT/A

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Sevdalis et al. (2007) UK	OR	To describe the content, initiators and recipients of communications that intrude or interfere with individual surgical cases. Development of a distraction intensity scale.	Nonexperiemental	RN sample not reported. Event sampling: 48 general surgical procedures. Direct structured observation	**Secondary task:** **Results not specific to nurses** Irrelevant conversation by team staff Irrelevant conversation by external staff Next patient Other patient/list Teaching Equipment/provisions Irrelevant conversation by attending staff Phone calls/bleeps Previous patient Unclear **Intensity of distraction:** Case irrelevant communications (CIC) related to equipment and provisions are more distracting than irrelevant comments/queries ($p < 0.01$), more distracting than patient-related CICs ($p < 0.05$), and, more distracting than teaching ($P<0.01$).

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Spencer, Coiera, & Logan (2003) Australia	ED	To determine whether there are differences in role-related communication patterns in the ED.	Nonexperimental	4 RN Direct structured observation and audio-recording	**Rate**: Nurse shift coordinators: 24.9 (95% CI 21.9 to 27.9) WI per hr. Nurses with an allocated patient load: 9.2 (95% CI 6.9 to 11.4) WI per hr. **Secondary task** : Indirect patient management : 36% (most frequent) **Duration** : Average duration: 53 sec
Tang et al. (2007) USA	ICU	To investigate workflow in intensive care unit remote monitoring.	Nonexperiemental	7 RN Direct structured observation	**Rate:** 7.5 WI / hr **Duration**: Average duration : 45 secs. **Reasons**: The need to attend to specific patients (i.e., focused monitoring): 87.2%.
Tucker & Spear (2006) USA	Mixed	To describe the work environment of hospital nurses with particular focus on the performance of work systems supplying information, materials, and equipment for patient care.	Mixed	11 RN Direct unstructured observation	**Rate** : 85 WI / 108 hr 18 min = 0.8 WI / hr
Turner *et al.* (2003) UK	Surgical	To investigate the feasibility of replacing a standard method of intravenous antibiotic reconstitution.	Quasiexperimental	RN sample not reported Direct structured observation	**Results**: Significant reduction in WI for nurses with the new reconstitution method: $F(2, 29)= 10.54$ $p = .0001$

Authors Country	Setting	Objective	Design	RN Sample Data Collection	Key Findings
Woloshynowych, Davis Brown and Vincent (2007) UK	ED	To identify the features of the communication load on the nurse in charge of the ED.	Nonexperimental	11 RN (nurse in charge) Direct structured observation and audio-recording	**Rate** : 836 WI / 20 hours = 41.8 WI / hr

Quality Assessment

Most reviewed studies adopted a quantitative approach to the study of work interruptions (n=21). Consequently, this section focuses on quality issues specific to quantitative studies among which samples' representativeness and nurses' work interruptions measurement are the most recurrent. These limitations should be taken into consideration in the subsequent sections.

Sample representativeness

Half of the quantitative samples included 10 or fewer nurses. A convenience sampling strategy, when reported, was used in all quantitative studies except one. Only two studies (Manias, Botti, & Bucknall, 2002; Z. Tang et al., 2007) provided information on the recruitment rate to estimate nursing sample representativeness. Six of nine studies that adopted an event sampling strategy (as opposed to a time sampling strategy) did not describe the participants.

Work interruption measurement

Another common limitation of the studies reviewed relates to the way work interruptions are measured. Distinct definitions, when present, were used to operationalize work interruptions. Frequently, the selected definition clearly influenced the actual rates of observed interruptions. In one study, observations were performed simultaneously by two researchers using two different definitions; as a result, the two researchers' interruption rate estimates are different (5.9 per hour compared to 3.4 per hour) (Potter et al., 2005). Others used the terms 'work interruptions' and 'distractions' interchangeably (Pape, 2003).

An additional issue related to quantifying nursing work interruptions is the number of interruption sources considered. Some authors examined a single source (Medland & Ferrans, 1998), whereas others focused on communication interruptions—which, by definition, are initiated by another person (Spencer, Coiera, & Logan, 2004). Certain authors considered the nurses' patients as a source of interruption (Hedberg & Larsson, 2004); others did not (Pape, 2003). As regards the definition selected, the number of sources lessened the ability to compare results among studies.

Once a definition was selected and the sources carefully considered, data should be reliably collected. Most studies relied on direct observation to collect work interruption data. Estimates of observer agreement are reported only by Spencer et al. (2004) and Pape (2003), using percentage agreement. The absence of reported reliability estimates and other pre-identified quality issues serves to weaken the inferences that can be drawn from this review. The results presented in the upcoming sections should be considered accordingly.

Interruption Rate

By pooling the data from 14 studies reporting both work interruption frequency and total length of observation, the interruption rate is estimated at 6.7 per hour (range = 0.8 to 41.8). This number is based on a total of 2 622 work interruptions and 402.5 hours of observation. Furthermore, all 14 studies on which this estimate is based measure work interruptions through direct observation along with the multiple interruption sources considered. These quality criteria were selected to maximize the validity of the estimate.

Characteristics of Work Interruptions

Interruptions have been characterized according to interruption source; the channel through which the work interruption is conveyed; the task being performed when interrupted (primary task); the requested task by the interrupting source (secondary task); duration; and location. Interestingly, work interruption characteristics are less studied than nurses' actual rate of work interruptions. The paucity of evidence on work interruption characteristics precludes data synthesis; a descriptive approach was chosen instead to present the evidence on these characteristics. Unless otherwise specified, the evidence presented applies to nursing work in general and is not specific to medication administration.

Sources

The sources of work interruptions represent the persons or inanimate objects that initiate them. Two broad categories are present among the reviewed studies: individuals (e.g. healthcare professionals, patients, family members) and technical (e.g. missing equipment, alarms). Some studies focused on the individual, others on the technical; still others include both categories.

In the individual category, the most frequent source of interruption is nursing staff (RNs and assistants), accounting for 36.5% of all interruptions experienced by nurses (Hedberg & Larsson, 2004). Patients initiated fewer interruptions compared to other nurses, with reported proportions of 24.7% (Hedberg & Larsson, 2004) and 26.4% (Lyons et al., 2007) respectively. A considerably lower proportion of 4.7% of work interruptions initiated by patients is also reported (Pape, 2003). The latter result is partially explained by the exclusion of patients under nurses' care as a source of work interruptions.

On the other hand, technical sources of work interruptions include alarms originating from inanimate objects (Hedberg & Larsson, 2004) and operational failures, i.e. "the inability of the work system to reliably provide information, services, and supplies when, where, and to whom needed" (Tucker & Spear, 2006, p. 646). A nurse participant unable to find an IV pump to administer total parental nutrition (TPN) to a patient is an example of work interruption due to operational failure (Tucker & Spear, 2006). The proportion of all work interruptions with a technical source varies between 4.5% (Tucker & Spear, 2006) and 13% (Hedberg & Larsson, 2004).

One issue to consider when examining work interruption sources is the erroneous inclusion of the telephone as a source of interruption. The caller and not the telephone should be considered the source, since it is the caller who initiates the phone call; the telephone is simply a communications channel. By implication, studies considering the telephone as a source of interruptions have generally underestimated the frequency of work interruptions initiated by other individuals. It is therefore safe to state that the majority of interruptions are initiated by nurses themselves and other members of the nursing team, although a non-negligible number of interruptions have a technical source.

Channel

The channel is the medium through which work interruptions are conveyed. Face-to-face interactions, telephones, and pagers are examples of the different channels reported when the interruption source is an individual. Technical channels usually refer to inanimate objects like vital signs monitoring devices (Z. Tang et al., 2007). Work interruptions channels whose source is an individual have not been explicitly reported among studies included in this review. However, based on the results of four studies, it

can be deduced that the most important channel to convey work interruptions is face-to-face interaction (Coiera et al., 2002, Alvarez and Coiera, 2005, Coiera and Tombs, 1998, Spencer et al., 2004). Work interruptions are, as defined in these four studies, communication events in which a synchronous channel is used. A synchronous channel is "when two parties exchange messages across a communication channel at the same time" (Spencer et al., 2004, p. 270). Face-to-face interactions are the most important synchronous communication channel in these studies, representing at minimum 87% of all communication channels used (Alvarez & Coiera, 2005; Coiera, Jayasuriya, Hardy, Bannan, & Thorpe, 2002; Coiera & Tombs, 1998; Spencer et al., 2004).

Primary task

The primary task characteristics describe the activities nurses are performing when interrupted. Evidence on primary task characteristics enables a determination of whether some nurses' activities are more at risk of interruption than others. One study provides evidence on primary task characteristics (Hedberg and Larsson, 2004). Most work interruptions occur during direct patient care (62%) as opposed to indirect care (32%) (Hedberg & Larsson, 2004). Medication administration is the most interrupted nursing activity, with 29% of all work interruptions occurring during this activity (Hedberg & Larsson, 2004). Documentation is the next most frequent interrupted nursing activity, representing 14% of all work interruptions (Hedberg and Larsson, 2004). Work interruptions among the remaining nursing care activities were approximately equally divided.

Secondary task

The secondary task characteristics describe what the nurse is asked to do when interrupted. The secondary task characteristics of interruptions have rarely been quantitatively described, with the exception of Spencer et al. (2004), who report that indirect (36%) and direct patient care (28%) constitute the bulk of secondary tasks for nurses with an allocated patient load (Spencer et al., 2004). In support of these findings, Hedberg and Larsson (2004) provide a qualitative description of the main characteristics of secondary tasks. These include exchange of information, instructions and assistance. They state: "The patient, the relatives of the patient and the staff interrupted the nurses when they wanted information from her or when they wanted to inform the nurse of something they felt was important about treatments, examinations or discharge planning" (Hedberg and Larsson, 2004: 319). Based on these results, indirect patient management seems to characterize most of the secondary tasks related to interruptions.

Duration

Duration refers to the length of the interruption, usually expressed in minutes or seconds. Whereas Spencer et al. (2004) report a mean work interruption duration of 1 min 22 seconds, Tang et al. (2007) report a mean duration of 45 seconds. From these results, the interruption duration appears relatively short.

Nurses' locations when interrupted

Location describes the physical environment in which nurses are located when interrupted. Evidence on nurses' locations when interrupted is scarce. The most frequent location seems to be the medication room, which accounts for 22% of all interruptions

(Potter et al., 2005). Some medication rooms, designed as open spaces where nurses are 'at hand,' may promote interruptions (Hedberg & Larsson, 2004). The preparation of medication using a wall-mounted cupboard in each patient's room results in 64% fewer work interruptions compared to a medication cart, supporting the argument that open spaces (medication room, hallway) are more prone to work interruptions (Bennett, Harper-Femson, Tone, & Rajmohamed, 2006).

In summary, interruptions are characterized as being initiated mainly by nurses themselves and other members of the nursing team, conveyed through face-to-face interactions, occurring for patient management purposes, and being of short duration. There is some evidence that medication administration is the most interrupted nursing activity, especially in the room where medications are prepared. A summary table presents studies containing evidence on the characteristics of interruptions applicable to nurses (Table 6). This table makes explicit that frequency and sources as the two characteristics most liable to be studied, and demonstrates the dearth of evidence related to other characteristics.

Interruptions as a contributing factor to medication administration errors

Among the literature reviewed, one nonexperimental quantitative study specifically addresses interruptions as a contributing factor to medication administration errors (Scott-Cawiezell et al., 2007). This study's overall aim was to determine the impact of various levels of educational preparation on medication error. Based on a sample of 39 participants (12 RNs, 8 LPNs, and 19 certified medication technician/aides) and using direct observation to collect data on both work interruptions and the rate of medication administration errors, a significant positive association between interruptions and rate of

medication errors is present when the wrong time category is excluded (p = .01). The relationship is also present and significant (p= 0.04) between work interruptions and the rate of medication errors when wrong time medication errors are included but the relationship is inverse.

Scott-Cawiezell et al. (2007) are among the first to show quantitative evidence indicating interruptions as a contributing factor to medication administration errors. The fact that data were collected using direct observation both for work interruptions and the medication administration errors increased the validity and reliability of the results. Previous attempts to examine contributors of medication administration errors have been almost exclusively based on secondary data analysis of administrative databases, this constitutes an important limitation (White & McGillis Hall, 2003). Error underreporting partially explains this situation (Flynn et al., 2002; Wakefield et al., 1999). On the other hand, information supporting sample representativeness and reliability estimates for interruptions and medication administration errors measures are absent as most studies included in this review. Moreover, no other contributing factors except for educational background were considered. The study was not specifically design to examine the relationship between work interruptions and medication administration errors which could potentially explain the absence of other contributing factors.

Table 6 Studies Reporting Characteristics of interruptions

Study	Frequency	Source	Channel	Primary task	Secondary task	Duration	Location
Alvarez et al. (2005)	X		X				
Bennett et al. (2006)	X						
Coiera et al. (2002)	X		X				
Coiera et al. (1998)	X	X	X				
Ebright et al. (2003).	X						
Fairbanks et al. (2007)	X						
Hedberg et al. (2004)	X	X		X			
Luketich et al. (2002)	X	X					
Lyons et al. (2007)	X	X					
Manias et al. (2002)	X	X					
McLean (2006)	X						
Pape (2003)		X					
Potter et al. (2005)	X						X
Spencer et al. (2004)	X				X	X	
Tang et al. (2007)	X	X				X	
Tucker and Spear (2006)	X						
Woloshynowych et al. (2007)			X				
Total	16	7	4	1	1	2	1

Discussion

The main objective of this review was to identify evidence on work interruptions—their rate of frequency, characteristics and contribution to medication administration errors—that goes beyond data obtained through surveys. The results of this review are discussed around three main themes: the quality of the reviewed studies, the contribution of interruptions to medication administration errors, and possible avenues for interventions aimed at reducing work interruptions in nursing practice.

Quality of the reviewed studies

Shortcomings are present at the conceptual and methodological levels among the reviewed studies. From a conceptual perspective, the results of this review indicate two main problems: the diversity of definitions of work interruptions, and the absence of a theoretical framework on work interruptions and how they potentially contribute to medication administration errors.

Efforts need to be made to better define interruptions. This is a prerequisite to further knowledge development. In this review, two main conceptualizations of interruptions are present. One is task-oriented and defined by its adherents as "an activity that stops the RN from performing an immediate task" (Potter et al., 2005, p. 32). The alternate conceptualization is communication-oriented and defines interruptions as "a communication event in which the subject did not initiate the conversation and in which a synchronous channel was used" (Spencer et al., 2004, p. 270). The choice of either conceptualization is dependent, in part, on the objective being pursued.

One could argue that a task-oriented conceptualization of interruptions might be preferable for two reasons. A task-based perspective considers all sources of interruptions present in the work environment. A communication-oriented conceptualization only considers communication events initiated by another individual, leaving aside technical sources of work interruptions such as system glitches and alarms, which are non-negligible factors of interruptions (Hedberg & Larsson, 2004). In addition, a task-based orientation takes into account the duration of, not only the communication event (e.g. "Could you please take a blood sample?"), but the time required to accomplish the secondary task (taking the sample). Together with the work interruption frequency, the

duration of the secondary task has been hypothesized to have a negative impact on task performance (Gillie & Broadbent, 1989).

Efforts also need to be made to improve the methodological quality of studies on interruptions. Sample size and representativeness as well as how work interruptions are measured are recurrent issues among quantitative observational studies reviewed, and need to be addressed to move research forward. Sample size could be increased to promote the external validity of the results. Greater attention to sample size determination through power analysis would help address the issue. Power analysis helps estimate the minimum sample size required considering the type of analysis to be performed and the desired significance level, power, and effect size. Participation rates and the characteristics of the sample should be minimally provided in addition to sample size justification. Observational studies are vulnerable to selection bias. Providing information on sample and, when possible, population characteristics helps evaluate the extent to which the risk of bias might be present (Higgins & Green, 2008).

Direct structured observation should be the privileged data collection method for interruptions over unstructured observation and self-report. Unstructured observation is less reliable when the objective is to determine nurses' work interruptions frequency (Bakeman, 2000). Self-report, on the other hand, could be considered unsuitable due to work interruptions pervasiveness and frequency rendering nurses' capacity to recollect their occurrences limited (Marsch et al., 2005). Reliability estimation is absent in most studies despite interobserver agreement being considered a *sine qua non* condition to observation-based research (Bakeman, 2000). Interobserver agreement helps evaluate

inconsistencies in findings from different observers who collect basically the same information (Shoukri, Asyali, & Donner, 2004).

Interobserver agreement is mainly estimated using either percentage agreement or the kappa statistic. Percentage agreement is the ratio of the number of occasions both observers agree the behaviour occurred to the sum of those occasions plus occasion on which they disagreed (Birkimer & Brown, 1979). Pape (2003) claimed to have achieved above 90% reliability, but this result was obtained based on the total frequency of distractions and not by determining agreement for each distraction occurrences (Baer, Harrison, Fradenburg, Petersen, & Milla, 2005). Percentage agreement is certainly one positive step toward better reliability reporting, but percentage agreement tends to overestimate agreement because it does not account agreement that would be expected purely by chance (Sim & Wright, 2005). For this reason, the Kappa statistics, should be preferred (Landis & Koch, 1977). The kappa statistics, a chance corrected index of agreement, indicates the proportion of agreement beyond that expected by chance.

Contribution of interruptions to medication administration errors

Limited empirical evidence exists on the contribution of interruptions to medication administration errors. One nonexperimental study examines the potential contribution of interruptions to medication administration errors and its results are supportive of such contribution (Scott-Cawiezell et al. 2007). Here, the dearth of evidence is similar to other published reviews on the contributing factors to medication administration errors (Carlton & Blegen, 2006), which reiterates the need for research in this area. This is particularly important, since the evidence reviewed indicates that medication administration could be at particular risk from work interruptions. The

production of new research evidence will require more robust methods to inform adequately future directions in practice, research, and policy.

Reality is complex; interruptions do not take place in a vacuum, but are situated in a context (Brixey et al., 2007). Interruptions are one of the potential contributors to medication administration errors. Safety culture (Aspden, 2007), nursing leadership (Wong & Cummings, 2007), the number of hours worked by nurses (Rogers, Hwang, Scott, Aiken, & Dinges, 2004), their workload (Tissot et al., 2003), and medication administration complexity (Scott-Cawiezell et al., 2007) have also been identified as potential contributory factors. The inclusion of these emerging contributing factors in future studies would enable an estimate of the relative contribution of interruptions compared to other contributors through multivariate statistical analysis. This will facilitate the prioritization of efforts toward reducing the number of medication administration errors by prioritizing the greatest contributors. Furthermore, the inclusion of other potential contributors will offer evidence on the contextual factors under which interruptions are most detrimental.

Another potential means of limiting the detrimental effect of interruptions on medication administration is by reducing their frequency. This requires a better understanding of their characteristics, and thus the need for descriptive research on interruptions. Evidence on secondary task characteristics that examines the reasons for interruptions is especially needed. Such evidence will help determine the work interruptions that are avoidable. Another strategy to minimize the potential detrimental effect of interruptions is to examine how nurses manage them. Different options are available to the interrupted nurse: he or she can execute the secondary task immediately,

negotiate it, or mediate it through another individual with a filtering function (McFarlane & Latorella, 2002). No studies to date report quantitative evidence on the strategies employed by nurses to manage work interruptions. Manias et al. (2002) and Hedberg and Larsson (2004) both identify the tendency for nurses to immediately respond to work interruptions—a tendency that might not be the most effective way to minimize the detrimental effects of these interruptions. Evidence on interruption management strategies to maximize medication administration safety are especially needed, as some work interruptions will remain despite efforts to reduce them.

Intervening on work interruptions

Work interruptions are frequent. This review identified evidence that nurses are, on average, interrupted every nine minutes, with some evidence supporting a detrimental effect on medication administration practices leading to errors. Efforts to reduce work interruptions due to work system failures could certainly be deployed, since they are theoretically avoidable (Tucker & Spear, 2006). An example of work system failures applied to medication administration is missing medication, a recurrent problem faced by nurses (Hurley et al., 2007). When a medication is missing, the nurse has to interrupt her medication administration to locate or to communicate with the pharmacy, and remember to administer it at a later time.

Some work interruptions initiated by another person can also be reduced. The intervention described by Pape (2003) is an example of interventions that directly targets distraction during medication administration. One of these interventions was for nurses to wear a red vest with the inscription: "Medsafe Nurse, Do Not Disturb" while administering medication administration. Proactive communication strategies to meet

information needs of family members in ICU and thus reduce the number of incoming calls is another example of how work interruptions can be minimized. Interventions should target work interruptions more than distractions, since the detrimental effect of the former would appear to be greater than the latter.

Despite any interventions implemented, work interruptions will remain a part of nursing work, due to its very nature. Patients' conditions are constantly changing and adjustments to treatments consequently required. Members of interprofessional teams need to communicate information about patient management, making a certain number of work interruptions unavoidable. This situation results in an error-producing conditions, as described by James Reason's *Human Error Model* (Reason, 1990), leading to errors that could conceivably affect the patient if not intercepted by a defence barrier. Defence barriers as safeguards (e.g. double-checks) occupy a key role in a system perspective on error prevention. Consequently, it becomes important to implement these defence barriers to maximize patient safety considering the work interruptions will likely remain despite efforts aimed at reducing their occurrences.

Limitations

This literature review was subject to some limitations. First, the search strategy relied on keywords to identify articles that address interruptions, since there are currently no subject headings that apply to this concept in the databases searched. Keywords used were 'interruptions' and 'distractions.' It is possible that some papers may have been missed due to the decision to retain only these keywords. However, the identification of 415 articles for review, along with the search of reference lists of the included articles, makes it less probable that any major studies on nursing interruptions were missed. Secondly, data were extracted by a single reviewer. This data extraction process might

lead to systematic bias, although results have been discussed extensively among the authors.

Implications

The following implications for research and practice are formulated based on this review of the evidence regarding the rate of work interruptions in nursing practice, their characteristics, and their contribution to medication administration errors.

Further research is needed to better document the contribution of work interruptions to medication administration errors considering the limited evidence found. Full consideration should be given to how work interruptions are embedded in a cluster of factors that best predict medication administration errors. Future research should demonstrate improved methodological rigour that includes a precise definition of the concept of work interruptions, which translates into a clear operationalization of what is to be reliably measured. Concurrently, descriptive studies are also needed to better understand work interruptions characteristics such as their sources, interrupted primary task, secondary task, duration, and work interruptions strategies employed by nurses.

A better understanding of work interruption characteristics will inform front-line nurses and administrators to develop effective interventions to reduce the number of work interruptions experienced by nurses. Meanwhile, two avenues have already been identified from this review. Work interruptions resulting from work system failures (e.g. missing medications) represent a prime target of intervention because theoretically avoidable. Another avenue is the implementation of defence barriers (e.g. double-checks) is imperative to prevent medication administration errors from reaching patients, considering that certain work interruptions may be unavoidable.

Conclusion

Evidence so far would indicate that nurses' work environment is characterized by frequent work interruptions that are initiated mostly by members of the nursing team, consist mainly of face-to-face interactions, are mainly for patient management purposes, and are of short duration. Limited evidence exists on whether these work interruptions actually contribute to medication administration errors. This observation calls for further studies which will require a comprehensive approach through the inclusion of other emerging, key contributing factors to medication administration errors. Such evidence is urgently needed to develop effective prevention strategies.

Manuscript #1 of this dissertation work presented an evidence review on work interruptions in nursing and their contribution to medication administration errors. Work interruptions are one of the main predictors of MAE examined in this dissertation along with medication administration complexity and nurses' workload. The literature on medication administration complexity as a predictor of MAE preceded manuscript #1. The literature review thus continues by looking at the evidence on nurses' workload as a predictor of MAE. Last, the literature review concludes with a presentation of the study framework and objectives.

Nursing Workload

Through surveys of nurses and other health care professionals, workload also is reported to be one of the most important contributors to MAE (Bond, Raehl, & Franke, 2001; Cohen et al., 2003; Gladstone, 1995; Hicks, Becker, Krenzischeck, & Beyea, 2004; Tang, Sheu, Yu, Wei, & Chen, 2007). Compared to work interruptions, workload, as a predictor of MAE, has received more attention from the research community. The majority of these studies are secondary data analyses of an administrative data set, although one relies on direct observation (Tissot et al., 2003) and another uses a self-report measure to collect data on MAE (Sochalski, 2004).

Workload is found to be a significant predictor of MAE in at least six studies. In four of these studies, an increase in nurses' workload predicted an increase in the frequency of reported medication related incidents (Roseman (Roseman & Booker, 1995; Sochalski, 2004; Tissot et al., 2003; Whitman, Kim, Davidson, Wolf, & Wang, 2002) and two found the opposite—higher nurses' workload predicted less reported incidents (Blegen & Vaughn, 1998; Bond et al., 2001). The remaining studies did not find any

statistically significant relationships between these two variables (Blegen, Goode, & Reed, 1998; Cho, Ketefian, Barkauskas, & Smith, 2003; R. S. Evans, Lloyd, Stoddard, Nebeker, & Samore, 2005; Mark & Belyea, 2009; McGillis Hall, Doran, & Pink, 2004; Taunton, Kleinbeck, Stafford, Woods, & Bott, 1994).

The study by Tissot et al. (2003) is the most methodologically sound as it relies on direct observation to collect data on MAE. The researchers found that the risk of MAE for a nurse with more than 5.2 patients was 2.44 (95% CI: 1.30 – 4.60) times higher compared to a nurse with less than 5.2 patients. The nurse-to-patient ratio measure is in common use in research examining the relationship between nurse staffing and patient outcomes (Aiken, Clarke, Sloane, Sochalski, & Silber, 2002). However, this measure has some limitations considering that patients' characteristics are the main predictors of nurses' workload (O'Brien-Pallas, Irvine, Peereboom, & Murray, 1997) and, in fact, a nurse caring for three patients may have a higher workload than a nurse caring for four patients.

In addition to the questionable reliability of incident reports already identified, the measure of workload based on administrative databases has also a number of important limitations as well in terms of reliability, sensitivity, and validity. Nurses' workload is measured by aggregating organizational or unit-level data such as nursing hours per patient days (Clarke, 2005). A number of challenges are encountered in determining what constitutes nursing hours. It is often difficult to identify nursing hours of practitioners at the bedside because these hours are merged with hours from those with a more administrative role such as nurse educators (Needleman, Buerhaus, Mattke, Stewart, & Zelevinsky, 2001). In light of these reliability issues, it is not surprising to find mixed

evidence on the relationship between nurses' workload and MAE, a situation which hinders the drawing of any clear conclusions.

A micro-level approach to nursing workload at the situation level is recommended to overcome the existing issues about workload measurement in relation to patient safety research (Carayon & Gurses, 2005). These types of workload measures have been developed in the field of human factor research such as the NASA-TLX (Hart & Staveland, 1988). The NASA-TLX has been used in health care including nursing (Gregg, 1993; Morey et al., 2002; Totterdell, Spelten, & Pokorski, 1995). This measure can capture nurses' workload specifically at the time when a nurse is administering medication and also can detect variation in workload among different medication administration cycles (Rubio, Diaz, Martin, & Puente, 2004). This type of measure could potentially resolve the nurses' workload measurement issues and allow an analysis at the situation level, which has never been possible with the methods previously used.

The results of Bond et al. (2001) and Blegen and Vaughn (1998) in which higher workload predicts a lower frequency of MAE deserve further attention. More specifically, more nurses per occupied bed (i.e. less workload) predicts more reported medication incidents (β= 1.6234, p=0.03) (Bond et al., 2001). The hypothesis to explain their results, which also can be applied to the results of Blegen and Vaughn (1998), is that an increase in the number of nurses does not necessarily lead to an increase in MAE but to an increase in the number of MAE reported (Bond et al., 2001). Nurses are more likely than any other professional to have ever completed a report (S. M. Evans et al., 2006).

Until now, the literature review has addressed some of the current knowledge gaps related to the predictive power of medication administration complexity, work

interruptions, and nursing workload in relation to MAE. The adoption of a system perspective calls for not only a consideration of system-level predictors but also a consideration of the presence of any mediating or interacting effect among predictors (Reason, 1990; Wilson, 2000). If few researchers have explored system-level predictors of MAE, even fewer have explored this aspect (Hoff et al., 2004). This perspective might be particularly important considering that both work interruptions (Speier et al., 2003) and task complexity (Campbell, 1988) have been conceptualized as workload contributors. Nurses' workload becomes a mediator partially explaining the predicting effect of both medication administration complexity and work interruptions. This conceptualization leads to the study framework adopted in this study (Figure 3).

Some empirical evidence, not produced in the context of research on MAE, is available to support such a relationship. Work interruptions significantly predicted workload, explaining 37% of workload variance among police dispatchers (Kirmeyer, 1988). Zijlstra, Roe, Leonova, and Krediet (1999) built on Kirmeyer's results and hypothesized that interruptions cause an increase in required mental effort. Participants were interrupted during a text editing task. A significant difference was found in mental efforts between participant interrupted once, twice, and three times ($F=28.5$, $p < 0.001$).

Medication administration complexity also could significantly predict workload, since the former also has been conceptualized as a contributor of the latter (Campbell, 1988). As well, in nursing, the more general concept of nursing care complexity has been used to predict workload (O'Brien-Pallas et al., 1997; Soeken & Prescott, 1991). A strong correlation between complexity and nurses' workload supports this conceptualization

(0.67, p< 0.05) (Soeken & Prescott, 1991). Therefore, it would be expected that the same relationship is present in the specific context of medication administration.

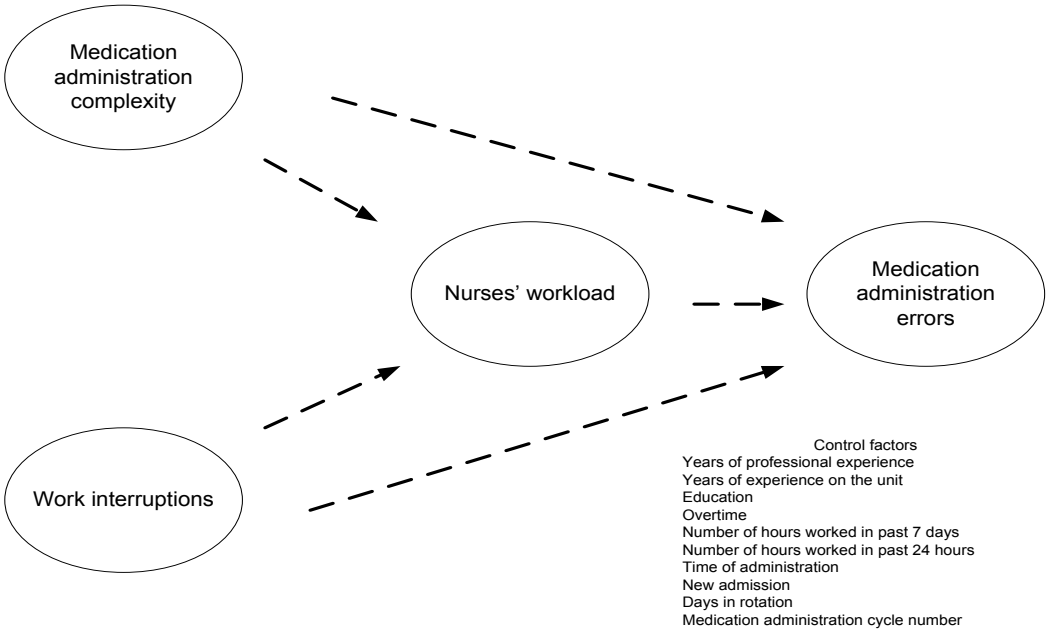

Figure 3 Predictors of Medication Administration Errors Study Framework

Control Variables

In light of the literature review, medication administration complexity, work interruptions, and nurses' workload could potentially play key roles in predicting MAE, but the evidence is relatively absent, or the conclusions that can be drawn are limited due to theoretical and methodological problems. Nurse characteristics, patient characteristics, and organizational culture also have been studied to predict MAE. These factors are reviewed to identify which should be studied or controlled for.

Nurse characteristics.

The following nurse characteristics have interested researchers for some time as potential predictors of MAE: the number of hours worked (Rogers et al., 2004), professional experience (Roseman & Booker, 1995), educational background (Blegen et al., 1998), calculation skills (Grandell-Niemi, Hupli, Leino-Kilpi, & Puukka, 2003), and medication related knowledge (Armitage & Knapman, 2003). However, often, these nurse characteristics have been considered in isolation (Crigger, 2005). Within a system model, the interplay between nurses' characteristics and other system elements makes errors and violations more or less likely to occur (Vincent, 2006). In this context, the subsequent evidence on nurses' characteristics as predictors of MAE is reviewed.

Scott, Rogers, Hwang, and Zhang (2006) found that the odds of MAE for a nurse working in critical care more than 40 hours per week is 46% higher when compared to a nurse working less than 40 hours per week (OR= 1.46; p= 0.01). In this study, a log book technique relying on self-reporting to collect data on MAE was used. Each time MAE occur, the nurse writes them in a log book. The reliability of the log book technique to collect data on MAE has not been established, but it can be hypothesized that incidence rates obtained by this technique are lower due to their self-report nature. If so, this means that the 46% increase risk reported by Scott and colleague (2006) is possibly underestimated.

To date, only two studies were found that examine professional experience as a potential predictor of MAE (Han et al., 2005; McGillis Hall et al., 2004). Both studies found a non-significant relationship between years of professional experience and MAE. If professional experience does not protect against MAE, work experience specific to the

nursing unit could potentially be this protective factor. The risk of MAE by hospital pool nurses and temporary staffing agency nurses is significantly higher when compared to full time registered nurses (OR= 1.67; 95% CI= 1.04-2.68) (Prot et al., 2005). Moving from an individual nurse level to a unit level of analysis, Roseman and Booker (1995) find that each additional 10 shifts worked by temporary staff lead to a 15% increase in reported incidents (OR 1.15; $p< 0.05$). Based on these results, years of professional experience on a patient care unit might be a better predictor than the number of years in the profession.

A lower skill-mix, reflective of nurses' level of education at the unit or hospital level, has been found to significantly predict the number of reported incidents (Blegen et al., 1998; McGillis Hall et al., 2004). The same relationship was not significant in two other studies (Potter et al., 2003; Wan & Shukla, 1987) while findings in the opposite direction also were reported (Bond et al., 2001). In their discussion, Bond et al. (2001) propose that having a richer skill-mix does not lead to higher MAE but to a higher reporting rate, considering that nurses are more likely than any other professionals to have ever completed an incident report (S. M. Evans et al., 2006). Again, using direct observation to collect data on MAE could potentially overcome this limitation associated with studies based on incident reports.

Nurses' medication-related skills and knowledge have been proposed to be MAE by a number of authors (Armitage & Knapman, 2003; Hughes & Ortiz, 2005; O'Shea, 1999; Pape, 2001). The empirical evidence supporting such relationships is scarce. Descriptive studies report nurses' lack of confidence in their knowledge and calculation difficulties (Ashby, 1997; Grandell-Niemi et al., 2003; Grandell-Niemi, Hupli, Leino-

Kilpi, & Puukka, 2005), but whether these perceived knowledge deficits and calculation difficulties translate into real MAE has yet to be demonstrated.

In summary, some nurses' characteristics—such as the number of hours worked, professional experience, and educational background—have been found to predict MAE. Any attempts at studying medication administration complexity, work interruptions, and nurses' workload as predictors of MAE should control for these factors.

Patient characteristics.

The relationship between patient characteristics and MAE is problematic. Age, gender, co-morbidities, and severity of illness have been examined for their capacity to predict MAE. However, it can be argued that patient characteristics play a lesser role in predicting MAE compared to task characteristics, even though both are strongly related such as age and the number of medications prescribed (R. S. Evans et al., 2005). This perspective is empirically supported by the fact that patient age was not found to be a significant predictor of MAE (Han, Coombes, & Green, 2005; van den Bemt et al., 2002). Individuals over age 65 have a significantly higher incidence of preventable adverse events per admission compared to individuals under 65 (0.63% vs 0.17, $p < 0.05$), but this difference is no longer significant after adjusting for other patient and organizational characteristics (Thomas & Brennan, 2000). Gender also was found not to predict MAE (Han et al., 2005; van den Bemt et al., 2002).

However, patients play an important role in preventing MAE from reaching them. They are considered to be the ultimate line of defence against MAE (Hughes & Ortiz, 2005). Patients provide the final safety check by being aware of what has been prescribed

for them and by being actively involved in the decisions related to the medication regimen when they are hospitalized.

Safety culture and nursing leadership.

Interest is growing concerning factors situated at the organizational level which are thought to influence the error and violation producing conditions according to the Unsafe Medication Administration Practices (UMAP) System Model (figure 1). Among these factors, nursing leadership and safety culture have been said to play an important role (Page, 2004). Other studies have examined the influence of the type of nursing unit on MAE. The current evidence concerning these factors is reviewed in this section.

Cooper (2000) defines *safety culture* as "the observable degree of effort with which all organisational members direct their attention and actions towards improving safety on a daily basis." Safety culture is a component of organizational culture which represents the shared perceptions of organisational work practices within organisational units that may differ from other organizational units (van den Berg & Wilderom, 2004). According to Reason (1990), safety culture is particularly salient for explaining violations of practice standards made by individuals within organizations because individuals do not plan and execute their actions in isolation, but within a regulated milieu. These regulation processes partly determine what the accepted norms will be on a given unit.

Despite the growing interest about safety culture, published empirical evidence of safety culture as a predictor of MAE is limited (Westrum, 2004). Research has focused mainly on understanding the sources of variation and the interventions that might improve such a culture (Pronovost & Sexton, 2005). For example, Ginsburg, Norton, Casebeer, and Lewis (2005) tested the effect of a training intervention on nurse leaders' perceptions

of a safety culture. As such, this concept has been used mostly as a dependent variable, and to a lesser degree as an independent variable. It remains to be investigated whether nursing units or health care organizations that have a stronger culture of safety report less errors and violation producing conditions related to medication use as suggested by Reason's model (Reason, 1990, 2005).

The same holds true for nursing leadership. Nursing leadership is thought to play a key role in instilling a culture of safety (Ruchlin, Dubbs, & Callahan, 2004). It is suggested that nursing leadership can modulate, to a certain extent, the organizational culture to ensure safe medication administration practices (Ginsburg et al., 2005). This role comes into play by implementing the required organizational structures, such as committees and policies, by ensuring that educational opportunities are available, and by planning for change (Nicklin et al., 2004). One study explored the relationship between nursing leadership practices at the unit and the organizational levels, and the degree of sophistication of the medication safety program (Walsh, 2004), although no statistically significant relationships were found. Even though empirical support for safety culture and nursing leadership is scarce, attempts should be made to control for these variables by selecting a single nursing unit for a study setting.

Finally, the type of nursing unit as a predictor of MAE has received some attention. For instance, when controlling for the number of medications administered in the last 24 hours, no significant difference was found in the number of MAE among ICUs and medical-surgical units (Cullen et al., 1997). Blegen and Vaugh (1998) found more MAE in medical-surgical units compared to intensive care units (ICUs), but they failed to control for the number of medications administered. The number of MAE might be higher

on medical surgical units simply because more medications are administered on those units. When controlling for the number of medications administered, more MAE seem to occur on medical than on surgical units (Lisby et al., 2005). These findings support the need for further research on medical units.

Conclusion

Recent reported rates of MAE underlie the importance of addressing an issue which is recognized both at the national and international level (Canadian Nurses Association, 2003; Kohn et al., 2000; Page, 2004; World Health Organization, 2004). An effective consideration of this issue requires a concerted effort from all those involved. Researchers have a key role to play in this collective action by producing the evidence to help practitioners, administrators, and policy makers intervene effectively to reduce the occurrence of MAE. Evidence is especially needed on the predictors of MAE. Medication administration complexity, work interruptions, and nursing workload all have been proposed as predictors, but the methods used have considerably limited the inferences that can be drawn. A new approach which focuses on a micro level analysis using direct observation is required. Such an approach offers the potential of moving an understanding of predictors of MAE one step further.

Chapter 3 Method

This dissertation study unfolded into two phases to meet the objectives set forth. The first phase was a pilot study, which has set the stage for the main study. Accordingly, first, the pilot study is presented followed by an overview of the main study method.

Pilot Study

The objectives pursued in the pilot study were to develop and evaluate the psychometric properties of the Medication Administration Complexity (MAC) coding scale and to ensure that the coding schemes for both MAE and work interruptions were optimal (See figure 4 for a summary of the pilot study). Manuscript #2 of this dissertation work reports the development and psychometric testing of the Medication Administration Complexity coding scale. The method and results of the coding schemes evaluation are reported following manuscript #2. A brief conclusion of the pilot study is then offered.

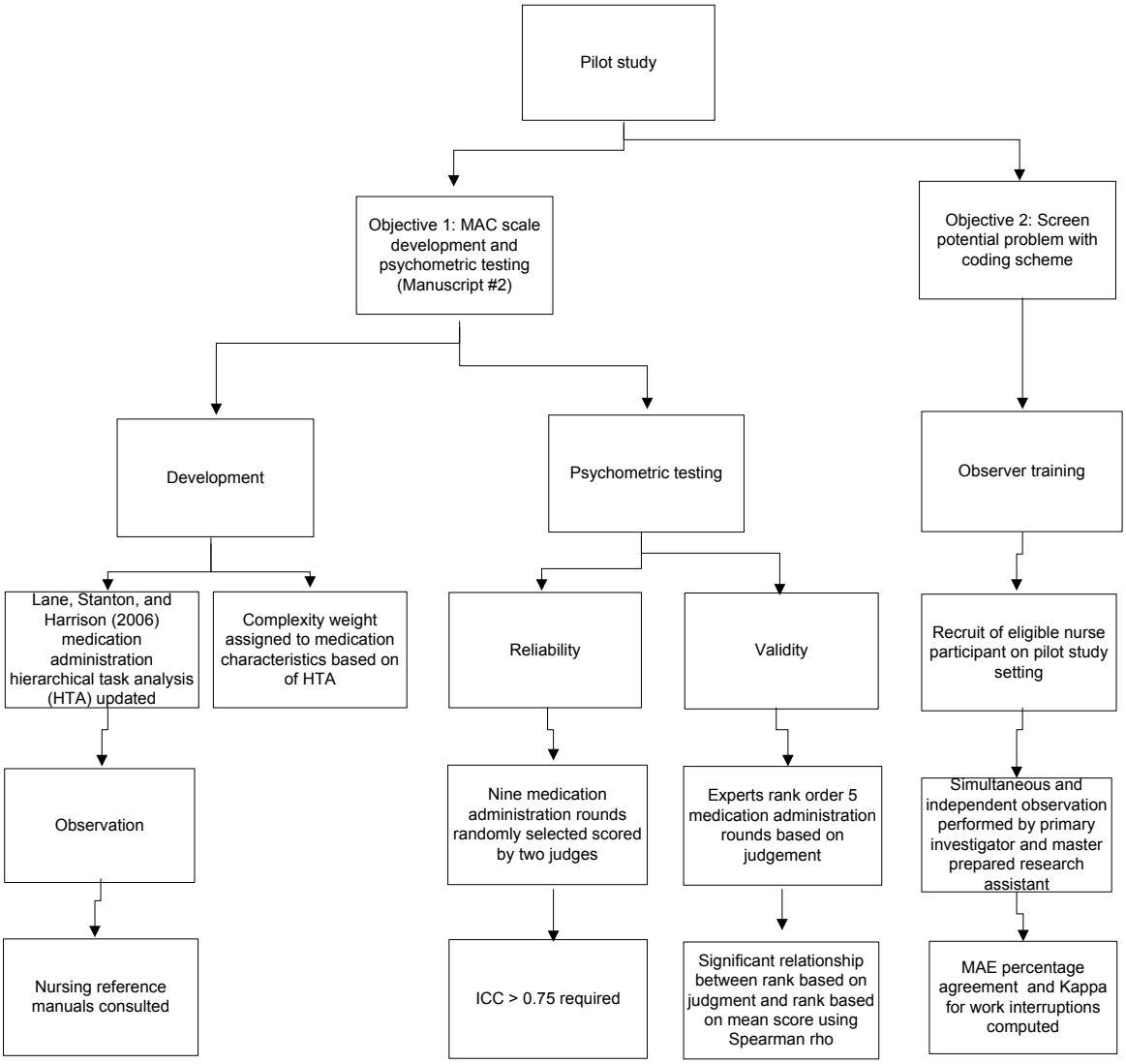

Figure 4 Pilot study method overview

Manuscript #2: Medication Administration Complexity Scale : Development and Psychometric Testing

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Submitted for publication at the International Journal for Quality in Healthcare

Preface

Manuscript #2 presents the development and psychometric testing of the Medication Administration Complexity (MAC) scale performed during the pilot study. Medication administration complexity has seldom been considered empirically as a predictor of MAE, although attempts have been made to find medication characteristics that may predict MAE. In part, this limitation is the result of an absence of a valid and reliable measure of medication administration complexity that reflects a full conceptual definition. The development and psychometric testing of such a measure represented a necessary preliminary step towards empirically testing its contribution to MAE.

Abstract

Objective: To report on the development and psychometric testing of the Medication Administration Complexity (MAC) scale.

Method: A two-dimension, component and coordinative complexity, coding scale was developed based on Wood's conceptualization of task complexity. Items for the two subscales were generated by using hierarchical task analysis (HTA) to determine actions and information cues required for medication administration. Based on the task analysis, fixed complexity weights were assigned proportional to the number of required acts and information cues identified. The assigned complexity weights were used to calculate a complexity score. Once developed, interrater reliability was evaluated using two raters scoring and 15 medication administration rounds randomly selected. Interrater reliability provided an intraclass correlation coefficient (ICC) of 0.974, reflecting excellent reliability. Convergent validity was estimated using five experts who ranked five medication administration rounds in order of increasing complexity. In support of validity, the mean ranked based on experts' judgment correlated perfectly using Spearman's Rho (r =1.00) with the rank obtained using the total MAC scores.

Conclusions: The Medication Administration Complexity scale preliminary psychometric properties suggest that this new instrument is promising in gathering evidence on an important contributing factor to medication administration safety. Predictive validity testing of the MAC should be pursued. In line with this objective, the validation process would consider how the scale relates to other important system-level contributors to medication administration errors such as work interruptions and workload.

Key words: Complexity, medication administration, measurement, medication errors

Background

Medication errors are frequent in hospitals (Kohn et al., 2000) and a significant proportion of patients are adversely affected by these medication errors. Adverse drug events (ADE), injuries related to the use of a drug such as permanent disability and death, occur at a rate of 52 ADEs per 100 admissions (Nebeker et al., 2005). Mostly performed by nurses but not exclusively, medication administration is associated to a third of medication errors leading to adverse drug events (Kopp et al., 2006). Although the importance of addressing this problem is recognized internationally, medication administration still has the fewest safeguards against errors in the medication-use process underscoring the need for timely and effective prevention strategies (Aspden, 2007).

Thus, a better understanding of key contributing factors to medication administration errors is urgently needed to develop effective error prevention strategies (Vincent, 2006). In line with this goal, Reason's work (Reason, 1990) has played a pivotal role in shifting from a person-centered focus to a system perspective in healthcare (Page, 2004). A system approach posits that although individuals are responsible for the quality of their work, more medication administration errors can be avoided by focusing on the system rather than solely on individuals. Consequently, if the system approach is correct, one of the first steps in a medication administration error reduction program is the identification of system-related contributing factors.

Among the system-related contributing factors, medication administration complexity is proposed to explain medication administration errors occurrences (Scott-Cawiezell et al., 2007). Medication administration complexity refers to medication intrinsic characteristics that place high cognitive demands on nurses for its administration

(Campbell, 1988). Two dimensions of medication administration complexity include component and coordinative complexity (Wood, 1986). Component complexity is a direct function of the number of required acts that needs to be executed and the number of information cues to be processed to perform a given task (Wood, 1986). The coordinative dimension refers to the nature of the relationship between task inputs and task products and particularly the sequencing of inputs (Wood, 1986). The sequencing of inputs involved in coordinative complexity might be particularly important for medication administration. A number of medications requires actions and information cues before their administration to determine if they should be administered or if dosage needs adjusting. This coordinative dimension adds to the medication administration complexity.

Despite its presume importance, a reliable and valid medication administration complexity scale has yet to be found. A number of medication complexity measures have been developed in the context of patient adherence studies [15-17]. These instruments measure the medication complexity from a patient's perspective. The medication administration task performed by nurses is undeniably different from patient self-administration. Medication forms, classes, mode of administration encountered by nurses are more diverse. Further, these medication complexity measures are not theoretically-driven and lack certain dimensions of medication administration complexity (Wood, 1986) with the potential to jeopardize their validity when studying contributing factors to medication administration errors.

Medication administration complexity has seldom been considered empirically as a contributor to medication administration errors, although a number of studies have examined the contribution of different medication characteristics (Kopp et al., 2006;

Taxis & Barber, 2004). The evidence gathered so far are inconclusive. In part, this limitation is the result of the absence of a reliable and valid measure of medication administration complexity that is conceptually anchored. Filling this gap would contribute to a better understanding of contributing factors to medication administration errors which, in turn, would lead to better informed error prevention strategies through the targeting of modifiable medication characteristics.

Objective

To report on the development and preliminary psychometric properties of the Medication Administration Complexity (MAC) scale.

Process Overview

The development and psychometric testing of the MAC scale was performed into three distinct phases each with their own method. The first phase involved the process of the MAC scale development, the second phase reliability estimation, and the third phase the validation process.

Phase 1: Tool Development

Hierarchical task analysis (HTA) was used to identify required acts and information cues inherent to the medication administration task (Shepherd, 2001). HTA is derived from a system perspective to explain skilled performance based on a hierarchy of goals and subgoals (Shepherd, 2001). Each goal and subgoal requires a number of information cues and acts to achieve the selected goal. Stanton's method (Stanton, 2006) was used to conduct the analysis necessary to break the medication administration task into composites of actions and information cues processed. This practical framework is made

up of a series of steps from defining the purpose of the analysis to the verification of the task analysis results with subject-matter experts.

The task analysis was bounded to medications administered by nurses in non-critical care units where the bulk of medication administration occurs within hospitals. Continuous intravenous medications, if not prepared during a medication round, were excluded from the HTA. Continuous IV medications are monitored by nurses and not necessarily administered. Further, this monitoring is not necessarily performed during the standard medication administration times. Because of this, it was decided to exclude continuous IV medication when the prepared during the round to ensure the scale measures the complexity of that medication administration round.

Once the boundaries were determined, the hierarchical task analysis was performed. A number of information sources were accessed to realize the task analysis. The starting point was the results of a previously published task analysis on medication administration (Lane, Stanton, & Harrison, 2006). Modifications were made to ensure that all formats and route of administration were represented. The unidose medication dispensing format, pre-prepared intravenous medications, and some parenteral route (e.g. nasogastric) are among the medication administration subtasks analyzed and added to the previously published HTA (Lane et al., 2006). The identification of the required acts and information cues involved in these added subtasks relied a number of information sources such as direct observation of nurses administering medication (9 hr 50 min), reference books (Kozier, 2000; Smith, Duell, & Martin, 2000), published guidelines (College of Nurses of Ontario, 2005), and clinical experts. Once required acts and information cues involved in medication administration were identified based on HTA, a fixed complexity weights was

assigned proportional to the number of required acts and information cues associated with each medication subtask. Subtasks were then grouped in different categories such as route of administration to facilitate scale use.

This regrouping gave rise to the component complexity subscales made up of 36 different weights tailored to medication objective characteristics. A weight was also added when the dose administered is a controlled substance or when double-checks are required. Each dose administered during a medication administration round contributes to its component complexity. All characteristics applicable to each dose administered are marked on the scale. The frequency of a particular characteristic for a medication administration round is multiplied by its corresponding weight, which provides a medication characteristic score. Component complexity subscores include the summation of all medication characteristics scores.

The coordinative complexity subscale required the identification of required acts and information cues involved in subtasks necessarily performed before a nurse can administer medication for a contingent or PRN order. For example, assessing pain is a subtask performed before the nurse can administer analgesics. The hierarchical task analysis of these subtasks started by the identification of the different medication classes for which actions and information cues are required prior to medication administration. The identification of these medication classes was made by reviewing existing medication protocols and by consulting nurses and pharmacists. Once the medication classes identified, the medication administration task for the identified classes were analyzed using the same information sources as for the component complexity subscale development.

The task analysis gave rise to the coordinative complexity subscale divided into two parts. The first part refers to medications from regular orders for which additional actions and information cues need to be processed: antiarrythmic, antihypertensive, anticoagulant, and antipsychotic. The second part contains 14 different medication classes for which a contingent or a PRN order could be written. A single weight was determined for each of medication classes except for nonsteroidal anti-inflammatory drugs (NSAIDs). The number of required information cues and acts for a contingent or PRN order of NSAIDs varies whether it is for analgesic or antipyretic purposes. The assigned weight for each medication class is proportional to the number of required acts and information cues necessary to administer medication for the corresponding medication class.

The scoring for coordinative complexity is different from component complexity. It is the number of patients with one or more medication administered or held in each of the medication class which is multiplied by its corresponding weight. The number of patients and not the number of medication administered is considered because, for instance, actions involved in taking a patient's blood pressure are performed only once even though two antihypertensive medications are administered at the same time. The coordinative complexity score equals the summation of the number of patients having medication administered or held per medication classes multiplied by the corresponding weight of the medication class. This summation is then multiplied by two to reflect the greater contribution of coordinative as opposed to component complexity to the overall task complexity (Wood, 1986). Total medication administration complexity scores for a given medication administration round are obtained by adding the component and the coordinative complexity subscores.

Phase 2: Reliability

The reliability of the newly developed MAC scale was estimated using a random sample of 15 medication administration rounds from a data bank of 102 medication administration rounds collected for a larger study. This sample size is based on requirements for ICC when two coders are used (Shoukri et al., 2004). The rounds took place on a medical unit within a tertiary university teaching hospital in Montreal, Quebec, Canada. A medication administration round corresponds to all medications administered by a nurse at specific times (e.g., at 0800, 1000, 1200, 1400, and 1800) to all of his or her assigned patients. In the hospital where the study took place, a nurse was usually assigned to five patients on the 12 hr day shift and each administration round contains an average of 8.8 medications. The reliability procedure involved the primary author and an experienced nurse with a masters degree independently scoring these 15 rounds using the MAC. Information found on medication administration records (MAR) was used to score each medication administration round with the MAC scale. Once the scoring was completed by both raters, data were analyzed using the intraclass correlation coefficient (ICC) to estimate interrater reliability (Model 2,1) where the rater is the independent variable (Shrout & Fleiss, 1979).

The sample of the medication administration rounds included, on average, 12.5 medications (*SD* = 10.9, range = 1 to 36). The component complexity mean subscore was 170,1 (*SD* = 130, range = 12 to 443) whereas coordinative complexity mean subscore was 55,0 (*SD* = 38,8, range = 0 to 118). The mean total medication administration complexity score was 225,0 (*SD* = 154, range = 15 to 523). Interrater reliability for two coders using the intraclass correlation coefficient (ICC) (Model 2,1) was 0.974. Consequently, less

than three percent of observed variance was explained by differences between raters. An ICC of 0.75 or above reflects good reliability (Portney & Watkins, 2000).

Phase 3: Validity

With the reliability coefficient judged to be satisfactory, criterion validity was subsequently estimated. Convergent validity is usually assessed by correlating the new scale with another tool measuring the same construct (Streiner & Norman, 2003). Because no other published scale exists for the measurement of medication administration complexity, experts were used (Streiner & Norman, 2003). These experts originated from four different domains of expertise: staff nurse, clinical nurse specialist, education, risk management, and information processing theorizing recruited either within the healthcare institution or its associated university. These five experts were provided with the conceptual definition of medication administration complexity, a set of standard instructions, and a description of medications administered within five medication administration rounds. These five medication administration rounds were also randomly selected from the databank collected for the larger study. Medication administration rounds to be ranked had, on average, 2.2 patients for which medications were administered and 5.5 doses per medication administration round. The majority of doses administered were tablets. One medication administration round included parenteral medications and inhalers.

Based on their judgement, experts independently ranked in ascending order of complexity the five medication administration rounds provided. Agreement among experts on the ranks attributed was examined using Kendall's W before estimating convergent validity. The five experts had high agreement on the ranking of complexity of

the medication administration process for the five medication administration rounds (Kendall's W = 0.84; $p = 0.002$) (see Table7). Significant agreement among experts on the attributed ranks supports the proposed medication administration complexity conceptualization. Convergent validity, on the other hand, involved using Spearman's Rho to correlate experts' rankings with the rank based on MAC scores. A perfect correlation ($r = 1.00$) was obtained between experts' mean rankings and MAC scores which supports of the MAC scale convergent validity.

Table 7 Rankings[1] Obtained Based on Experts and MAC Scores to Evaluate MAC Sale Validity

Medication Admin. Round	Expert Mean Ranking	MAC Score Ranking	Experts				
			Staff Nurse	Clinical Nurse Specialist	Risk Mgt	Information Processing Theorizing	Education
A	4	4	4	5	4	4	4
B	3	3	3	2	3	3	2
C	2	2	2	1	2	2	3
D	5	5	5	4	5	5	5
E	1	1	1	3	1	1	1

1. The numbers are in order of complexity.

Discussion

The MAC scale is a promising tool for the gathering of evidence on contributing factors to medication administration safety. Theoretically-driven, the MAC scale contains two subscales reflecting two significant components of medication administration complexity. The MAC scale is applicable to different clinical settings because only broad

medication classes were used. Preliminary psychometric testing supports its reliability and validity. The interrater reliability of the MAC scale, based on two raters and 15 medication administration rounds, provided evidence of reliability (Portney & Watkins, 2000). An ICC of 0.974 implies that less than three percent of observed variance is explained by differences between raters (Portney & Watkins, 2000). Among the factors potentially explaining this relatively high ICC is the heterogeneity of the sample use to estimated reliability. An heterogeneous sample increases the complexity variance as reliability expresses the ratio of subject variance to subject and error variance (Streiner & Norman, 2003).

A perfect correlation between experts' mean ranks and the rank based on MAC scores supports its convergent validity. Perfect correlations are usually not expected when estimating convergent validity. When present, it could mean the new scale offers little added value compared to the measure used to correlate the new scale (Streiner & Norman, 2003). However, the use of the MAC scale promotes reliable data collection and brings more efficiency to the research process. Also, the issue of a perfect correlation would have been more significant if parametric statistics would have been employed. The reliance on non-parametric correlation (Spearman's Rho) implies a lost of the numerical values and precision. The perfect correlation, in this case, indicates that experts' complexity rankings of the five medication administration rounds were exactly the same as the one obtained when using the MAC.

Limitations

Results stemming from the present study are limited in terms of the heterogeneity of the sample to estimate reliability. Reliability testing using more homogenous samples is

required. In addition, only convergent validity was assessed. Validity testing of the MAC should be pursued as, for instance, the testing of the MAC scale propensity to predict medication administration errors. In line with this objective, the validation process should also consider how the scale relates to other system-level contributors to medication administration errors (e.g., work interruptions, workload). One proposition is that work interruptions have more detrimental effects during complex task performance (Speier et al., 2003). Further, both work interruptions (Speier et al., 2003) and task complexity (Campbell, 1988) have been conceptualized as significant contributors to workload. Examining these propositions through rigorous research using the MAC scale would provide additional insights into the scale's psychometric properties.

Conclusion

The MAC represents an important contribution to medication administration complexity measurement. Initial support for its reliability and validity is promising. A better understanding of the multiple contributing factors to medication administration errors is essential to the development, implementation and testing of effective medication administration error prevention strategies. The MAC may contribute to the identification of modifiable medication characteristics to better ensure safe medication administration. This tool may be useful in safety programs to assist nurses in ensuring medication administration safety.

Acknowledgments

The authors would like to thank nurses who participated in this study. The primary author acknowledges the contribution of the FERASI Centre for Training and Expertise in

Nursing Administration Research, Fonds de la recherche en santé du Québec (FRSQ), and Ministère de l'éducation et des loisirs du Québec for their support through doctoral fellowship awards.

Manuscript #2 of this dissertation work presented the development and psychometric testing of the Medication Administration Complexity coding scale. The second objective of the pilot study was to screen for potential problems with coding schemes. The method employed to meet this second objective of the pilot study is described in the next section.

Screening Potential Problems with Coding Schemes

The pilot study second objective was to ensure that the coding schemes for both MAE and work interruptions were optimal. To meet this objective, observer training was provided and interobserver reliability estimated for MAE and work interruptions.

Observer training.

Observer training is among the available strategies to enhance the reliability of the observation (Baer et al., 2005). The training received by the observer included lectures and practice sessions. The lectures covered principles of observation-based data collection (non-intrusion, observer expected behavior, reaction to staff request, etc), codes and their definitions, introduction to the observation grid and data collection forms, and ethical issues specific to observation in the context of MAE studies. Practice sessions on the pilot study unit were performed to achieve a certain level of fluency with the recording tools after the lectures were provided (Flynn et al., 2002). Practice sessions also enabled to identify ways to facilitate the use of the observation grid by the observers (Appendix B). A number of iterations were necessary before the observers felt confident with its use and could proceed with the estimation of the reliability of the coding schemes.

Interobserver reliability.

Interobserver reliability is sine qua none of observational research (Patton, 2002). Interobserver agreement helps evaluate inconsistencies in findings from different observers who collect basically the same information (Shoukri et al., 2004). Interobserver agreement is mainly estimated using either percentage agreement or the kappa statistic. Percentage agreement is the ratio of the number of occasions both observers agree the behaviour occurred to the sum of those occasions plus occasion on which they disagreed (Birkimer & Brown, 1979). The kappa statistics, on the other hand, is a chance corrected index of agreement which indicates the proportion of agreement beyond that expected by chance (Sim & Wright, 2005). Different methods of calculating the Kappa statistic exists. The selection of the appropriate calculation method depends on the type of behaviours observed. The point-by-point method is used when the observers record the onset and offset times of events (Bakeman, 2000) which was the case for work interruptions. When such times are available and agreement with respect to duration matters, then time units can be tallied using an agreement matrix and kappa computed based on this matrix. To meet the objectives of the main study, a percentage agreement above 80% (Hartmann, 1977) while a kappa value above 0.61 (Landis & Koch, 1977) were considered necessary before main study data collection could be initiated.

Data to estimate the reliability of the coding schemes were collected on an active geriatric unit within the same tertiary care university teaching hospital where the main study took place. This active geriatric care unit was selected because the medication distribution system was similar to the medication distribution system in place on the

selected unit for the main study and nurses demonstrated interest in contributing to this dissertation study.

The required sample sizes were based on requirements specific to each statistical analysis used to estimate the reliability. Percentage agreement was based on a sample of 120 administered doses to estimate MAE reliability. The kappa statistics was based on 280 minutes of observation to estimate the reliability of the work interruption coding scheme. This latter sample size was determined using a 30% work interruptions prevalence found during the observer practice period and criteria set forth by Sim and Wright (2005).

The procedure involved the nurse manager approaching potential nurse participants to briefly explain the pilot study. Then, the primary investigator met with the interested nurses to explain the pilot study objectives and answer questions. Nurses who agreed to participate to the pilot study were asked to sign a consent form (Appendix C, D). An observation schedule was then elaborated based on the number of consenting nurse participants and when they were present at work. On each data collection day of the pilot study, the primary investigator met with nurse participants to determine which medication administration rounds would be observed. On the agreed time for observation, the primary investigator and a master prepared research assistant simultaneously and independently observed the entire medication administration round. This procedure was repeated until sample size requirements for the reliability study were met.

Data were then analyzed for both percentage agreement and kappa statistics. The percentage agreement was calculated by dividing the number of doses observers agreed on the medication, dose, patient, time of administration, and route over the total number

of doses observed. Observers agreed on all specified medication characteristics for 118 doses administered over 120 doses observed for a percentage agreement of 98.3%. This result met the objective previously set forth. For the Kappa statistics, both observers agreed 261 times over 280 observation points for a Kappa of 0.78. This results reflect substantial level of agreement (Landis & Koch, 1977).

Pilot study conclusion

In this pilot study, the development and psychometric testing of the Medication Administration Complexity (MAC) scale was performed and reported in manuscript #2 of this dissertation. The development and psychometric testing of such a measure represented a necessary preliminary step towards empirically testing its contribution to MAE as done in the main study. The second objective pursued through the pilot study was to ensure the coding scheme for MAE and work interruptions were optimal. This procedure was also a necessary preliminary step before initiating the main study data collection. Following a training period for the observers, the results of the reliability estimation of the coding schemes provided sufficient evidence to undertake the main study of this dissertation on MAE predictors. An overview of the method of this main study is presented next.

Main Study Method Overview

A prospective correlational design was used to examine the predictive power of three potential contributing factors to MAE: work interruptions, medication administration complexity, and nurses' workload on a medical unit in a tertiary care hospital. Data were collected on a 46 bed medical-unit in a large university teaching hospital in Montreal. The medication distribution system used is the unit-dose. Medications are kept in a single medication preparation room.

In this study, the unit of observation is the medication administration cycle. This unit of observation was sampled through a convenience sampling strategy. Sample size was determined based on the requirements for Generalized Estimating Equations (GEE) (Rochon, 1998). The parameters used were based on the results of Tissot et al. (2003) for the relationship between nurses' workload and MAE. Additionally, the following parameters were used: 0.05 level of significance, power 0.8, a conservative correlation between individual nurse measures of MAE of 0.5, an exchangeable correlation matrix, and 6 measures per nurse. Based on these parameters, a sample size of 100 observations was required. This meant that 17 nurses needed to be recruited.

The measurement of the four main variables of the study relied on three different strategies: structured observation, chart review, and self-report (see Table 8). Data on MAE were collected using direct non-participant observation by using an adapted version of the method proposed by Barker et al. (2002). A *Medication administration error* was operationally defined as any deviation between the inscription in the medication administration record (MAR) and actually administered medication or deviation from the general hospital protocols. The categories to classify MAE are based on those used by

Flynn et al. (2002): unauthorized drug, extra dose, wrong dose, omission, wrong route, wrong form, and wrong time. Wrong administration technique (Tissot et al., 1999) and wrong rate of administration (Greengold et al., 2003) were added to Flynn and colleagues' categories to bring more specificity. The number of MAE per medication administration cycle was calculated by adding the number of administrations with one or more MAE (Flynn et al., 2002).

Table 8 Key variables, measures proposed, data sources, and time of administration

Variables	**Measures**	**Method / Sources**	**Time of administration**
Medication administration complexity	MAC scale (manuscript #2) (Appendix E).	MAR review	Upon completion of observations
Work interruptions	Investigator developed observation grid (Appendix B)	Direct structured observation	Simultaneously to observation of MAE
Workload	NASA TLX (Hart & Staveland, 1988) (Appendix F)	Self-report	Within 15 minutes after each observed cycle
	Single Item (Appendix G)	Self-report	Within 15 minutes after each observed cycle
MAE	Observation method of detection of medication errors (Barker et al., 2002) (Appendix B)	Direct observation and chart review	During the medication administration cycle
Control	Investigator developed (Appendix G)	Participant self-report	Within 15 minutes after each observed cycle
Socio-demographic	Investigator developed (Appendix H)	Participant self-report	At the time of consent

Two investigator-developed questionnaires collected self-report information on potential confounders related to nurse participants. The first questionnaire (Appendix H) collected information on nurses' socio-demographic characteristics, such as educational background, years of professional experience, and whether they have a part-time or full-time position. A second questionnaire (Appendix G) collected information on nurse characteristics specific to each administration cycle, such as the number of hours worked and overtime worked in the past seven days, number of assigned patients, number of consecutive worked days, and shift lengths.

During the observation period, a single observer shadowed a nurse participant during the entire medication administration cycle. To minimize the potential for the Hawthorne effect associated with observation, the observer kept a distance from the observed nurse participant (Allan & Barker, 1990). After the medication administration cycle, the nurse participant completed the rated NASA-TLX scale (Hart & Staveland, 1988). The participants read the rating scale definitions and then provided a rating for the six dimensions of the scale. Then, the observer made a copy of the patients' prescription for which the observed nurse participant had administered medication, as well as the medication administration record (MAR). The MAR was used to determine MAE by comparing them to observations notes once the data collection completed (see figure 5 for an overview of the main study procedure).

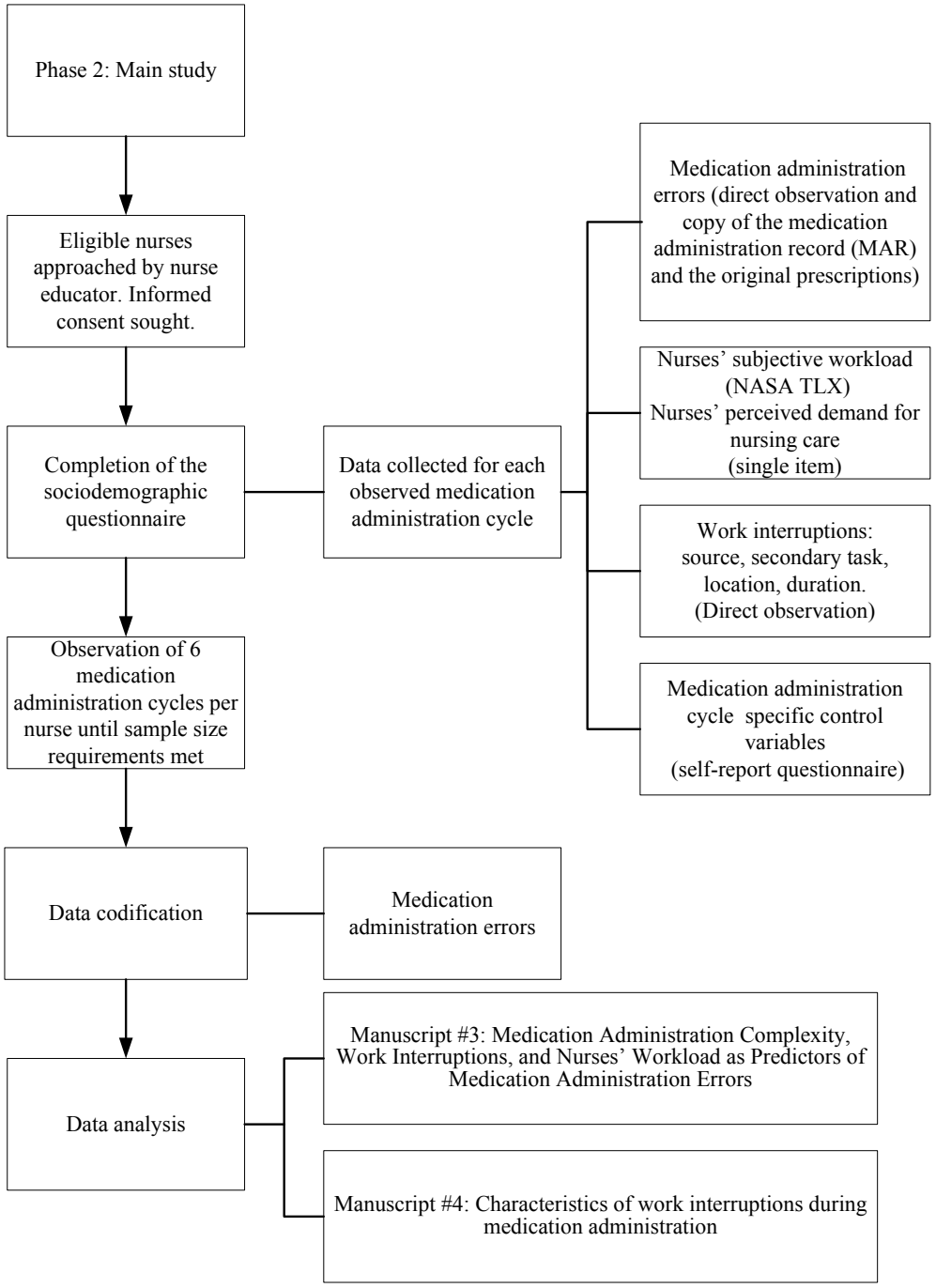

Figure 5 Main study overview

Data were analyzed through parametric and descriptive statistics. A multivariate logistic regression model, within a framework of a generalized estimating equation (GEE), was used to examine MAE predictors. GEE is a method for dealing with clustering factors among data which may result in correlation of data within the cluster

(Zeger, Liang, & Albert, 1988). In this study, the medication administration cycle was identified as the unit of analysis and the nurse participant as the clustering factor. The logistic regression model was used because the dependent variable is ratio (the number of administration with one or more MAE divided by the sum of the number observed drug administrations and the number of omitted drug administrations) (Diggle & Diggle, 2002). The exchangeable correlation structure in which correlation between subsequent measures are assumed to be the same through time was used (Twisk, 2003). The strategy for testing the workload mediating effect was based on Baron and Kenny (1986).

The study protocol was submitted to the Institutional Review Board (IRB) for ethical review (Appendix I). Informed consent was obtained from nurse participants. Patients were not the participants in this study, although they are incidentally involved in the sense that they are needed to determine the accuracy of medication administration. It is necessary to observe the patient receiving medications and then review the medication orders and the medication administration record (MAR) on the chart to determine if nurses accurately administered the medications.

Obtaining informed consent from nurse participants implied their awareness of the overall objectives of the study. It has been argued that nurses' awareness of the objectives of a study creates the potential for the Hawthorne effect, which refers to the alteration of participants behaviour and/or study outcomes due to a subject's awareness of being observed (Mangione-Smith, Elliott, McDonald, & McGlynn, 2002). Disguised observation has been proposed to minimize this potential Hawthorne effect (Allan & Barker, 1990). However, disguised observation has raised some ethical debates among researchers studying health professionals' behaviours (Diaz-Navarlaz & Segui-Gomez,

2006; Fernandez, 2005; Perneger, 2005). The concealment of information necessarily impinges on the process of informed consent (Fischman, 2000). Beside impinging on the process of informed consent, the empirical support for the presence of a Hawthorne effect in studies on MAE is scarce (Armitage, 2005). The behaviour of nurses seems not to change with exposure to observation (Dean & Barber, 2001). In light of this, an undisguised approach was used.

This study posed minimal risks to nurse participants, all of which were related to the confidentiality of the data. Minimal risk is deemed present when the risks associated with research participation by nurses are no greater than those involved in their everyday practice (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada, 1998). Breach of confidentiality could have potentially jeopardized the reputation of a nurse participant.

Confidentiality for nurse participants was protected through a number of strategies. Nurse participants' names were not recorded. A code number was used to match data consisting of their father's date of birth and the first three digits of their postal code. This code was replaced by a serial number (double-coding) after data have been matched to further protect participants' confidentiality. All hard copy data were stored in locked filing cabinet in a locked office at the School of Nursing, McGill University. Any potential identifying information was and will not be revealed in any publications.

Nurse participants were made aware of their right to withdraw at any point in the course of the study. Consent forms specific to the pilot and main study phase were provided in English (Appendix J) and French (Appendix K) and a copy of it was given to

participants once signed. The name of the ombudsman was provided for information concerning the rights of study participants. This study had no direct benefit for nurse participants. At the conclusion of the study, results were shared with the nursing unit involved and the institution; these results may be useful for quality improvement initiatives both at the unit and hospital level. Compensation was not offered.

A waiver of consent request was addressed to the MUHC Director of Professional Services (DPS) to access patients' charts (Appendix L). The purpose of chart review was to determine the accuracy and complexity of nurses' medication administration. This waiver of consent request has been formulated considering: (1) the risks were minimal for patients in observing nurses administering medication to them- research has shown that observation is not disruptive nor does it alter the error rate if performed unobtrusively (Dean & Barber, 2001); (2) no directly identifiable data was collected from them. Patient's identifiers present on the chart were covered when copies were made. Patient's room number and initials were used to link the observations with the chart data and eliminated as soon as the two sources were matched.

The principle of non-maleficience requires that when an error that can cause harm to a patient is observed, the observer has the ethical obligation to stop it (Diaz-Navarlaz & Segui-Gomez, 2006). The reliance on direct observation in this study implied some MAE were directly observed putting the observer in the deontological obligation to intervene. However, the need to intervene was limited. First, following the procedure proposed by Barker et al. (2002), the observers were blind at the time of observation to medications prescribed. The determination of the presence of a MAE was made after the completion of the data collection period by comparing the original prescription, the medication

administration record (MAR) and the observation notes. Second, only approximately seven percent of MAE may lead to an adverse drug event (Barker, Flynn, Pepper et al., 2002), which is when the observers were required to intervene.

In a situation where a nurse clearly made an error which would have minimally required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm based on the observer's judgment (National Coordinating Council for Medication Error Reporting and Prevention, 2006), the observer intervened by discreetly asking the nurse to recheck the medication, and not in the presence of the patient to avoid the loss of trust between nurses and their patients. If a nurse had not detected the error with this reminder and proceeded to administer the drug, the observer would have stopped the administration. An observer never had to stop an administration during data collection for this study which is concordant with a group of researchers that have used direct observation to collect data on MAE for more than 40 years as the tactful question has sufficed (G. Pepper, personal communication, July 11th 2006).

The identification of MAE during the analysis, on the other hand, also brought some obligations. Quebec's legislation regarding incidents within health care organizations requires that all incidents be declared. An *anonymous* report of incidents identified during the analysis of the data was sent to the organization's quality management department to conform to Quebec's legislation on incident reporting. This procedure to report medication incidents identified during the analysis was developed with the collaboration of diverse parties including Quality Management (Appendix M) as well as the Director of Nursing (Appendix N) who both provided their support.

Conclusion

This chapter presented the results of the pilot study and an overview of the method for the main dissertation study. Through the pilot study, the MAC scale was developed and tested as reported in manuscript #2 and it was ensured the coding schemes were optimal. This chapter continued by presenting an overview of the method for the main dissertation study. The next chapter presents the main findings that emerged from this main dissertation study. These findings are reported in manuscript #3 and #4 of this dissertation.

Chapter 4 Findings

The findings of the main dissertation study are presented in manuscript #3 and #4. Manuscript #3 is entitled: "Medication Administration Complexity, Work Interruptions, and Nurses' Workload as Predictors of Medication Administration Errors". Manuscript #3 specifically documents the relative contribution of each predication. Manuscript #4 presents a finer analysis of work interruptions that contributed to medication administration errors occurrences. This finer analysis was undertaken to guide the selection of possible interventions to reduce the number of work interruptions experienced by nurses while administering medications.

Manuscript #3: Medication Administration Complexity, Work Interruptions, and Nurses' Workload as Predictors of Medication Administration Errors

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Submitted for publication at Quality and Safety in Healthcare

Preface

Manuscript #3 is the first of two on the results of the main study examining medication administration complexity, work interruptions, and nurses' workload as predictors of medication administration errors. This first manuscript specifically documents the relative contribution of each predictor. The second manuscript found in this chapter presents a finer analysis of work interruptions during medication administration. This finer analysis was undertaken to guide the selection of possible intervention to reduce the number of work interruptions experienced by nurses considering their predictive power.

Abstract

Background: Evidence to date in support of system-related factors accounting for medication administration errors (MAE) remains scant and inconclusive.

Objective: To examine the predictive power of medication administration complexity (component and coordinative), work interruptions and nurse workload as potential contributing factors to MAE.

Method: A prospective correlational design using a convenience sample of medication administration rounds performed by nurses on a medical unit was used to meet the study objective. Data were collected using direct observation (MAE and work interruptions), self-report instruments (subjective workload, nurse characteristics) and the Medication Administration Complexity (MAC) coding scale.

Results: One hundred and two rounds were observed, during which 965 doses were administered and performed by 18 nurses. When wrong administration time errors were included, MAE rate was 28.4% whereas it decreased to11.1% when time errors were excluded. An interruption during the medication preparation phase (OR 1.602; 1.04- 2.47) significantly increased the odds of MAE. Two significant interaction effects were found (patient demand for nursing care X overtime and patient demand for nursing care X professional experience). These interactions pointed to more negative effects of overtime and professional experience among nurses who rated the demand for nursing care as above average. Contrary to expectations, coordinative medication administration complexity significantly *decreased* the odds of MAE (OR 0.558; .322-.967).

Conclusion: Based on these findings, work interruptions, demand for nursing care, overtime, and professional experience constitute significant factors that should be considered to reduce medication administration errors. The potential protective effect of

medication administration coordinative complexity protective effect against MAE also should be further explored.

Background

Medication use constitutes one of the major threats to patient safety within healthcare organisations (Aspden, 2007). Although medication errors are found at every stage of the medication use process, they occur most frequently at the prescribing and administration stages within hospitals (Leape et al., 1995). Contrary to errors occurring in preceding stages of the medication use system, medication administration errors are seldom intercepted, partly because they take place at the end of the medication use process (Bates et al., 1995). Medication administration errors reaching patients are found in one fifth of all doses administered by nurses (Barker, Flynn, Pepper et al., 2002). Some of these medication administration errors can be catastrophic for patients and, in fact, constitute the main safety concern for hospitalised patients (Burroughs et al., 2008). Given the limited safeguards against errors and the incidence of MAE, addressing specific issues associated with medication administration within healthcare organisations offers great potential in maximizing medication safety.

Beyond the diagnosis of safety problems, evidence is currently needed to support the implementation of intervention methods capable of effectively tackling medication safety issues (Bates, 2008). One step towards meeting this objective is the gathering of evidence on key factors that contribute to medication errors. Most studies on MAE contributing factors addresses the structure outcome relationship, while processes leading to safety issues are less studied (Hearld, Alexander, Fraser, & Jiang, 2008). Medication administration offers a unique opportunity to better understand those processes leading to safety issues because they are frequently performed by nurses on medical units (Keohane et al., 2008).

Medication administration complexity, work interruptions, and nurse workload have been repeatedly identified in surveys as factors that may contribute to MAE (Balas et al., 2004; Cohen et al., 2003; Stratton et al., 2004). Limitations in previous attempts to examine these predictors involve a reliance on secondary administrative databases in measuring medication errors (White & McGillis Hall, 2003). The possibility of interaction and mediation among predictors, congruent with a system perspective such as the Human Error Model (Reason, 1990), is another limitation (Hoff et al., 2004). These possibilities should be considered as medication administration complexity, defined as intrinsic characteristics of medication which place high cognitive demands on nurses during its administration (Campbell, 1988), and work interruptions, defined as halts in activities being performed for monitoring purposes or the carrying out of a secondary task (Hopp et al., 2005), have both been conceptualised as workload contributors (Campbell, 1988; Speier et al., 2003). The predictive power of work interruptions and medication administration complexity could therefore be mediated by workload.

The relative absence of robust evidence on MAE predictors inhibits further development of knowledge about the underlying causes, and until these causes are better understood any interventions proposed risk being ineffective. The study of medication administration complexity, work interruption and workload as MAE predictors has the potential of expanding current knowledge on the underlying causes.

Objective

The objective of this study was to document the predictive power of medication administration complexity, work interruptions, and nurse workload in relation to medication administration errors.

Method

Design

A prospective correlational design was selected to meet the study's objective.

Setting

Data collection took place in a single medical patient care unit within a tertiary university teaching hospital in Quebec, Canada. The medication administration record is paper based and the unit dose medication distribution system along with a centralized IV admixture service is currently used. Medications are kept in a single medication preparation room where nurses prepare all medications for their assigned patients at a specific time. Once prepared, nurses administer them to one patient at a time. The documentation is performed once the medications are administered. Data were collected in the fall of 2007.

Sample and Sample Size

Data are based on a convenience sample of 102 medication administration rounds performed by 18 registered nurses with at least six months of professional experience. The sample size was determined according to the requirements of Generalized Estimating Equations (GEE) (Rochon, 1998), using the results taken from Tissot et al. (2003) along with a 0.05 significance level, a power of 0.8, an exchangeable correlation matrix and an average of six observations per nurse. Based on these parameters, the required sample size was estimated at 100 medication administration rounds.

Measures

Medication administration errors

Medication administration errors were detected using direct structured observation (Flynn et al., 2002). MAE were identified by comparing medication administration records (MAR) and observation notes. MAE categories were based on those used by Flynn et al. (2002): unauthorized drug, extra dose, wrong dose, omission, wrong route, wrong form, and wrong time. Wrong administration technique (Tissot et al., 1999) and wrong rate of administration (Greengold et al., 2003) were also considered. The frequency of errors was the number of administrations with one or more errors divided by the sum of the number of observed drug administrations, and the number of omitted drug administrations (Barker, Flynn, Pepper et al., 2002). The observations were performed by two nurses (primary author AB and a master prepared research assistant) with a percentage agreement estimated at 97.7%.

Medication administration complexity

Medication administration complexity was measured using the Medication Administration Complexity (MAC) coding scale (Biron, Loiselle, & Lavoie-Tremblay, submitted). The MAC coding scale has two complexity dimensions: component and coordinative (Wood, 1986). Component complexity is the sum of all the steps required and information cues processed by the nurse during medication administration. The MAC coding scale enables to rapidly determine the number of steps required and information cues processed by attributing a fixed component complexity weights for each medication objective characteristic (route, form, dispensing format). The component complexity

score equals the sum of all components weights for a medication administration round. The second dimension, coordinative complexity, is present among medication which require on nurses' part to determine whether the medication should be administered or if the dose requires adjustment (e.g. insulin). Additional steps are performed and information cues processed (vital signs, capillary blood glucose, *etc.*) for these types of medications. The scale provides a fixed coordinative complexity weight for every medication class within which this coordinative dimension might be present. The medication administration complexity score equals the sum of component and coordinative dimensions. Interrater reliability provided an intraclass correlation coefficient (ICC) of 0.974.

Work interruptions

Data for work interruptions were collected using direct observation and operationally defined as "a break in task activity, evidenced by cessation of a task" (Healey, Sevdalis, & Vincent, 2006, p. 590). A Kappa of 0.78 was initially estimated followed by a Kappa of 0.66 at mid point in the data collection. Both Kappa reflected a substantial level of agreement among observers (Landis & Koch, 1977).

Nurses' Workload

Subjective nurse workload data was collected using two self-reporting measures: the NASA-TLX (Hart & Staveland, 1988) and a single item inquiring about nurse's perception of the patient's demand for nursing care compared to the last five worked shifts, on a 5-point scale (definitely less to definitely more). Patient demand for nursing

care was conceptualised as contributing to nurse workload (Morris, MacNeela, Scott, Treacy, & Hyde, 2007).

Control Variables

Control variables were collected using two questionnaires developed by the authors. The first questionnaire collected data on the number of hours worked and overtime worked in the past seven days, number of assigned patients, number of consecutive worked days, and shift lengths were completed following each observation. Overtime was defined as "time worked exceeding the duration of the scheduled work shift or if the nurse worked on a scheduled day off in the past seven days" (Scott et al., 2006, p. 32). A second questionnaire collected data on nurses' years of professional experience, professional experience on the unit, education and completed prior to the initial observation.

Data Collection Procedures

The data were collected on 12-hour day shifts, seven days per week. On average three medication administration rounds were observed per study day. A medication administration round corresponds to the time span during which a nurse begins and ends the administration of all assigned patient medications due at a specific time. Each medication administration cycle was observed by a single observer.

Data Analysis

A multivariate logistic regression model, within a framework of a generalized estimating equation (GEE), was used to examine MAE predictors. The medication administration round was the unit of analysis while nurses were identified as the

clustering factor. Mediation testing was first undertaken according to the procedure proposed by Baron and Kenny (1986). Model building strategies based on Hosmer and Lemeshow (2000) were then used. These model building strategies first involved univariate analysis of each predictor (Table 11). All variables with a p-value greater than 0.25 in the univariate test were entered in the model (Hosmer and Lemeshow, 2000). The contribution of each variable was estimated using the Wald statistic. Variables that did not contribute to the model were eliminated. The likelihood ratio test was used to detect improvement in model prediction. The parameter for significance was set at $p < 0.05$. The variables that contributed significantly to the model were then tested for the possibility of interaction. Log linear transformation of the total number of work interruptions was performed in order to normalize its distribution and medication coordinative complexity was dichotomised to reflect medication administration cycles with and without such medication administration coordinative complexity dimension. Years of experience on the unit was removed from the analysis because strongly correlated ($r= 0.932$) with years of professional experience Professional experience was dichotomized to facilitate the interpretation of the significant interaction term found in the final model.

Ethical Consideration

The study protocol was submitted to the hospital's Research Ethic Board (REB) for ethical review. Written informed consent was obtained from nurse participants and a waiver of consent request was submitted to access patients' charts. The reliance on direct observation in this study implied some MAE would be directly observed or discovered during the analysis, however, the need to intervene was limited. First, following the procedure proposed by Barker et al. (2002), the observers could not see medications

originally prescribed at the time of observation. The presence of a MAE was determined once the data collection period had been completed, by comparing the MAR with the observation notes. Second, only approximately seven percent of MAE might lead to an adverse drug event (ADE), at which time the observers would be required to intervene.

Results

Descriptive

During the data collection period, 102 medication administration rounds were observed during which 965 doses were administered, for an average of 8.83 doses (SD 7.0) per observation. Twenty-one nurses were invited to participate, but two refused and one withdrew before the first observation, for a total of 18 nurse participants. Nurse participants were mostly female (n=16), worked full time (n=16) and half (n=9) had a university degree. Nurse participants had an average of 9.86 years of professional experience (SD 8.58). For 36.3% (n=37) of the observations, nurses had worked overtime in the past seven days. The sample was comparable in terms of education and less experienced when compared to other nurses working in Quebec, Canada. The proportion of nurses with a university degree in Quebec is 42% with the average age being 43.6 years (Ordre des infirmières et infirmiers du Québec, 2008).

Medication Administration Error Rate

Of the 965 opportunities for errors, 274 had at least one error (MAE rate = 28.4%). When wrong administration time errors were excluded, the number of doses with at least one error was reduced to 108 (MAE rate without wrong administration time errors = 11.1%). Table 9 lists the frequency of MAE for each category. Four interventions were made by observers to prevent a medication administration error from reaching a patient.

In such cases, the error was deemed to have occurred and included as an error within the analysis.

Table 9 Error rates by medication administration error category

Error Category	n (%)
Wrong time	176 (62,0)
Omission	64 (22,5)
Wrong dose	26 (9,2)
Unauthorized	1 (0,4)
Wrong form	4 (1,4)
Extra dose	1 (0,4)
Wrong route	1 (0,4)
Wrong tech	11 (3,9)
Wrong rate	0 (0)
Total =	284 (100,0)

Medication administration complexity

Medication administration complexity average score for each medication administration round was 184.3 (min= 15, max 576; SD 124.1). The mean score for the component complexity dimension was 143.2 (SD 95.8) and the coordinative dimension had a mean score of 41.0 (SD 39.3). A coordinative medication administration complexity dimension was present during 73 (71.6%) of medication administration rounds.

Work interruptions

Nurses were interrupted 374 times out of 59 hrs 02 min of observation (rate = 6.3 work interruptions/hr). The interruption rate was lower during the preparation phase (5.2 WI/hr) compared to the administration phase (6.8 WI/hr). Nurses were interrupted at least once when preparing medication in 53 (53.9%) of observations.

Nurses' workload

The unweighted mean of the six-dimension NASA-TLX scores (Hart & Staveland, 1988) used to measure nurse subjective workload are shown in Table 10. Worth noting, the mean score for the performance dimension is twice the average mean score found on other dimensions. This performance dimension was measured with the only negatively worded item and thus may indicate some validity issues within the context of this study. Nurses' perceived patient demand for nursing care, measured on a single item 5-point scale, had a mean score of 2.96 (SD 1.25).

Table 10 Mean NASA-TLX score for each dimension

Dimensions	Mean	SD
Mental Demand	39.8	29.1
Physical Demand	32.7	29.2
Temporal Demand	35.3	28.5
Effort	36.2	30.3
Performance	79.4	26.3
Frustration	28.3	27.7

MAE Predictors

When wrong administration time errors were excluded, work interruptions during the medication preparation phase significantly increased the odds of MAE (OR 1.596; 1.044 - 2.441) whereas the presence of a coordinative medication administration complexity dimension, contrary to expectation significantly decreased these odds of MAE (OR 0.991; .987-.995) (Table 12). Also significantly related to medication administration errors were two interaction effects of patient demand for nursing care by overtime and by professional experience.

These interactions indicated differential effects for overtime and professional experience according to nurses' perceived demand for nursing care. The effect of

overtime on the odds of making a medication administration error increases with patient demand for nursing care. This increase is significant for nurses who rated the demand for nursing care as slightly or definitely more than average (Table 13). In particular, the odds of making a medication administration error for a nurse who rated the demand for nursing care as definitely more than average were 2.82 times that of a nurse with the same perception of the demand for nursing care but had not worked overtime in the past seven days.

Professional experience also interacted with demand for nursing care. The odds of a medication administration error were significantly higher among nurses with more than five years of professional experience and who rated the demand for nursing care as slightly or definitely more than average compared to nurses with less than five years of professional experience (Table 14). In particular, the risk for nurses with five years of professional experience and more and who rated the demand for nursing care as definitely more was 2.68 that of a nurse who rated the demand for nursing care similarly but who had less than 5 years of professional experience.

Table 11 Univariate analysis of predictors of medication administration errors based on GEE

Predictors	**Variable**	**Excluding wrong time MAE OR (95% CI)**	**Including wrong time MAE OR (95% CI)**
Complexity	MAC total	.999 (.997-1.002)	1.002 (.999 – 1.005)
	MAC component	1.000 (.996 – 1.003)	1.003 (1.000 – 1.007)
	MAC coordinative (RC[1] no MAC coordinative)	.687 (.362 – 1.305)	1.209 (.694 – 2.108)
Work interruption	Interruption total number (Ln)	1.168 (0.74 – 1.762)	1.831 (1.202 – 2.788)
	Administration interruptions (Ln)	1.057 (0.765 – 1.461)	1.515 (1.098 - 2.090)
	Preparation interruption (RC no interruptions)	1.443 (0.929 – 2.241)	1.240 (1.010 – 1.523)
Workload	NASA-TLX	1.011 (.989 – 1.035)	1.029 (1.004 – 1.056)
	Perceived demand	1.192 (.994 – 1.430)	1.341 (1.035 – 1.738)
Control	Overtime performed in past 7 days (RC no overtime)	1.499 (.893 – 2.514)	1.115 (.546 – 2.279)
	Hours worked in past 7 days	1.001 (.980 – 1.023)	1.006 (.985 – 1.028)
	Number of patients assigned	1.203 (.840 – 1.722)	1.737 (1.108 – 2.726)
	Number of consecutive days of work	1.064 (.792 – 1.429)	.992 (.663 – 1.486)
	8 hrs scheduled shift (RC 12 hrs)	.958 (.350 – 2.620)	.482 (.165 - .1.412)
	Administration time:		
	08.00 hrs	1.093 (.646 – 1.850)	.609 (.350 – 1.060)
	10.00 hrs	2.359 (1.233 - 4.514)	2.593 (1.173 – 5.732)
	12.00 hrs	.843 (.359 – 1.981)	.431 (.231 – .803)
	14.00 hrs	.953 (.304 – 2.987)	.472 (.203 – 1.094)
	17.00 hrs	RC	RC
	Professional experience	1.027 (1.000 – 1.054)	1.001 (.971 – 1.033)
	Education (Bacc RC)	1.357 (.796 – 2.325)	1.801 (1.034 – 3.137)

1. RC= Reference category

Table 12 Predictors of medication administration errors based on GEE when excluding wrong administration time errors

Predictor	**OR**	**95% CI**	**p**
Intercept	.104	0.067 - 0.162	.000
Prep interruptions	1.596	1.044 - 2.441	.031
MAC coordinative	.558	0.322 - 0.967	.037
Overtime	1.539	0.962 - 2.462	.072
Prof experience	1.248	0.818 - 1.904	.304
Patient demand for nursing care	.764	0.617 - 0.947	.014
Overtime X Patient demand	1.353	0.070 - 1.712	.012
Prof exp. X Patient demand	1.463	1.193 - 1.796	.000

Table 13 Estimated odds ratios and 95% confidence intervals for overtime, controlling for patient demand for nursing care

Patient demand	Definitely less	Slightly less	same	Slightly more	Definitely more
Odd ratio	0.84	1.14	1.54	2.08	2.82
95% CI	0.38-1.86	0.62-2.09	0.96-2.46	1.37-3.18	1.72-4.63

Table 14 Estimated odds ratios and 95% confidence intervals for professional experience, controlling for patient demand for nursing care

Patient demand	Definitely less	Slightly less	same	Slightly more	Definitely more
Odd ratio	0.58	0.85	1.25	1.83	2.68
95% CI	0.32-1.07	0.53-1.38	0.82-1.90	1.15-2.90	1.51-4.75

When including wrong medication administration time errors, component medication administration complexity and patient demand for nursing care increased the odds of MAE while controlling for nursing education and the time of administration (see Table 13). Work interruptions significantly predicted nurses' perceived patient demand for nursing care and medication errors while work interruptions became non-significant

when workload was introduced into the model, supporting the possible mediating effect of workload in the relationship between work interruptions and medication administration errors (Baron & Kenny, 1986).

Table 15 Predictors of medication administration errors based on GEE including wrong administration time errors

Predictor	**OR**	**95% CI**	**p**
Intercept	.287	(.173 - .474)	.000
MAC component dimension	1.039	(1.016 - 1.062)	.001
Patient demand for nursing care	1.221	(1.061 - 1.405)	.005
Bachelor's degree	.483	(.326 - .716)	.000
17.00 hr administration	2.684	(1.584 – 4.548)	.000
14.00 hr administration time	1.613	(.594 – 4.378)	.348
12.00 hr administration time	.956	(.565 - 1.618)	.868
10.00 hr administration time	3.184	(1.807- 5.609)	.000
08.00 hr administration time	1	-	-

Discussion

The objective of this study was to document the predictive power of medication administration complexity, work interruptions, and nurse workload in relation to MAE. Work interruptions, , demand for nursing care moderated by overtime and professional experience and medication administration complexity are system related factors that significantly predicted MAE occurrences. Intervening in these predictors could potentially reduce medication administration errors occurrences. The MAE rate with (28.4%) and without (11.1%) wrong administration time errors found in this study is similar to previous reports (Barker, Flynn, Pepper et al., 2002; Kopp et al., 2006). This MAE rate implies four MAE per 12-hour day shift, other than wrong administration time per nurses, considering that an average of 39 doses is administered. Omitting to administer a dose is the most likely type of error that might occur, other than wrong

administration time, and is also in line with previous reports (Barker, Flynn, Pepper et al., 2002; Prot et al., 2005).

Work interruptions during medication preparation, while patient demand for nursing care moderated by overtime and professional experience were found to increase the odds of MAE. Coordinative medication administration complexity, on the other hand, decreased the odds of MAE when excluding wrong administration time errors. Contrary to Scott-Cawiezell et al. (2007), only work interruptions while nurses prepared their medications and not their total number significantly predicted MAE.

The preparation of medication is a critical phase in medication administration. Medication preparation requires that information found in the MAR be matched with the information found on the unit dose envelope. Work interruptions during that particular phase may result in information encoding problems, leading to MAE (Reason, 1990). Based on current practice, the chances of intercepting this error once it has occurred are minimal. Nurses on the study unit prepared all medications for their assigned patients at a specific time. The nurse, for each patient, opened the unit dose envelope and then poured the medication into a medication cup before going into each patient's room. Information for each dose was no longer accessible, thus jeopardizing the nurse's ability to carry out a second verification at the bedside.

The interactions found among predictors provide new insights regarding their potential contribution to MAE. Job demand is among the variables postulated to act as moderator in the relationship between worked hours and work performance (Caruso, 2006). Overtime has been previously reported to predict nursing errors (Rogers et al., 2004; Scott et al., 2006). Fatigue also has been proposed to explain the relationships among overtime, job demands and errors occurrences (Philibert, 2005). Working

overtime appears to interfere with nurses' capacity to recover from work while at the same time prolonging their exposure to job demands leading to fatigue (Caruso et al., 2006). Further, working overtime, based on the results obtained herein, appears to have lasting negative effects. How long these negative effects associated to overtime last has yet, however, to be understood and likely to be moderated by job and nurses' characteristics(Caruso et al., 2006).

Professional experience was found to interact with nurses' perceived patient demand for nursing care. This interaction is congruent with changes associated with an older workforce (Charness, 2008). These interactions, although some of small magnitude, reiterate the importance of not searching for simplistic solution to MAE. The relationship between nurses' work environment and MAE is probably multifaceted and calls for solutions of the same nature (Clarke, 2009).

The potential protective effect of coordinative medication administration complexity was not expected. Coordinative medication administration complexity is present when supplementary patient information and actions are required before administrating certain medication, such as antidiabetic, antihypertensive and opiates (Wood, 1986). The protective effect may be triggered by the inherent additional verification performed by nurses for these medications. The medication administration records (MAR) are read twice: once to determine whether additional patient information is required and again to determine the dose to be administered, according to the information collected on the patient. This double verification is included among the safety strategies used to prevent errors (Reason, 1990).

Including wrong administration time errors in the logistic model changed the cluster of predictors. Component medication administration complexity, work

interruption and patient demand for nursing care were found to be predictors of MAE while controlling for education and time of administration. Wrong administration time errors might be conceptually different from errors that would explain the different set of predictors found. Wrong administration time errors probably correspond more to violation of practice standards than the MAE *per se* (Han, Coombes, & Green, 2005). Violation of practice standards implies the deliberate deviation from known practices deemed necessary to maintain safe operation (Reason, 1990). These predictors limited the nurse's capacity to administer medication as scheduled. Adaptive strategies such as administering medications scheduled for 8.00 am and 10.00 am together to save time were deliberately selected by nurses.

Limitations

Limitations to this study include issues related to study design, sampling strategy, data collection means, and the unknown clinical significance of observed MAE. Correlational designs do not allow a determination of causal relationships. More robust study design would be required to establish this causal relationship. Correlational designs, also, need representative samples for results to be generalizable. This study used a non-probability sampling strategy which may lead to sampling bias. Nurse participants were less experienced compared to other nurses working in similar settings in Quebec, Canada. On the other hand, most nurses gave their consent to participate, thus enhancing the generalisability of the results. The characteristics of the medication use system such as the unit dose and the centralized IV admixture service should also be considered in evaluating the generalisability as both influenced medication administration safety. Finally, the clinical significance of observed MAE is unknown. For ethical reasons,

clinical significance cannot be assessed prospectively and a group of peers is usually relied upon to predict probable outcome, once data collection is terminated (Han et al., 2005). At the same time, medication administration is a high risk process frequently performed by nurses and thus it provides a unique opportunity to efficiently study the influence of the nurse's work environment on patient safety.

Conclusion

Based on the evidence gathered herein, work interruptions, demand for nursing care, overtime, and professional experience constitute significant factors to be considered to reduce medication administration errors. Interventions to ensure an increased supply of human resources in nursing while looking at possible work reorganization to improve its efficiency is necessary to limit the reliance on overtime. The protective effect of coordinative complexity should be further studied. An enhanced understanding of this protective effect may provide novel ways to maximize medication administration safety.

Acknowledgment

The authors would like to thank nurses who participated in this study. The authors also wish to thank Sean P. Clarke, Patricia Lefebvre, and Linda Ward who commented an earlier version of the manuscript.

Competing interest

None.

Funding

Alain Biron wishes to thank the FERASI Centre for Training and Expertise in Nursing Administration Research, Fonds de la recherche en santé du Québec (FRSQ), and Ministère de l'éducation et des loisirs du Québec for their support through doctoral fellowship awards.

Manuscript #4: Characteristics of work interruptions as contributors to medication administration errors: A descriptive study

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Accepted for publication at the Journal of Nursing Scholarship (Appendix O)

Preface

The evidence produced in this dissertation and reported in manuscript #3 support the significant contribution of work interruptions in the medication preparation phase to medication administration errors. At the same time, there is a paucity of descriptive work on the characteristics of work interruptions. This work could enhance nurses' propensity to effectively reduce the number of work interruptions and optimize medication administration process (as reported in manuscript #1). A finer-grain analysis of work interruptions characteristics in the context of medication administration was thus undertaken to guide the selection of interventions to reduce the number of work interruptions experienced by nurses. These work interruption reduction interventions represent, based on the findings of this dissertation, a promising avenue to maximize medication administration safety within organizations.

Abstract

Objective: To document characteristics of nurses' work interruptions (WI) during medication administration.

Design: A descriptive observational study design was used along with a sample of 102 medication administration rounds. Data were collected on a single medical unit using a unit dose distribution system during fall 2007.

Method: Data collection on work interruptions relied on direct structured observation. The following work interruptions characteristics were recorded: source, secondary task, location, management strategies, and duration.

Results: 374 WI were observed over 59 hrs 2 min of medication administration time (6.3 WI / hr). During the preparation phase, nurse colleagues (n=36; 29.3%) followed by system failures such as missing medication or equipments (n=28; 22.8%) were the most frequent source of WI. Nurses were interrupted during the preparation phase mostly to solve system failures (n=33, 26.8%) or for care coordination (n=30; 24.4%). During the administration phase, the most frequent sources of work interruptions were self-initiation (n= 41; 16.9%) and patients (n=39; 16.0%). The most frequent secondary task undertaken during the administration phase was direct patient care (n=105; 43.9%). WI lasted 1 min 32 sec on average, and were mostly handled immediately (n=357; 98.3%).

Conclusion: The process of medication administration is not protected against work interruptions which pose significant risks.

Clinical relevance: Interventions to reduce work interruptions during the medication administration process should target nurses and system failures to maximize medication administration safety.

Key words: work interruptions, patient safety, medication administration errors, nursing care, communication, system analysis

Background

Work interruptions (WI), a break in the activity being performed to carry out a secondary task (Hopp, Smith, Clegg, & Heggestad, 2005), are pervasive in nursing practice. Evidence suggests that nurses' are interrupted at a rate of 2.8 WI / hr (Hedberg & Larsson, 2004) to 14.0 WI / hr (Alvarez & Coiera, 2005). As a result, nurses are rarely able to complete a nursing care activity without being interrupted. The safety risks posed by these work interruptions are receiving more attention at a time when nurses strive to maximize patient safety within their organization (Biron, Loiselle, & Lavoie-Tremblay, in press).

Safety risks posed by WI are especially important with regards to medication administration - a high-risk nursing activity - for at least two reasons. First, medication administration is among the most interrupted nursing care activity (Hedberg & Larsson, 2004; Potter et al., 2005). Second, emerging evidence supports the significant contribution of work interruptions to medication administration errors (Biron, Loiselle, & Lavoie-Tremblay, submitted; Scott-Cawiezell et al., 2007). The odds of medication administration errors are found to increase by 60%, if a nurse is interrupted during the preparation phase (Biron et al., submitted).

Medication preparation seems a critical step in medication administration in preventing MAE. Medication preparation requires that information found in the medication administration record (MAR) be matched with the information provided by the medication distribution system (e.g. the unit dose envelope). For example, nurses interrupted while reviewing the MAR, need to remember where they were at when resuming their tasks. Omissions errors are likely at this point simply because nurses may

believe to be further along in the task sequence. Such omissions linked to prospective memory failures are among the most prevalent views to explain the relationship between work interruptions and human errors (Grundgeiger & Sanderson, 2009).

A better understanding of work interruptions characteristics is required to tackle these medication safety issues effectively. As such, work interruptions sources are among the WI characteristics most studied in nursing (Biron et al., in press). Nurse colleagues seem to be the most frequent work interruption sources identified accounting for up to 36.5% of all interruptions experienced by nurses (Hedberg & Larsson, 2004). Patients initiate fewer interruptions compared to nurses, with reported proportions varying between 24.7% (Hedberg & Larsson, 2004) and 26.4% (Lyons et al., 2007). An additional non-negligible source of nurses' work interruptions reported are system failures defined as "the inability of the work system to reliably provide information, services, and supplies when, where, and to whom needed" such as missing equipment (Tucker & Spear, 2006). The proportion of all work interruptions associated with system failures is 4.5% (Tucker & Spear, 2006).

Most of the evidence on work interruptions is not specific to medication administration rounds, the period of time spanning when a nurse begins and ends the administration of all assigned patient medications due at a specific time (Pape, 2003), but applies to nurses' work in general. System failures such as missing medications are a recurrent problem faced by nurses (Hurley et al., 2007). The significance of system failures as a work interruption source for medication administration could be greater than for nurses' work in general. Little is currently known on other work interruptions characteristics such as secondary tasks undertaken by nurses when interrupted or strategies used to manage these work interruptions.

The evidence to date on the specific characteristics of work interruptions is mostly limited to the frequencies and sources and not specific to medication administration. The latter gap jeopardizes nurses' capacity to effectively reduce the number of work interruptions experienced when administering medications. An enhanced understanding of work interruption characteristics would allow nurses to tailor their interventions on factors most likely to have a significant impact and thus, contribute to maximize medication administration safety within their organization.

Objective

To document the rate, sources, secondary tasks undertaken, duration and strategies employed by nurses to manage work interruptions during medication administration.

Method

Design

A descriptive study design using direct structured observation was used to meet the study objective.

Setting

Data collection took place on a single medical patient care unit in a tertiary university teaching hospital in Quebec, Canada using a unit dose distribution system between September and November 2007. Medications, within this patient care unit, are kept in a single medication preparation room located in the middle of the patient care unit. Nurses prepare all medications for assigned patients at a specific time in this medication preparation room and then, administer them one patient at a time.

Sample and sample size

Registered nurses with at least six months of professional experience, were invited to participate in the study. An event sampling strategy was adopted. The event sample was the medication administration round. The sample size was based on the requirements for a larger study from which this study is derived examining predictors of medication administration errors (Biron et al., submitted) which was estimated at 100 medication administration rounds.

Measures

A paper-based observation grid was developed by the primary author to record the following work interruptions characteristics: source, secondary task, location, strategies, the work interruption start time and end time. Work interruptions were operationally defined as a break in task activity, evidenced by cessation of a task (Healey, Sevdalis, & Vincent, 2006). Categories of work interruption sources were: nurse, orderly, patient, family members, physician, healthcare professional (other), assistant head nurse / head nurse, unit coordinator, self-initiated, alarms, system failures, and other. These categories are based on previously published works on work interruptions (Brixey et al., 2007; Hedberg & Larsson, 2004; Pape, 2003) and validated during the observers training period. Patients under nurses' care were also considered a possible source of work interruptions as per Hedberg and Larsson (2004).

Secondary task definitions originated from work sampling (Pelletier & Duffield, 2003). The main categories of nursing care activities are direct care, indirect care, unit-related, and personal. Direct care is defined as all nursing care activities performed in the presence of the patient and/or family while indirect care represented all nursing care

activities done away from the patient, but on a specific patient's behalf. Further distinctions were made for indirect care using operational definitions put forward by Pelletier and Duffield (2003).

Last, work interruption management strategies were categorized as immediate or scheduled (McFarlane & Latorella, 2002). The immediate work interruption management strategy was present when the nurse initiated and completed the requested secondary task before resuming medication administration. The scheduled work interruptions strategy was deemed present when the observed nurse made an explicit agreement to complete the requested secondary task at a latter time.

Data collection procedure

Upon approval from the hospital Institutional Review Board (IRB), data were collected by two observers (primary author AB and a Master-prepared research assistant) on 12-hour day-shifts, seven days per week between September and November 2007, with a single observer handling each medication administration round. On average, three medication administration rounds were observed per study day. Interobserver agreement was estimated twice during data collection; during observer training to estimate reliability before proceeding with data collection and at mid-point of data collection to detect any observer drift. Observer drift refers to "the tendency of observers to modify scoring rules over time" (Smith, 1986). A Kappa of 0.78 was initially estimated followed by a Kappa of 0.66 at mid point in the data collection. Both Kappa reflect substantial level of agreement among observers (Landis & Koch, 1977) and support the absence an observer drift.

Data analysis

Descriptive statistics were used to document WI characteristics along with the Kappa statistic to determine interobserver agreement. Kappa is a chance corrected index of agreement (Landis & Koch, 1977). The agreement pertains to whether or not a work interruption is present at a specific time.

Results

During the data collection period, 102 medication administration rounds were observed. Each medication administration round lasted, on average, 34 min: 43 sec (SD 23 min 08 sec) for a total of 59 hr 29 min of observation time. The total time spent in the preparation phase was 23 hrs 53 min while 35 hours 36 min were dedicated to the administration phase. Twenty-one nurses were invited to participate, two refused, and one withdrew prior to the first observation for a total of 18 nurse participants. Participants were mostly female (n=16), worked full time (n=16), and half (n=9) had a university degree. Nurse participants had an average of 9.86 years of professional experience (SD 8.58). The sample was comparable in terms of education and yet probably less experienced when compared to other nurses working in Quebec, Canada. The proportion of nurses with a university degree in Quebec is 42%, and the average age 43.6 years (Ordre des infirmières et infirmiers du Québec, 2008)

Work interruption rate

Nurses were interrupted 374 times during the observation period for a rate of 6.3 work interruptions per hour (preparation = 5.2 WI/hr; administration = 6.8 WI/hr). Nurses were interrupted at least once when preparing medication in 53 (53.9%) of observations.

Work interruption sources

Sources were documented for 366 work interruptions, and generally the nurse colleagues were the main source of work interruptions (n=65; 17.8%) particularly during the preparation phase (n=36, 29.3%). System failures (n=28; 22.8%) were the second most frequent WI source during the preparation phase. Missing medications, looking for the medication administration records or searching for the keys to access narcotic were system failures frequently encountered by nurses. A different pattern was observed during the medication administration phase where self-initiation (n= 41; 16.9%) and patients (n=39; 16.0%) were the most frequent observable sources of work interruptions. Sources of work interruptions were more evenly distributed during the administration compared to the preparation. Table 1 provides the details of work interruptions sources for both phases of medication administration.

Table 16 Sources of work interruptions during medication preparation and administration

Sources	Preparation n (%)	Administration n (%)	Total n (%)
Nurses	36 (29.3)	29 (11.9)	65 (17.8)
Self-initiated	21 (17.1)	41 (16.9)	62 (16.9)
Others	16 (13.0)	40 (16.5)	56 (15.3)
System Failures	28 (22.8)	26 (10.7)	54 (14.8)
Patients	0 (0.0)	39 (16.0)	39 (10.7)
Families	0 (0.0)	20 (8.2)	20 (5.5)
Physician	8 (6.5)	12 (4.9)	20 (5.5)
Orderly	3 (2.4)	13 (5.3)	16 (4.4)
Assistant Managers	5 (4.1)	7 (2.9)	12 (3.3)
Alarm	2 (1.6)	8 (3.3)	10 (2.7)
Other Professionals	2 (1.6)	5 (2.1)	7 (1.9)
Unit coordinators	2 (1.6)	3 (1.2)	5 (1.4)
Total	243 (66.4)	123 (33.6)	366 (100)

Secondary Tasks Undertaken

Work interruptions occur as the intrusion of a secondary, unplanned, and unscheduled task into the medication administration activity (Brixey et al., 2007). Secondary tasks were documented for 362 work interruptions (see Table 2). Direct patient care was the most frequent secondary task completed during medication administration activity (n=109; 30.1%). No specific pattern of direct patient care activities was identified. Patients and families interrupted nurses during medication administration for diverse reasons such as obtaining information on an upcoming procedures or discharge

plans. When preparing medication, the most frequent occurring secondary task was system failure resolutions (n=33; 26.8%) and coordination of care, involving information exchange among professionals regarding patient's progress (n=30; 24.4). Nurses interrupted other nurses preparing medication mostly to discuss personal matters (n=13; 36.1%) and to provide verbal reports of patient status for the purpose of either unit to unit transfer or break coverage (n=8; 22.2%) (see Table 3). During the administration phase, the most frequent secondary task was direct patient care (n=105; 43.9%).

Table 17 Secondary Tasks involved in work interruptions

Secondary Task	Preparation n (%)	Administration n (%)	Total n (%)
Direct care	3 (2.4)	106 (44.4)	109 (30.1)
Coordination	30 (24.4)	42 (17.6)	72 (19.9)
Failure resolution	33 (26.8)	34 (14.2)	67 (18.5)
Personal	18 (14.6)	9 (3.8)	27 (7.5)
Other	14 (11.4)	11 (4.6)	25 (6.9)
Communication	6 (4.9)	12(5.0)	18 (5.0)
Verbal report	9 (7.3)	6 (2.5)	15 (4.1)
Teaching	5 (4.1)	9 (3.8)	14 (3.9)
Clerical	3 (2.4)	7 (2.9)	10 (2.8)
Meetings / Admin	2 (1.6)	3 (1.3)	5 (1.4)
Total	123 (100.0)	239 (100.0)	362 (100,0)

Table 18 Sources of work interruptions per secondary task during medication preparation

Task / Source	Comm[a]	Verbal report	Direct care	Coordination	Adminis-tration	Teaching	Clerical	Personal	Failure resolution	Other	Total
Nurse	0	8	1	4	0	1	2	13	3	4	36
Orderly	2	0	1	0	0	0	0	0	0	0	3
Alarm	1	0	0	0	0	0	0	0	0	1	2
HCP[b]	0	0	0	2	0	0	0	0	0	0	2
Physician	0	0	1	6	0	0	0	1	0	0	8
AM[c]	0	0	0	4	0	0	0	0	0	0	0
Unit coordinator	0	0	0	1	0	0	1	0	0	0	2
Self-initiated	0	0	0	6	1	1	0	1	6	6	21
Other	1	1	0	5	1	3	0	2	2	1	16
S. Failure[d]	2	0	0	2	0	0	0	0	22	2	28
Total	6	9	3	31	2	5	3	18	33	14	123

[a] Comm = Communication
[b] HCP = Healthcare professional
[c] AM = Assistant Manager
[d] S. Failure = System failure

Work interruptions management strategies and duration

Work interruption management strategies were documented for 363 work interruptions. Almost all work interruptions were managed immediately by nurses (n=357; 98.3%). This proportion was similar whether the nurse was preparing (98.8%) or administering (97.6%) medications. The handling of work interruption management took relatively little time (1 min 32 sec; SD 2 min).

Discussion

The objective of this study was to document the rate, sources, secondary tasks undertaken, management strategies, and duration of work interruptions during medication administration. The documented work interruption rate of 6.3 WI / hr is similar to the reported rate of 6.7 WI / hr based on pooled data analysis of 14 studies with nurse participants and non-specific to medication administration (Biron et al., in press). Medication administration is among the most frequent activity performed by nurses (Keohane et al., 2008) which probably explains why medication administration has been reported to be the most interrupted nursing care activity (Hedberg & Larsson, 2004). Obtaining similar rates implies, however, that medication administration is not protected against work interruptions and safety risks are present.

Interventions to reduce the number of work interruptions experienced by nurses during medication administration should target the most frequent sources especially while preparing medication. Nurse colleagues are the most frequent source of work interruptions, and this finding is congruent with previous reports (Hedberg & Larsson, 2004). Nurses interrupted each other while preparing medication mostly to discuss

personal matters and to exchange verbal reports. Changing these practices is, theoretically, possible and necessary to maximize medication administration safety. Informing nurses is certainly a preliminary step towards changing these practices but adopting a system perspective would offer greater potential (Reason, 1990) such as optimizing the medication-use system to prevent work interruptions.

Various medication-use models exist, including central medication administration rooms, medication administration carts, and cabinets within each patient's room. The proximity of nurses in central medication administration rooms, however, can create opportunities for informal interaction (Hedberg & Larsson, 2004; Heerwagen, Kampschroer, Powell, & Loftness, 2004). Although based on a cross-sectional design, some evidence suggests that nurses experienced less work interruptions when medication cabinets are located in patients' rooms instead of centrally on a patient care unit (Bennett, Harper-Femson, Tone, & Rajmohamed, 2006). Further evidence comparing nurses' work interruption rates for different medication-use system could assist in the selection of medication-use systems and thus provide a sustainable way to reduce work interruptions during medication administration.

Improvement in the efficiency of medication administration systems is clearly needed as system failures resolution is the most frequent secondary task identified during the medication preparation phase. Nurses' difficulties accessing the supplies and equipment they need are not specific to medication administration. The unavailability of supplies and equipment was associated to 14.2% of nurses' work interruptions in a trauma center (Brixey et al., 2008). Medication-use systems is healthcare are complex and thus improving their efficiency requires that all parties involved throughout this system make concerted efforts to do so. Missing dose problems are multifactorial and probably context

specific. Nurses, pharmacists, and administrators should evaluate all possible methods of increasing efficiency by reducing system failures as a source of work interruptions, and thus maximize medication administration safety within their organizations.

Coordination of care is the second main secondary task carried out by nurses when interrupted while preparing medications. Coordination of care includes nursing care activities such as communication with doctors and allied health workers or other nurses regarding care, including telephone calls (Pelletier & Duffield, 2003). The need to communicate information to coordinate care is predominant in healthcare as patients' clinical conditions are constantly changing. Adjustment to treatment plans required by these changes need to be communicated and nurses predominantly use face-to-face interaction to communicate adjustments (Spencer, Coiera, & Logan, 2004). Face-to-face interaction is a mode of communication that generates work interruptions. A judicious use of information technology could certainly reduce some of these interruptions.

Addressing nurses' propensity to immediately manage work interruptions is another potential avenue to tackle this medication administration safety risk. Any work interruption bears the potential to have detrimental effects on work performance (Reason, 1990). The primary objective should be to protect nurses' from work interruptions during medication administration. However, handling immediately work interruptions might be more detrimental compared to negotiated work interruptions once they occurred (McFarlane, 2002). Changing nurses' management strategies to mitigate the potential detrimental effects associated of work interruption will require a socio-cultural shift. Expectations and rewards to immediately handle work interruptions are deeply embedded in the organisational culture (Perlow, 1999). Documenting through research and

questioning these expectations and rewards present at the patient care unit level could represent an initial step in triggering this cultural shift.

An additional finding worthy of note is the observed difference in the sources of interruptions and type of secondary tasks undertaken between preparation and administration phases. Direct patient care, contrary to medication preparation, is the most predominant secondary tasks undertaken by nurses when interrupted during the administration phase. This observed difference could be partially explained by the reliance on a central medication room to prepare medications on the patient care unit where this study took place. This medication room is not easily accessible to patients. Patients were, thus, unlikely to be a source of work interruptions. Patients as a source of work interruptions could, however, represent a safety risk among healthcare organisations where nurses prepare medication closer to the bedside. This finding also reiterates the need study work interruption rates for different medication-use system and intervention studies and for intervention studies. Such evidence would help select the optimal environment for nurses to ensure safe medication administration.

Limitations

Limitations to this study include issues related to study design, setting, sampling strategy, and data collection means. Descriptive studies require representative samples for results to be generalizable. This study used a convenient sampling strategy which may lead to sampling bias. Nurse participants were more educated and less experienced compared to other nurses working in similar settings in Quebec, Canada. Further, a single patient care unit was selected. Some work interruptions characteristics are context-dependent such as system failures and will vary among healthcare settings. On the other

hand, a low refusal rate enhances the generalizability of the results. The possibility of the Hawthorne effect associated with direct observation represents another potential limitation. Rigorous observer training was provided to limit this possibility, and no observer drift detected.

Conclusion

Work interruptions are frequent and pose significant safety risks. Nurse colleagues are the most frequent source of these work interruptions. Improving the medication administration system's efficiency is clearly necessary, given that the resolution of system failures is the most frequent secondary task identified during the medication preparation phase. To effectively reduce the number of work interruptions experienced by nurses, system level interventions addressing these factors are required. Ultimately, these interventions will contribute to maximizing medication administration safety within healthcare organizations.

Clinical resources

The Institute for Safe Medication Practices: www.ismp.org
Canadian Patient Safety Institute: http://www.patientsafetyinstitute.ca
NHS National Patient Safety Agency: http://www.npsa.nhs.uk/nrls/medication-zone/

Chapter 5 Final Conclusions and Summary

The overall objective of this dissertation was to examine the predictive power of three potential contributing factors to MAE: medication administration complexity, work interruptions, and nurses' workload on a medical unit in a university teaching hospital. Four manuscripts emerged from this dissertation:

Manuscript #1: Work interruptions and their contribution to medication administration errors: an evidence review.

Manuscript #2: Medication Administration Complexity Scale : Development and Psychometric Testing

Manuscript #3: Medication Administration Complexity, Work Interruptions, and Nurses' Workload as Predictors of Medication Administration Errors

Manuscript #4: Characteristics of work interruptions as contributors to medication administration errors: A descriptive study.

This section summarizes the main findings that have emerged from this dissertation. This summary sets the stage to identify potential implications derived from the findings in light of the inherent limitations of the work presented herein.

Errors and Violations: Two Dimensions of Unsafe Medication Administration Practices with Different Predictors

Different clusters of predictors were found depending on the inclusion or exclusion of wrong medication administration time errors from the analysis. When wrong administration time errors were excluded and controlling for professional experience, a

work interruption during the medication preparation phase and overtime worked within the past seven days significantly increased the odds of MAE. Patient demand for nursing care contributed significantly and its effect was moderated by overtime and professional experience. Coordinative medication administration complexity, contrary to expectation, was associated significantly with a decrease in the odds of MAE (figure 6).

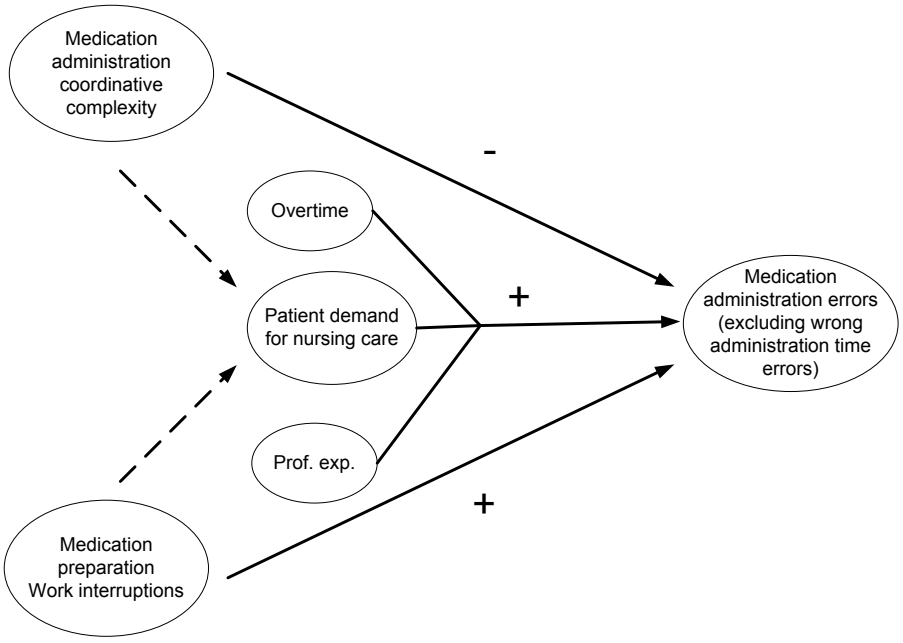

Figure 6 : Summary framework of medication administration errors predictors when excluding wrong administration time errors.

When including wrong medication administration time errors, component medication administration complexity and patient demand for nursing care increased the odds of MAE while controlling for nursing education and time of administration. Work interruptions significantly predicted nurses' perceived patient demand for nursing care and medication errors while work interruptions became non-significant when workload

was introduced in the model - supporting the possible mediating effect of workload in the relationship between work interruptions and medication administration errors (figure 7)

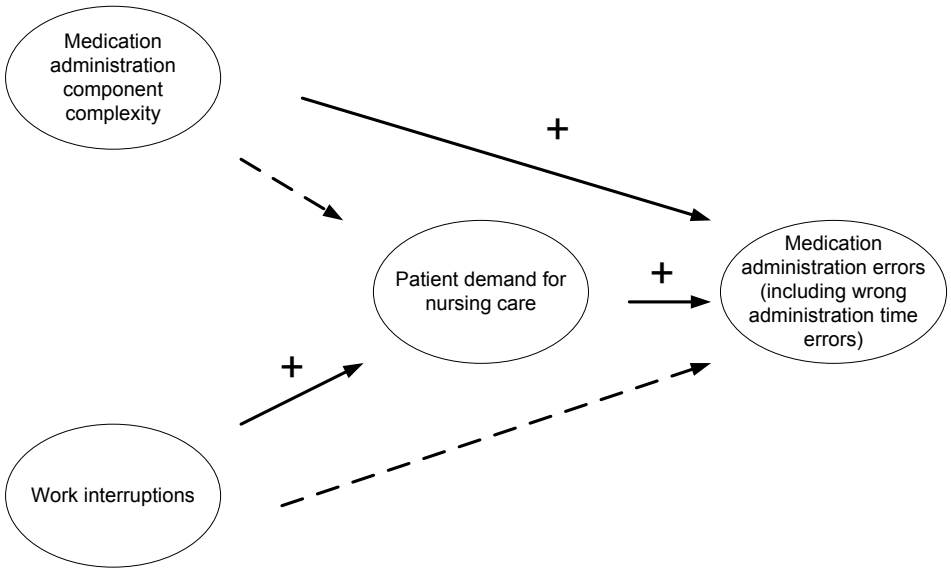

Figure 7 Summary framework of medication administration errors predictors when including wrong administration time errors

Wrong administration time errors were proposed to be conceptually different from medication administration errors to explain this observed difference. Wrong administration time errors might better reflect the concept of violation to practice standards. Violation of practice standards implies the deliberate deviation from known practices deemed necessary to maintain safe operation (Reason, 1990). These two concepts form unsafe medication administration practices (UMAP). An increased patient demand for nursing care and component medication administration complexity reflect an increased number of actions to be performed by a nurse within a given time. Nurses often develop adaptive strategies to manage increase demands. Such adaptive strategies were deliberately selected by nurses in this study by administering medications scheduled for 8.00 hr and 10.00 hr together, to save time.

These documented predictors provide new evidence on the possible underlying causes of medication administration errors and violation of practices standards. This enhanced understanding of MAE predictors would guide the selection of prevention strategies. MAE prevention strategies should also consider some of the key evidence generated for each of the main predictors summarized in the next sections.

Medication administration complexity

The finding that coordinative medication administration complexity had protective effects was not expected. This protective effect may be triggered by the inherent additional verification performed by nurses for these medications. The medication administration records (MAR) is read twice: once to determine whether additional patient information is required and again, to determine the dose to be administered according to this information. This double verification is part of safety strategies recommended to prevent errors (Reason, 1990).

Component medication administration complexity was found to be a significant predictor of MAE, when wrong administration time errors were included. Component complexity is the sum of all steps required and information cues processed by the nurse during medication administration (Wood, 1986). This finding may reflect nurses' difficulty to administer medication, as scheduled, as the number of actions and information cues processed increase.

Work interruptions

A better understanding of work interruption characteristics was sought because significantly associated to MAE. Nurses themselves were the main source of work

interruptions along with system failures during medication preparation. Nurses interrupted other nurses who were preparing medication mostly to discuss personal matters and to provide verbal reports of patient status. The most frequent secondary task undertaken by nurses when interrupted included system failure resolutions and coordination of care.

Congruent with a system perspective, assessing at nurses' modes of medication administration such as central medication rooms, medication carts, or cabinets within patient's room and comparing nurses' work interruptions rates for these different modes could assist in the selection of medication-use systems. The objective of this selection process is to minimize the number of work interruptions experienced by nurses. Such intervention at the system level could represent an effective and sustainable way to reduce work interruptions during medication administration thus, enhancing medication administration safety.

MAE associated to the medication preparation phase are seldom intercepted. An avenue to counteract this, is the implementation of defence barriers to intercept medication administration errors before reaching patients. Bar-code assisted medication administration is an example of such defence barrier. Bar-code assisted medication administration is a technology that allows a double-verification by scanning a barcode found on the patient's identification wristband and on the unit dose package, allowing the system determine if there is a match. Studies supporting the efficacy of such technology in preventing medication administration errors from reaching patients are emerging (Morriss et al., 2009). The nursing community should promote the development and

testing of such technologies and their efficacy in maximizing medication administration safety.

Workload

Nurses' perceived patient demand for nursing care increased the odds of MAE and its effect was moderated by overtime and professional experience. The significant interaction between patient demand for nursing care and overtime brings new insights to the potential relationship between overtime and MAE. Overtime (> 40 hours per week) has been previously reported to predict MAE with an odd ratio of similar magnitude but using self-reported errors rather than direct observation. This study adds robustness to this evidence. Nurses' perceived patient care demand was also found to be a significant predictor when wrong administration time errors were included (with no interactions effects).

Measuring nurses' workload remains a challenge. In this dissertation, nurses' subjective workload data were collected using two self-report measures: the NASA-TLX (Hart & Staveland, 1988) and a single item inquiring about nurses' perceptions of patients' demand for nursing care. Patient demand for nursing care was conceptualized as contributing to nurses' workload (Morris et al., 2007). The mean score for the performance dimension, the only negatively-worded item, was twice the average mean score found on other dimensions. This finding may indicate validity issues with the NASA-TLX in the context of this study. Although the use of single items to measure workload is common in ergonomic (Carayon & Gurses, 2005), this practice has a number of limitations. Efforts should be pursued to identify a more valid and reliable measure of

nurses' workload to overcome the existing issues about workload measurement in relation (Carayon & Gurses, 2005).

Medication administration complexity and work interruptions as predictors of nurses' workload

The adoption of a system perspective calls, not only for a consideration of system-level predictors, but also the presence of any mediating or interacting effect among predictors (Reason, 1990; Wilson, 2000). The examination of such possibility in this dissertation is a departure from previous research (Hoff et al., 2004). Work interruptions significantly predicted nurses' perceived patient demand for nursing of care and medication errors whereas work interruptions became non-significant when workload was introduced in the model. This finding supports the potential mediating effect of workload in the relationship between work interruptions and medication administration errors.

Medication administration complexity was not a significant predictor of perceived demand for nursing care. The effect of medication administration complexity of either of its dimensions thus, was not mediated by perceived patient demand for nursing care. This non-significant relationship does not support the theoretical proposition put forward by Campbell (1988). The potential validity issues of the NASA-TLX to assess nurses' subjective workload may help explain these findings.

UMAP Model

The evidence produced in this dissertation support the role of medication administration complexity, work interruptions, and nurses' workload as error producing and violation producing conditions as conceptualized by the Human Error Model

(Reason, 1990) and adapted in this dissertation to the context of UMAP (figure 1). Error producing conditions are influenced by organizational level factors such as safety culture and nursing leadership as depicted in the UMAP model. Further, organizations with high-risk processes have defence barriers acting as safeguards to prevent errors from reaching patients. The model reminds us that UMAP occurrences are multifactorial. The evidence produced in this dissertation contributes to an enhanced understanding, in turn, can translate into better prevention of their occurrences.

Dissertation strengths

Medication administration complexity, work interruptions, and nursing workload have been proposed as potential robust predictors, but the methods used have considerably limited the inferences that can be drawn. Previous attempts to examine these predictors have almost exclusively been based on secondary data analyses of administrative databases. Reliance on administrative databases to study MAE predictors constitutes an important limitation partly because MAE are systematically underreported (Flynn et al., 2002). A new approach, which focuses on a micro level analysis using direct observation, was used in this dissertation to overcome prior methodological flaws problems. An additional limitation of prior studies is the absence of a theoretical basis for predicting suboptimal medication administration (White & McGillis Hall, 2003). Models depicting predictors are seldom found (Hoff et al., 2004). This limitation is particularly important considering that both work interruptions (Speier et al., 2003) and task complexity (Campbell, 1988) have been conceptualized as workload contributors. Congruent with a system's perspective (Wilson, 2000), the evidence produced herein supports the complex nature of the relation between predictors studied and MAE through

documented interactions and mediating effects. These theoretical and methodological innovations enhance the overall quality of the evidence produced.

Limitations

Limitations to this dissertation include issues related to study design, sampling strategy, data collection, and the selection of MAE as the main dependent variable. Correlational designs do not allow determination of causal relationships. More robust designs would be required to establish causal relationships. Predictors point to the potential causal relationships but do not establish them. Correlational designs, also, need representative samples for results to be generalizable. A non-probability sampling strategy was used herein, which may lead to sampling bias. Nurse participants were more educated and less experienced compared to other nurses working in similar settings in Quebec, Canada. On the other hand, the low refusal enhanced the generalisability of the results.

The possibility of a Hawthorne effect associated with direct observations represents another potential limitation. Rigorous observer training was provided to limit this possibility, and there was no significant change in the observed MAE rate per participant over time. Trends in the data would have occurred if nurses became accustomed to being observed. Last, the clinical significance of observed MAE is unknown. At the same time, medication administration is a high risk process frequently performed by nurses and thus, it provides a unique opportunity to efficiently study the influence of nurses' work environment on patient safety.

Implications

If corroborated by further investigations, the following implications are formulated based on the research evidence produced in this dissertation.

Practice

1. Efforts should be made to reduce the number of work interruptions particularly during the medication preparation phase.
2. System-level interventions to reduce the number of work interruptions experienced while preparing medication by nurses should target nurses who are the main work interruption sources.
3. Improving medication administration system's efficiency is clearly needed as system failure resolution is the most important secondary task carried out following work interruptions during the medication preparation phase.
4. Overtime should be used with caution based on the accumulating evidence and the added predicting effect of nurses' workload on medication administration errors.
5. The establishment of defence barriers should be encouraged to enable intercepting medication administration errors before reaching patients.

Future Research

1. The predictive power of medication administration complexity, work interruptions, nurses' workload and overtime with clinically significant MAE as the dependent variable (those associated to an adverse outcome for a patient, including an injury or complication) should be examined. Such study would consider:
    a. Using a validated and reliable measure of nurses' workload.

   b. Document overtime in more detail (e.g. when performed and record the actual number of hours worked overtime).

2. System level intervention studies documenting the impact of different medication-use system (central medication room, movable medication carts, beside lockers) on nurses' work interruptions rates and MAE.
3. The presence of a potential protective effect associated to medication administration coordinative complexity should be further studied. An enhanced understanding of this protective effect may provide novel ways to maximize medication administration safety.

Conclusion

The examination of system-related predictors of MAE is at a crucial point in time (Perneger, 2006). The evidence produced in this dissertation contributes to an enhanced understanding of the underlying causes of MAE. A better understanding of MAE underlying causes is essential to intervene effectively in preventing MAE occurrences. These interventions are certainly needed as a significant number of patients are unnecessarily harmed every day due to medication errors. The path leading to a safer healthcare is certainly tortuous. Evidence produced through research can, however, contribute to discovering better paths to follow. This was the objective pursued by examining medication administration complexity, work interruptions, and workload as predictors of MAE.

References

Agency for Healthcare Research and Quality. (2002). Systems to Rate the Strength of Scientific Evidence. Retrieved April 1st, 2008, from http://www.ahrq.gov/clinic/epcindex.htm

Allan, E. L., & Barker, K. N. (1990). Fundamentals of medication error research. *Am J Hosp Pharm, 47*(3), 555-571.

Alvarez, G., & Coiera, E. W. (2005). Interruptive communication patterns in the intensive care unit ward round. *Int J Med Inform, 74*(10), 791-796.

Armitage, G. (2005). Drug errors, qualitative research and some reflections on ethics. *J Clin Nurs, 14*(7), 869-875.

Armitage, G., & Knapman, H. (2003). Adverse events in drug administration: A literature review. *J Nurs Manag, 11*(2), 130-140.

Armutlu, M., Foley, M.-L., Surette, J., Belzile, E., & Jane, M. (2008). Survey of nursing perceptions of medication administration practices, perceived sources of errors and reporting behaviours. *Healthcare Quarterly, 11*(Sp), 58-65.

Aspden, P. (2007). *Preventing Medication Errors*. Quality Chasm Serie. Washington, DC: National Academies Press.

Baer, D. M., Harrison, R., Fradenburg, L., Petersen, D., & Milla, S. (2005). Some pragmatics in the valid and reliable recording of directly observed behavior. *Research on Social Work Practice, 15*(6), 440-451.

Bakeman, R. (2000). Behavioral Observation and Coding. In H. T. Reis & C. M. Judd (Eds.), *Handbook of Research Methods in Social and Personality Psychology* (pp. 138-159). Cambridge, UK: Cambridge University Press.

Balas, M. C., Scott, L. D., & Rogers, A. E. (2004). The prevalence and nature of errors and near errors reported by hospital staff nurses. *Applied Nursing Research, 17*(4), 224-230.

Barker, K. N., Flynn, E. A., & Pepper, G. A. (2002). Observation method of detecting medication errors. *Am J Health Syst Pharm, 59*(23), 2314-2316.

Barker, K. N., Flynn, E. A., Pepper, G. A., Bates, D. W., & Mikeal, R. L. (2002). Medication errors observed in 36 health care facilities. *Arch Intern Med, 162*(16), 1897-1903.

Baron, R. M., & Kenny, D. A. (1986). The moderator-mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *J Pers Soc Psychol, 51*(6), 1173-1182.

Bates, D. W. (2008). Mountains in the clouds: Patient safety research. *Qual Saf Health Care, 17*(3), 156-157.

Bates, D. W., Cullen, D. J., Laird, N., Petersen, L. A., Small, S. D., Servi, D., et al. (1995). Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *Jama, 274*(1), 29-34.

Bennett, J., Harper-Femson, L. A., Tone, J., & Rajmohamed, Y. (2006). Improving medication administration systems: An evaluation study. *Can Nurse, 102*(8), 35-39.

Birkimer, J. C., & Brown, J. H. (1979). Back to basics: Percentage agreement measures are adequate, but there are easier ways. *Journal of Applied Behavior Analysis, 12*(4), 535-543.

Biron, A. D., Loiselle, C., & Lavoie-Tremblay, M. (submitted). Medication administration complexity scale: Development and psychometric testing. *International Journal for Quality in Health Care*.

Blegen, M. A., Goode, C. J., & Reed, L. (1998). Nurse staffing and patient outcomes. *Nurs Res, 47*(1), 43-50.

Blegen, M. A., & Vaughn, T. (1998). A multisite study of nurse staffing and patient occurrences. *Nurs Econ, 16*(4), 196-203.

Bond, C. A., Raehl, C. L., & Franke, T. (2001). Medication errors in United States hospitals. *Pharmacotherapy, 21*(9), 1023-1036.

Brixey, J. J., Robinson, D. J., Johnson, C. W., Johnson, T. R., Turley, J. P., & Zhang, J. (2007). A concept analysis of the phenomenon interruption. *Advances in Nursing Science, 30*(1), E26-42.

Brixey, J. J., Tang, Z., Robinson, D. J., Johnson, C. W., Johnson, T. R., Turley, J. P., et al. (2008). Interruptions in a level one trauma center: A case study. *Int J Med Inform, 77*(4), 235-241.

Burroughs, T. E., Waterman, A. D., Gallagher, T. H., Waterman, B., Jeffe, D. B., Clairborne Dunagan, W., et al. (2008). Patients concerns about medical errors during hospitalization. *Joint Commission Journal on Quality and Patient Safety, 33*(1), 5-14.

Campbell, D. J. (1988). Task complexity - A review and analysis. *Academy of Management Review, 13*(1), 40-52.

Campbell, D. J., & Gingrich, K. F. (1986). The interactive effects of task complexity and participation on task-performance - a field experiment. *Organizational Behavior and Human Decision Processes, 38*(2), 162-180.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada. (1998). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (with 2000, 2002, 2005 amendments)*. Retrieved December 12th, 2006. from www.pre.ethis.gc.ca.

Canadian Patient Safety Institute. (2003). The Canadian Patient Safety Dictionary. Retrieved September 21st 2005, from http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf

Carayon, P., & Gurses, A. P. (2005). A human factors engineering conceptual framework of nursing workload and patient safety in intensive care units. *Intensive Crit Care Nurs, 21*(5), 284-301.

Carayon, P., Wetterneck, T., Hundt, A., Ozkaynak, M., DeSilvey, J., Ludwig, B., et al. (2007). Evaluation of nurse interaction with bar code medication admnistration technology in the work environment. *Journal of Patient Safety, 3*(1), 34-42.

Carlton, G., & Blegen, M. A. (2006). Medication-related errors: A literature review of incidence and antecedents. *Annu Rev Nurs Res, 24*, 19-38.

Caruso, C. C. (2006). Possible broad impacts of long work hours. *Ind Health, 44*(4), 531-536.

Caruso, C. C., Bushnell, T., Eggerth, D., Heitmann, A., Kojola, B., Newman, K., et al. (2006). Long working hours, safety, and health: Toward a national research agenda. *Am J Ind Med, 49*(11), 930-942.

Charness, N. (2008). Aging and human performance. *Hum Factors, 50*(3), 548-555.

Chinburapa, V., Larson, L. N., Brucks, M., Draugalis, J., Bootman, J. L., & Puto, C. P. (1993). Physician prescribing decisions: The effects of situational involvement

and task complexity on information acquisition and decision making. *Soc Sci Med, 36*(11), 1473-1482.

Cho, S. H., Ketefian, S., Barkauskas, V. H., & Smith, D. G. (2003). The effects of nurse staffing on adverse events, morbidity, mortality, and medical costs. *Nurs Res, 52*(2), 71-79.

Clarke, S. P. (2005). The policy implications of staffing-outcomes research. *J Nurs Adm, 35*(1), 17-19.

Clarke, S. P. (2009). Three metaphors and a (mis)quote: Thinking about staffing-outcomes research, health policy and the future of nursing. *Journal of Nursing Management, 17*(2), 151-154.

Classen, D. C., Pestotnik, S. L., Evans, R. S., Lloyd, J. F., & Burke, J. P. (1997). Adverse drug events in hospitalized patients: Excess length of stay, extra costs, and attributable mortality. *JAMA, 277*(4), 301-306.

Cochrane Effective Practice and Organisation of Care Review Group. (2002). The data Collection Checklist. Retrieved April 1st, 2008, from www.epoc.uottawa.ca/checklist2002.doc

Cohen, H., Robinson, E. S., & Mandrack, M. (2003). Getting to the root of medication errors: Survey results. *Nursing, 33*(9), 36-45.

Coiera, E. W., Jayasuriya, R. A., Hardy, J., Bannan, A., & Thorpe, M. E. (2002). Communication loads on clinical staff in the emergency department. *Med J Aust, 176*(9), 415-418.

Coiera, E. W., & Tombs, V. (1998). Communication behaviours in a hospital setting: an observational study. *BMJ, 316*(7132), 673-676.

College of Nurses of Ontario. (2005). *Practice Standard: Medication.* . Toronto: College of Nurses of Ontario.

Cooper, M. D. (2000). Towards a model of safety culture. *Safety Science, 36*(2), 111.

Crigger, N. (2005). Two models of mistake-making in professional practice: Moving out of the closet. *Nurs Philos, 6*(1), 11-18.

Cummings, J., Bush, P., Smith, D., & Matuszewski, K. (2005). Bar-coding medication administration overview and consensus recommendations. *Am J Health Syst Pharm, 62*(24), 2626-2629.

Darchy, B., Le Miere, E., Figueredo, B., Bavoux, E., & Domart, Y. (1999). Iatrogenic diseases as a reason for admission to the intensive care unit: Incidence, causes, and consequences. *Arch Intern Med, 159*(1), 71-78.

Dean, B., & Barber, N. (2001). Validity and reliability of observational methods for studying medication administration errors. *Am J Health Syst Pharm, 58*(1), 54-59.

Diaz-Navarlaz, T., & Segui-Gomez, M. (2006). Commentary on Armitage G (2005) Drug errors, qualitative research and some reflections on ethics. *J Clin Nurs, 15*(9), 1208-1209.

Duclos, C. W., Eichler, M., Taylor, L., Quintela, J., Main, D. S., Pace, W., et al. (2005). Patient perspectives of patient-provider communication after adverse events. *Int J Qual Health Care, 17*(6), 479-486.

Ebright, P. R., Patterson, E. S., Chalko, B. A., & Render, M. L. (2003). Understanding the complexity of registered nurse work in acute care settings. *J Nurs Adm, 33*(12), 630-638.

Evans, R. S., Lloyd, J. F., Stoddard, G. J., Nebeker, J. R., & Samore, M. H. (2005). Risk factors for adverse drug events: A 10-year analysis. *Ann Pharmacother, 39*(7-8), 1161-1168.

Evans, S. M., Berry, J. G., Smith, B. J., Esterman, A., Selim, P., O'Shaughnessy, J., et al. (2006). Attitudes and barriers to incident reporting: A collaborative hospital study. *Quality & Safety in Health Care, 15*(1), 39-43.

Fairbanks, R. J., Bisantz, A. M., & Sunm, M. (2007). Emergency department communication links and patterns. *Ann Emerg Med, 50*(4), 396-406.

Fischman, M. W. (2000). Informed Consent. In B. D. Sales & S. Folkman (Eds.), *Ethics in Research with Human Participants* (pp. 35-49). Washington, D.C.: American Psychological Association.

Flynn, E. A., Barker, K. N., Pepper, G. A., Bates, D. W., & Mikeal, R. L. (2002). Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm, 59*(5), 436-446.

Gillie, T., & Broadbent, D. E. (1989). What makes interruptions disruptive? A study of length, similarity, and complexity. *Psychological Research, 50*(4), 243-250.

Ginsburg, L., Norton, P. G., Casebeer, A., & Lewis, S. (2005). An educational intervention to enhance nurse leaders' perceptions of patient safety culture. *Health Serv Res, 40*(4), 997-1020.

Gladstone, J. (1995). Drug administration errors: a study into the factors underlying the occurrence and reporting of drug errors in a district general hospital. *J Adv Nurs, 22*(4), 628-637.

Grandell-Niemi, H., Hupli, M., Leino-Kilpi, H., & Puukka, P. (2003). Medication calculation skills of nurses in Finland. *J Clin Nurs, 12*(4), 519-528.

Greengold, N. L., Shane, R., Schneider, P., Flynn, E., Elashoff, J., Hoying, C. L., et al. (2003). The impact of dedicated medication nurses on the medication administration error rate: A randomized controlled trial. *Arch Intern Med, 163*(19), 2359-2367.

Han, P. Y., Coombes, I. D., & Green, B. (2005). Factors predictive of intravenous fluid administration errors in Australian surgical care wards. *Qual Saf Health Care, 14*(3), 179-184.

Handler, J. A., Feied, C. F., Coonan, K., Vozenilek, J., Gillam, M., Peacock, P. R., Jr., et al. (2004). Computerized physician order entry and online decision support. *Acad Emerg Med, 11*(11), 1135-1141.

Hart, S., & Staveland, L. (1988). Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. In P. A. H. a. N. Meshkati (Ed.), *Human Mental Workload* (pp. 139-183). Amsterdam: North-Holland.: Elsevier Science Pub.

Hartmann, D. P. (1977). Considerations in the choice of interobserver reliability estimates. *J Appl Behav Anal, 10*(1), 103-116.

Healey, A. N., Sevdalis, N., & Vincent, C. A. (2006). Measuring intra-operative interference from distraction and interruption observed in the operating theatre. *Ergonomics, 49*(5-6), 589-604.

Hearld, L. R., Alexander, J. A., Fraser, I., & Jiang, H. J. (2008). Review: how do hospital organizational structure and processes affect quality of care? A critical review of research methods. *Med Care Res Rev, 65*(3), 259-299.

Hedberg, B., & Larsson, U. S. (2004). Environmental elements affecting the decision-making process in nursing practice. *J Clin Nurs, 13*(3), 316-324.

Hicks, R. W., Becker, S. C., Krenzischeck, D., & Beyea, S. C. (2004). Medication errors in the PACU: A secondary analysis of MEDMARX findings. *J Perianesth Nurs, 19*(1), 18-28.

Higgins, J., & Green, S. (Eds.). (2008). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.0*: The Cochrane Collaboration.

Hoff, T., Jameson, L., Hannan, E., & Flink, E. (2004). A review of the literature examining linkages between organizational factors, medical errors, and patient safety. *Med Care Res Rev, 61*(1), 3-37.

Hoonhout, L. H., de Bruijne, M. C., Wagner, C., Zegers, M., Waaijman, R., Spreeuwenberg, P., et al. (2009). Direct medical costs of adverse events in Dutch hospitals. *BMC Health Serv Res, 9*, 27.

Hopp, P. J., Smith, C. A., Clegg, B. A., & Heggestad, E. D. (2005). Interruption management: The use of attention-directing tactile cues. *Hum Factors, 47*(1), 1-11.

Hosmer, D. W., & Lemeshow, S. (2000). *Applied Logistic Regression* (2nd ed.). New York: Wiley.

Hughes, R. G., & Ortiz, E. (2005). Medication Errors: Why they happen, and how they can be prevented. *Am J Nurs, 105*(3), 14-24.

Hurley, A. C., Bane, A., Fotakis, S., Duffy, M. E., Sevigny, A., Poon, E. G., et al. (2007). Nurses' satisfaction with medication administration point-of-care technology. *J Nurs Adm, 37*(7-8), 343-349.

Institute for Safe Medication Practices. (2008). ISMP's List of High-Alert Medications. December 7th 2008, retrieved from http://www.ismp.org/Tools/highalertmedications.pdf

Kanjanarat, P., Winterstein, A. G., Johns, T. E., Hatton, R. C., Gonzalez-Rothi, R., & Segal, R. (2003). Nature of preventable adverse drug events in hospitals: A literature review. *Am J Health Syst Pharm, 60*(17), 1750-1759.

Kirmeyer, S. L. (1988). Coping with competing demands: Interruption and the Type A pattern. *Journal of Applied Psychology, 73*(4), 621-629.

Kohn, L. T., Corrigan, J., Donaldson, M. S., & Institute of Medicine (U.S.). Committee on Quality of Health Care in America. (2000). *To Err is Human : Building a Safer Health System*. Washington, D.C.: National Academy Press.

Kopp, B. J., Erstad, B. L., Allen, M. E., Theodorou, A. A., & Priestley, G. (2006). Medication errors and adverse drug events in an intensive care unit: Direct observation approach for detection. *Crit Care Med, 34*(2), 415-425.

Kozier, B. (2000). *Fundamentals of Nursing : Concepts, Process, and Practice* (6th ed.). Upper Saddle River, N.J.: Prentice Hall Health.

Kuzel, A. J., Woolf, S. H., Gilchrist, V. J., Engel, J. D., LaVeist, T. A., Vincent, C., et al. (2004). Patient reports of preventable problems and harms in primary health care. *Ann Fam Med, 2*(4), 333-340.

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *Biometrics, 33*(1), 159-174.

Lane, R., Stanton, N. A., & Harrison, D. (2006). Applying hierarchical task analysis to medication administration errors. *Appl Ergon, 37*(5), 669-679.

Larsen, G. Y., Parker, H. B., Cash, J., O'Connell, M., & Grant, M. C. (2005). Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. *Pediatrics, 116*(1), e21-25.

Leape, L. L., Bates, D. W., Cullen, D. J., Cooper, J., Demonaco, H. J., Gallivan, T., et al. (1995). Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA, 274*(1), 35-43.

Lisby, M., Nielsen, L. P., & Mainz, J. (2005). Errors in the medication process: Frequency, type, and potential clinical consequences. *Int J Qual Health Care, 17*(1), 15-22.

Luketich, J. D., Fernando, H. C., Buenaventura, P. O., Christie, N. A., Grondin, S. C., & Schauer, P. R. (2002). Results of a randomized trial of HERMES-assisted vs non-HERMES-assisted laparoscopic antireflux surgery. *Surgical Endoscopy, 16*(9), 1264-1266.

Lyons, M., Brown, R., & Wears, R. (2007). Factors that affect the flow of patients through triage. *Emerg Med J, 24*(2), 78-85.

Mangione-Smith, R., Elliott, M. N., McDonald, L., & McGlynn, E. A. (2002). An observational study of antibiotic prescribing behavior and the Hawthorne effect. *Health Serv Res, 37*(6), 1603-1623.

Manias, E., Botti, M., & Bucknall, T. (2002). Observation of pain assessment and management--the complexities of clinical practice. *J Clin Nurs, 11*(6), 724-733.

Mark, B. A., & Belyea, M. (2009). Nurse staffing and medication errors: Cross-sectional or longitudinal relationships? *Res Nurs Health, 32*(1), 18-30.

Marsch, S. C., Tschan, F., Semmer, N., Spychiger, M., Breuer, M., & Hunziker, P. R. (2005). Unnecessary interruptions of cardiac massage during simulated cardiac arrests. *Eur J Anaesthesiol, 22*(11), 831-833.

Maynard, D. C., & Hakel, M. D. (1997). Effects of objective and subjective task complexity on performance. *Human Performance, 10*(4), 303-330.

Mays, N., & Pope, C. (2000). Qualitative research in health care: Assessing quality in qualitative research. *BMJ, 320*(7226), 50-52.

McFarlane, D. C., & Latorella, K. A. (2002). The scope and importance of human interruption in human-computer interaction design. *Human-Computer Interaction, 17*(1), 1-63.

McFarlane, D.C. (2002). Comparison of four primary methods for coordinating the interruption of people in human-computer. Human-computer interaction, 17(1), 63-169.

McGillis Hall, L., Doran, D., & Pink, G. H. (2004). Nurse staffing models, nursing hours, and patient safety outcomes. *J Nurs Adm, 34*(1), 41-45.

McLean, D. (2006). Medicines administration rounds can be led by pharmacy technicians. *Pharmacy in Practice, 16*(1), 19-23.

Medland, J. J., & Ferrans, C. E. (1998). Effectiveness of a structured communication program for family members of patients in an ICU. *American Journal of Critical Care, 7*(1), 24-29.

Morris, R., MacNeela, P., Scott, A., Treacy, P., & Hyde, A. (2007). Reconsidering the conceptualization of nursing workload: Literature review. *J Adv Nurs, 57*(5), 463-471.

Morriss, F. H., Jr., Abramowitz, P. W., Nelson, S. P., Milavetz, G., Michael, S. L., Gordon, S. N., et al. (2009). Effectiveness of a barcode medication administration system in reducing preventable adverse drug events in a neonatal intensive care unit: A prospective cohort study. *J Pediatr, 154*, 363-368.

National Coordinating Council for Medication Error Reporting and Prevention. (2006). About Medication Errors. Retrieved May 25th, 2006, from http://www.nccmerp.org/aboutMedErrors.html

Nebeker, J. R., Hoffman, J. M., Weir, C. R., Bennett, C. L., & Hurdle, J. F. (2005). High rates of adverse drug events in a highly computerized hospital. *Arch Intern Med, 165*(10), 1111-1116.

Needleman, J., Buerhaus, P., Mattke, S., Stewart, M., & Zelevinsky, K. (2001). *Nurse Staffing and Patient Outcomes in Hospitals*. Boston: Harvard School of Public Health.

Nicklin, W., Mass, H., Affonso, D. D., O'Connor, P., Ferguson-Pare, M., Jeffs, L., et al. (2004). Patient safety culture and leadership within Canada's Academic Health Science Centres: Towards the development of a collaborative position paper. *Can J Nurs Leadersh, 17*(1), 22-34.

Nolan, T. W. (2000). System changes to improve patient safety. *BMJ, 320*(7237), 771-773.

O'Brien-Pallas, L., Irvine, D., Peereboom, E., & Murray, M. (1997). Measuring nursing workload: Understanding the variability. *Nurs Econ, 15*(4), 171-182.

Ordre des infirmières et infirmiers du Québec. (2008). *Rapport statistique sur l'effectif infirmier 2007-2008*. Westmount: Ordre des infirmières et infirmiers du Québec.

Page, A. (2004). *Keeping Patients Safe : Transforming the Work Environment of Nurses*. Washington, D.C.: National Academies Press.

Pape, T. M. (2003). Applying airline safety practices to medication administration. *Medsurg Nurs, 12*(2), 77-93.

Pape, T. M., Guerra, D. M., Muzquiz, M., Bryant, J. B., Ingram, M., Schranner, B., et al. (2005). Innovative approaches to reducing nurses' distractions during medication administration. *J Contin Educ Nurs, 36*(3), 108-116.

Patterson, E. S., Rogers, M. L., Chapman, R. J., & Render, M. L. (2006). Compliance with intended use of barcode medication administration in acute and long-term care: An observational study. *Hum Factors, 48*(1), 15-22.

Patton, M. Q. (2002). *Qualitative research & evaluation methods* (3rd ed.). Thousand Oaks, Calif.: Sage Publications.

Paxton, F., Heaney, D., Howie, J., & Porter, B. A. (1996). A study of interruption rates for practice nurses and GPs. *Nurs Stand, 10*(43), 33-36.

Perlow, L. A. (1999). The time famine: Toward a sociology of work time. Administrative Science Quarterly, 44(1), 57-81.

Perneger, T. V. (2006). A research agenda for patient safety. *Int J Qual Health Care, 18*(1), 1-3.

Philibert, I. (2005). Sleep loss and performance in residents and nonphysicians: A meta-analytic examination. *Sleep, 28*(11), 1392-1402.

Portney, L. G., & Watkins, M. P. (2000). *Foundations of Clinical Research : Applications to Practice* (2nd ed.). Upper Saddle River, NJ: Prentice Hall.

Potter, P., Wolf, L., Boxerman, S., Grayson, D., Sledge, J., Dunagan, C., et al. (2005). Understanding the cognitive work of nursing in the acute care environment. *J Nurs Adm, 35*(78), 327-335.

Pronovost, P. J., & Sexton, B. (2005). Assessing safety culture: guidelines and recommendations. *Qual Saf Health Care, 14*(4), 231-233.

Pronovost, P. J., Thompson, D. A., Holzmueller, C. G., Lubomski, L. H., & Morlock, L. L. (2005). Defining and measuring patient safety. *Crit Care Clin, 21*(1), 1-19.

Prot, S., Fontan, J. E., Alberti, C., Bourdon, O., Farnoux, C., Macher, M. A., et al. (2005). Drug administration errors and their determinants in pediatric in-patients. *Int J Qual Health Care, 17*(5), 381-389.

Rasmussen, J. (1986). *Information Processing and Human-Machine Interaction : An Approach to Cognitive Engineering*. New York: North-Holland.

Reason, J. T. (1990). *Human Error*. Cambridge England ; New York: Cambridge University Press.

Rochon, J. (1998). Application of GEE procedures for sample size calculations in repeated measures experiments. *Stat Med, 17*(14), 1643-1658.

Rogers, A. E., Hwang, W. T., Scott, L. D., Aiken, L. H., & Dinges, D. F. (2004). The working hours of hospital staff nurses and patient safety. *Health Aff (Millwood), 23*(4), 202-212.

Roseman, C., & Booker, J. M. (1995). Workload and environmental factors in hospital medication errors. *Nurs Res, 44*(4), 226-230.

Rubio, S., Diaz, E., Martin, J., & Puente, J. M. (2004). Evaluation of subjective mental workload: A comparison of SWAT, NASA-TLX, and workload profile methods. *Applied Psychology: An International Review, 53*(1), 61-86.

Ruchlin, H. S., Dubbs, N. L., & Callahan, M. A. (2004). The role of leadership in instilling a culture of safety: Lessons from the literature. *J Healthc Manag, 49*(1), 47-58; discussion 58-49.

Scott-Cawiezell, J., Pepper, G. A., Madsen, R. W., Petroski, G., Vogelsmeier, A., & Zellmer, D. (2007). Nursing home error and level of staff credentials. *Clin Nurs Res, 16*(1), 72-78.

Scott, L. D., Rogers, A. E., Hwang, W. T., & Zhang, Y. (2006). Effects of critical care nurses' work hours on vigilance and patients' safety. *Am J Crit Care, 15*(1), 30-37.

Sevdalis, N., Healey, A. N., & Vincent, C. A. (2007). Distracting communications in the operating theatre. *J Eval Clin Pract, 13*(3), 390-394.

Shepherd, A. (2001). *Hierarchical Task Analysis*. London ; New York: Taylor & Francis.

Shoukri, M. M., Asyali, M. H., & Donner, A. (2004). Sample size requirements for the design of reliability study: Review and new results. *Statistical Methods in Medical Research, 13*(4), 251-271.

Shrout, P. E., & Fleiss, J. L. (1979). Intraclass correlations - uses in assessing rater reliability. *Psychological Bulletin, 86*(2), 420-428.

Sim, J., & Wright, C. C. (2005). The kappa statistic in reliability studies: Use, interpretation, and sample size requirements. *Phys Ther, 85*(3), 257-268.

Smith, S. F., Duell, D., & Martin, B. (2000). *Clinical Nursing Skills: Basic to Advanced Skills* (5th ed.). Upper Saddle River, N.J.: Prentice Hall Health.

Sochalski, J. (2004). Is more better? The relationship between nurse staffing and the quality of nursing care in hospitals. *Med Care, 42*(2 Suppl), II67-73.

Speier, C., Vessey, I., & Valacich, J. S. (2003). The effects of interruptions, task complexity, and information presentation on computer-supported decision-making performance. *Decision Sciences, 34*(4), 771-797.

Spencer, R., Coiera, E., & Logan, P. (2004). Variation in communication loads on clinical staff in the emergency department. *Annals of Emergency Medicine, 44*(3), 268-273.

Stanton, N. A. (2006). Hierarchical task analysis: Developments, applications, and extensions. *Appl Ergon, 37*(1), 55-79.

Stetina, P., Groves, M., & Pafford, L. (2005). Managing medication errors--a qualitative study. *Medsurg Nurs, 14*(3), 174-178.

Stratton, K. M., Blegen, M. A., Pepper, G., & Vaughn, T. (2004). Reporting of medication errors by pediatric nurses. *J Pediatr Nurs, 19*(6), 385-392.

Streiner, D. L., & Norman, G. R. (2003). *Health Measurement Scales : A Practical Guide to Their Development and Use* (3rd ed.). Oxford ; New York: Oxford University Press.

Tang, F. I., Sheu, S. J., Yu, S., Wei, I. L., & Chen, C. H. (2007). Nurses relate the contributing factors involved in medication errors. *J Clin Nurs, 16*(3), 447-457.

Tang, Z., Weavind, L., Mazabob, J., Thomas, E. J., Chu-Weininger, M. Y. L., & Johnson, T. R. (2007). Workflow in intensive care unit remote monitoring: A time-and-motion study. *Critical Care Medicine, 35*(9), 2057-2063.

Taunton, R. L., Kleinbeck, S. V., Stafford, R., Woods, C. Q., & Bott, M. J. (1994). Patient outcomes. Are they linked to registered nurse absenteeism, separation, or work load? *J Nurs Adm, 24*(4 Suppl), 48-55.

Taxis, K., & Barber, N. (2003). Causes of intravenous medication errors: An ethnographic study. *Qual Saf Health Care, 12*(5), 343-347.

Taxis, K., & Barber, N. (2004). Incidence and severity of intravenous drug errors in a German hospital. *Eur J Clin Pharmacol, 59*(11), 815-817.

Thomas, E. J., & Brennan, T. A. (2000). Incidence and types of preventable adverse events in elderly patients: Population based review of medical records. *BMJ, 320*(7237), 741-744.

Tissot, E., Cornette, C., Demoly, P., Jacquet, M., Barale, F., & Capellier, G. (1999). Medication errors at the administration stage in an intensive care unit. *Intensive Care Med, 25*(4), 353-359.

Tissot, E., Cornette, C., Limat, S., Mourand, J. L., Becker, M., Etievent, J. P., et al. (2003). Observational study of potential risk factors of medication administration errors. *Pharm World Sci, 25*(6), 264-268.

Tucker, A. L., & Spear, S. J. (2006). Operational failures and interruptions in hospital nursing. *Health Serv Res, 41*(3 Pt 1), 643-662.

Turner, D., Eggleton, A., & Cadman, B. (2003). An assessment of IV antibiotic reconstitution methods. *Hospital Pharmacist, 10*(3), 127-130.

van den Bemt, P. M., Fijn, R., van der Voort, P. H., Gossen, A. A., Egberts, T. C., & Brouwers, J. R. (2002). Frequency and determinants of drug administration errors in the intensive care unit. *Crit Care Med, 30*(4), 846-850.

van der Sijs, H., Aarts, J., Vulto, A., & Berg, M. (2006). Overriding of drug safety alerts in computerized physician order entry. *J Am Med Inform Assoc, 13*(2), 138-147.

van Gijssel-Wiersma, D. G., van den Bemt, P. M., & Walenbergh-van Veen, M. C. (2005). Influence of computerised medication charts on medication errors in a hospital. *Drug Saf, 28*(12), 1119-1129.

Vincent, C. (2006). *Patient Safety*. Edinburgh ; New York: Churchill Livingstone.

Wakefield, D. S., Wakefield, B. J., Borders, T., Uden-Holman, T., Blegen, M., & Vaughn, T. (1999). Understanding and comparing differences in reported medication administration error rates. *Am J Med Qual, 14*(2), 73-80.

Walsh, K. E. (2004). The Relationship between leadership practices and a medication safety regimen. *Nursing Administration Quarterly, 28*(4), 306-308.

Westrum, R. (2004). A typology of organisational cultures. *Qual Saf Health Care, 13 Suppl 2*, 22-27.

White, P., & McGillis Hall, L. (2003). Patient Safety Outcomes. In D. Doran (Ed.), *Nursing-Sensitive Outcomes : The State of the Science* (pp. 211-243). Sudbury, Mass.: Jones and Bartlett Pub.

Wickens, C. D., & Hollands, J. (2000). *Engineering Psychology and Human Performance* (3rd ed.). Upper Saddle River, NJ: Prentice Hall.

Wilson, J. R. (2000). Fundamentals of ergonomics in theory and practice. *Appl Ergon, 31*(6), 557-567.

Woloshynowych, M., Davis, R., Brown, R., & Vincent, C. (2007). Communication patterns in a UK emergency department. *Ann Emerg Med, 50*(4), 407-413.

Wong, C. A., & Cummings, G. G. (2007). The relationship between nursing leadership and patient outcomes: A systematic review. *J Nurs Manag, 15*(5), 508-521.

Wood, R. E. (1986). Task complexity - definition of the construct. *Organizational Behavior and Human Decision Processes, 37*(1), 60-82.

World Health Organization. (2004). *World Alliance for Patient Safety: Forward Programme*. Retrieved May 25th 2006. from www.who.int/patientsafety.

World Health Organization Collaborating Center for Drug Statistics Methodology. (2006). Guidelines for ATC Classification and DDD Assignment. Retrieved Sept 5th, 2006, from http://www.whocc.no/atcddd/

Yu, K. H., Nation, R. L., & Dooley, M. J. (2005). Multiplicity of medication safety terms, definitions and functional meanings: When is enough enough? *Qual Saf Health Care, 14*(5), 358-363.

Zeger, S. L., Liang, K. Y., & Albert, P. S. (1988). Models for longitudinal data - A generalized estimating equation approach. *Biometrics, 44*(4), 1049-1060.

Zhan, C., & Miller, M. R. (2003). Administrative data based patient safety research: A critical review. *Qual Saf Health Care, 12 Suppl 2*, ii58-63.

Zijlstra, F. R. H., Roe, R. A., Leonora, A. B., & Krediet, I. (1999). Temporal factors in mental work: Effects of interrupted activities. *Journal of Occupational and Organizational Psychology, 72*, 163-185.

Appendix A Manuscript #1 acceptance confirmation

Alain Biron

From: onbehalfof@scholarone.com on behalf of J.Rycroft-Malone@bangor.ac.uk
Sent: 28 novembre 2008 06:41
To: Alain Biron
Subject: Worldviews on Evidence-Based Nursing - Decision on Manuscript ID WVN-08-020.R1

28 November 2008

Dear Alain

It is a pleasure to accept your manuscript titled "The contribution of work interruptions to medication administration errors: A literature review" in for publication in Worldviews on Evidence-Based Nursing. The comments of the reviewer(s) who reviewed your manuscript are included at the foot of this letter.

Thank you for your contribution. The editorial team and I look forward to your continued contributions to Worldviews on Evidence-Based Nursing.

Sincerely,
Regards
Jo

Dr. Jo Rycroft-Malone
Editor in Chief, Worldviews on Evidence-Based Nursing J.Rycroft-Malone@bangor.ac.uk

Reviewer(s)' Comments to Author:

Reviewer: 1
Comments to the Author
I am satisfied that the authors have successfully addressed the issues I raised in my initial review of the paper. I have no other issues of concern.

Reviewer: 2
Comments to the Author
I think this reads well now. All changes adequately addressed. A few minor grammatical errors that will be addressed on editorial check. Specifically:
Page 1. Line 36 Add it is after because.
Page 6 line 47 separate of and work
Page 23 line 11 delete as, add from
Page 28 line 20 delete s from conditions

Appendix B Observation Grid

MEDICATION ADMINISTRATION OBSERVATION GRID

Prep Start: ________ **Prep End:** ________ **Observer:** ________ **Patient ID** ________
Admin. Start: ________ **Admin End:** ________ **Date:** ________ **Nurse ID** ________

Medication	Origin	Admin time	Crush/Cut	IV mixing	Mixed	Station	Preparation 1	2	3	4	5	6	Administration 1	2	3	4	5	6	7
		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
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		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
		:	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

CODES Med. Admin.

Origin of med.
1. Pt drawer
2. Stock
3. Fridge
4. Bedside
5. Reserve
6. Narcotics
7. Other patient
8. Other

Prep. codes
1. Double checked
2. Check allergy
3. Check reference
4. Pt may take own med
5. Unlabeled
6. Missing

Admin. codes
1. Documents @ admin
2. Pt refused
3. Med held by nurse
4. Left at bedside
5. Verify med with pt
6. Invite questions
7. Informs pt re:med

Distractions

Time	Source	Location

Interruptions

Start time	End time	Source	Location	Strategy	Task

Codes Interruptions and Distractions

Source	Location	Strategy	Task
1. Nurse 2. Orderly 3. Alarm 4. Patient 5. Family 6. HCP 7. MD 8. AHN / HN 9. Unit coord. 10. Self initiate 11. Other	1. Med Room 2. Hallway 3. Pt room 4. Nsg station.	1. Immediate 2. Scheduled 3. Stacked	1. Communication 2. Verbal report 3. Direct care 4. Coordination 5. Meetings / Admin. 6. Teaching 7. Clerical 8. Personal 9. Other

Patient

General
- ☐ Patient not available
- ☐ Isolation
- ☐ Observer intervention

VS Results

T ______ HR ______ R ______
BP ______ O_2 sat ______ BS ______

Prep Actions:
- ☐ Assess Lab. values
- ☐ Assess Physical
- ☐ Assess Other
- ☐ Comm. Physician
- ☐ Comm. Nurse
- ☐ Comm. Pharm.
- ☐ Comm. Family
- ☐ Comm. Patient
- ☐ Comm. Other.

Admin. Actions :
- ☐ Validate pt's med
- ☐ Check Order
- ☐ Check Notes
- ☐ Check Other
- ☐ Assess History
- ☐ Ask pt's Name
- ☐ Check ID Band
- ☐ Wash Hands
- ☐ MAR into Room

Comments

Version : 2007-09-17 Adapted from Pepper (2007)

Page ______ of ______ Cycle #: ______

Appendix C Consent Form Pilot Phase

NURSES' WORK ENVIRONMENT AND MEDICATION ADMINISTRATION PRACTICES

Principal investigator

Alain Biron, N., PhD student
School of Nursing
McGill University, MUHC FERASI Fellow

Thesis co-supervisors

Carmen G. Loiselle, N., PhD
Assistant Professor, McGill University School of Nursing
Mélanie Lavoie-Tremblay, N., PhD
Assistant Professor, McGill University School of Nursing

INTRODUCTION

At this time, we are conducting a pilot phase to prepare for a study seeking to describe features of nurses' work environment and its influence on nursing medication administration practices. You are being invited to participate in this study because you are a nurse working on a unit who administers medication as part of her work.

Before you decide to participate, you should clearly understand its requirements, risks and benefits. This document provides information about the study. It may contain words you do not fully understand. Please read it carefully and ask the study staff any questions you may have. They will discuss the study with you in detail. You may take this form with you and discuss the study with any one else before making any decision. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

STUDY DESCRIPTION

Nurses work environment is being increasingly recognized as playing an important role in ensuring high quality care. However, little is known about the influence nurses' work environment may have on nurses' medication administration practices.

PURPOSE OF THE STUDY

The main objective of this pilot phase is to ensure that our observation methods are optimal. The purpose of the main study is to describe features of nurses' work environment and its influence on nursing medication administration practices. This study is being conducted at the Montreal General Hospital and the Royal Victoria Hospital.

STUDY PROCEDURES

If you agree to take part in pilot phase, you will be observed for a maximum of one hour during the administration of medication on a maximum of five different occasions while wearing an audio recording device. After each observation, you will be asked to complete a questionnaire requiring approximately 5 minutes. You will also be asked, prior to the first observation, some questions on your background such as your years of professional experience that requires approximately 3 minutes of your time. Your participation will require a total of approximately 30 minutes over a two-week period.

MEDICATION INCIDENT PROCEDURE

Because of the nature of the study, there is a possibility that medication administration incidents will be noted. If medication incidents are noted during the analysis of the results, an *anonymous* report based on all incidents identified will be sent to the quality management team to conform to Quebec's legislation on incident reporting. It is unlikely that the observer will notice a medication incident during the observation. It is unlikely because the observer will not know what medication the patient should be receiving. In a situation where a nurse is clearly making a harmful error, the observer will ask tactfully the nurse participant to recheck the medication. If the nurse does not detect the potentially harmful incident, the observer will stop the administration.

POTENTIAL BENEFITS

You should not expect any direct benefit from participating in the study. However, knowledge gained through this study will provide a more precise account of the influence nurses' work environment along with potential indications for actions to improve care.

POTENTIAL RISKS

Although this study would not foreseeably create any risk or liability for your employment, the results of this study could lead to hospital programs aimed at improving nursing care.

CONFIDENTIALITY

All information obtained during the course of the study will be kept strictly confidential in a locked filing cabinet in a locked office at the School of Nursing, McGill University. Confidentiality will be maintained by using a code number consisting of your father's date of birth along with the first three digits of your postal code to identify questionnaires. This code will be subsequently changed by a serial number to further protect your confidentiality. Any names that may appear on the audio recordings will be removed when coded. The audio recordings will be transcribed and subsequently destroyed within 5 years upon study completion.

The information from the study may be published, and other investigators participating in this research may have access to data; however, your identity will not be revealed in the combined results. In order to verify the research study data, monitors from one of the McGill University Health Centre (MUHC) Research Ethics Boards may review these records.

By signing this consent form, you give us permission to release information regarding your participation in this study to these individuals. Your confidentiality will be protected to the extend permitted by applicable laws and regulations.

COSTS AND COMPENSATION FOR PARTICIPATION

You will not be compensated for your participation in this study.

INDEMNIFICATION

The MUHC, the MUHC Research Institute, and investigators would not be able to offer compensation in the unlikely event of any injury resulting from your participation in this research study. However, you are not giving up any of your legal rights by signing this consent form and agreeing to participate in this study.

VOLUNTARY PARTICIPATION AND/OR WITHDRAWAL

Your participation in this study is strictly voluntary. If you decide not to participate, or if you discontinue your participation, you will forseeably suffer no prejudice regarding your work or your participation in any other studies. You may refuse to participate or may discontinue your participation at any time without explanation. By accepting to participate in this study, you do not waive any rights, nor do you release named investigators involved in this study of their legal and professional liabilities.

QUESTIONS AND CONTACT INFORMATION

If you have any questions regarding the study, the investigators can be reached at the following numbers:

Alain Biron, N. “page number will be provided”

If you have any questions regarding your rights as a study participant, the patient representative can be reached at: MGH (514) 935-8306, RVH: tel: (514) 934-1934 ext; 35655.

DECLARATION OF CONSENT

I have read this consent form, and I agree to participate in this study. I have had the opportunity to ask questions and my questions have been answered to my satisfaction. I have been given sufficient time to consider the above information and to seek advice if I choose to do so. I understand that I will be given a signed copy of this consent form. I have not given up any of my legal rights.

Participant signature: _____ Date: _____
Print name of participant: _____ Yr/ Mo/Day

To the best of my knowledge, the information in this consent form, and the information that I have provided in the response to any questions, represents the project fairly. I am committed to conducting this study in compliance with all the ethical standards that apply to projects that involve human subjects. I will ensure that the participant receives a copy of this consent form.

Investigator signature: _____ Date: _____
Print name of investigator: Alain Biron Yr/ Mo/Day

Appendix D Formulaire de consentement – Phase pilote

L'ENVIRONNEMENT DE TRAVAIL INFIRMIER ET LES PRATIQUES MEDICAMENTEUSES

FORMULAIRE DE CONSENTEMENT – PHASE PILOTE

Chercheur principal
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Directrices de thèse
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Professeur adjoint, École des sciences infirmières, Université McGill

INTRODUCTION

Pour le moment, nous procédons à une phase pilote pour planifier une étude dont l'objectif est de décrire l'environnement de travail des infirmières et son influence sur les pratiques infirmières reliées l'administration des médicaments. Vous êtes invité à participer à cette étude parce que vous êtes une infirmière oeuvrant en médicine et que vous avez à administrer des médicaments dans le cadre de votre travail.

Avant de prendre une décision, il est important de connaître ce que l'on attend de vous, les risques et avantages éventuels associés à la participation à cette étude. Il peut contenir des mots difficiles à comprendre. Veuillez lire attentivement ce formulaire et n'hésitez pas à poser des questions pour clarifier certains éléments au besoin. Vous pouvez apporter avec vous ce formulaire et discuter de son contenu avec quiconque avant de prendre une décision. Si vous décider de participer à cette étude, il vous sera demandé de signer ce formulaire.

DESCRIPTION DE L'ETUDE

L'environnement de travail des infirmières est de plus en plus reconnu comme jouant un rôle significatif dans la prestation de soins de qualité. Cependant, l'influence de l'environnement de travail infirmier sur les pratiques reliées à l'administration des médicaments est peu connue.

OBJECTIF DE L'ÉTUDE

Cette étude vise à décrire l'environnement de travail des infirmières et son influence sur les pratiques infirmières reliées l'administration des médicaments. L'objectif spécifique pour cette phase pilote est de s'assurer que les méthodes d'observation sont adéquates. Cette étude se déroulera à l'Hôpital Général de Montréal et l'Hôpital Royal-Victoria. Approximativement 17 infirmières participeront à cette étude.

PROCÉDURES

Si vous acceptez de faire partie de cette phase pilote, une personne vous observera administrer des médicaments pour une période maximale d'une heure et ce, à un maximum de 5 reprises tout en ayant une enregistreuse audionumérique sur vous. Après chaque observation, il vous sera demandé de compléter un questionnaire requérant environ 5 minutes de votre temps. De plus, il vous sera demandé de compléter un questionnaire sociodémographique au début de l'étude nécessitant environ 3 minutes. Votre participation nécessitera un total de 30 minutes de votre temps sur une période maximale de 2 semaines.

PROCÉDURE LORS D'UN INCIDENT MÉDICAMENTEUX

De par la nature de l'étude, il est possible que des incidents médicamenteux soient identifiés. Si des incidents médicamenteux sont identifiés lors de l'analyse des données, un rapport *anonyme* basé sur tous les incidents identifiés sera acheminé au département de la qualité afin de se conformer à la législation relative à la déclaration d'incident au Québec. Il est peu probable que des incidents soient identifiés lors de l'observation. Cela est peu probable car l'observateur ignorera quels médicaments le patient devrait recevoir. Dans la situation où une infirmière commet une erreur évidente pouvant avoir des conséquences pour le patient, l'observateur demandera avec tact à l'infirmière de vérifier de nouveau les médicaments. Si l'infirmière ne détecte pas l'incident avec cette intervention et procède, l'observateur stoppera l'administration.

AVANTAGES EVENTUELS

Vous ne tirerez aucun avantage direct de votre participation à cette étude. Cependant, les résultats de cette étude permettront de mieux connaître l'influence de l'environnement de travail afin de dégager des pistes d'actions.

RISQUES

Même si cette recherche ne comporte aucun risque connu pour votre emploi, les résultats pourraient être à l'origine de programmes visant l'amélioration des soins infirmiers.

CONFIDENTIALITÉ

Toutes les informations recueillies lors de cette étude sont strictement confidentielles et seront conservées dans une filière fermée à clef dans endroit barré à clef à l'école des sciences infirmières de l'Université McGill. La confidentialité sera protégée par l'utilisation par les participants d'un code formé par la date de naissance du père et les trois premiers caractères du code postal pour identifier les questionnaires. Ce code sera subséquemment changé par un code numérique afin de protéger davantage la confidentialité. Les noms contenus dans les enregistrements audio seront exclus lors de la transcription. Les enregistrements audio-numériques seront transcrits et détruits à l'intérieur d'une période de 5 ans une fois l'étude complétée.

Les résultats de cette étude peuvent être publiés et les autres chercheurs y participant pourront avoir accès aux données ; cependant, aucune information pouvant mener à l'identification de participants ou de l'unité de soins ne sera divulguée. Il est possible qu'un représentant du comité d'éthique de la recherche du Centre universitaire de santé McGill (CUSM) revoie les documents afin de vérifier que ce projet respecte les règlements relatifs à la conduite de recherche.

En signant ce formulaire de consentement, vous autorisé la divulgation d'information concernant votre participation à ces individus. Votre confidentialité sera assurée à l'intérieur des limites prescrites par les lois.

COÛT ET COMPENSATION

Aucune indemnisation ne sera offerte pour la participation à cette étude.

INDEMNISATION

Le CUSM, l'Institut de recherche du CUSM, et les chercheurs ne pourrait offrir une indemnisation dans la situation peu probable où vous seriez victime de préjudice découlant de la participation à cette étude. Cependant, vous renoncer à aucun de vos droits légaux en signant ce formulaire et en participant à cette étude.

PARTICIPATION VOLONTAIRE ET / OU RETRAIT

Votre participation est entièrement volontaire. Quelle que soit votre décision, elle n'entraînera aucune pénalité ou perte de bénéfices auxquels vous avez autrement droit. Votre refus de participer ou votre retrait de l'étude n'affectera en rien votre emploi ou toute évaluation de votre rendement.

QUESTIONS ET INFORMATION

Si avez des questions au sujet de cette étude, les chercheurs peuvent être contacté au numéro suivant :

Alain Biron, N. « PAGE NUMBER TO BE ADDED ONCE KNOWN »

Si vous avez des questions au sujet de vos droits en tant que participant à cette étude, vous pouvez contacter l'ombudsman du Centre universitaire de santé McGill (MUHC) au numéro : HGM (514) 935-8306, HRV : tel : (514) 934-1934 poste: 35655.

DECLARATION DE CONSENTEMENT

Je reconnais avoir lu ce formulaire de consentement et j'accepte de participer à cette étude. J'ai eu la possibilité de poser des questions et mes questions ont été répondues à ma satisfaction. J'ai disposé de suffisamment de temps pour réfléchir à l'information présentée et de consulter au besoin. Je comprends qu'une copie signée de ce formulaire me sera remis. En signant ce formulaire de consentement, je comprends que je conserve tous mes droits légaux.

Signature du participant: _____ Date: _____
Nom en lettres moulées: _____ Année/ Mo / Jr

Au meilleur de mes connaissances, l'information figurant sur ce formulaire de consentement et l'information que j'ai fournie en réponse à toute question décrivent de manière équitable le projet. Je m'engage à procéder à cette étude conformément à toutes les normes éthiques qui s'appliquent aux projets comportant la participation de sujets humains. Je m'engage à m'assurer que le participant recevra un exemplaire de ce formulaire de consentement.

Signature du chercheur: _____ Date: _____
Nom en lettres moulées Alain Biron inf. PhD ét. Année/ Mo / Jr

Appendix E NASA-TLX

Instructions NASA-TLX (Hart & Staveland, 1988)

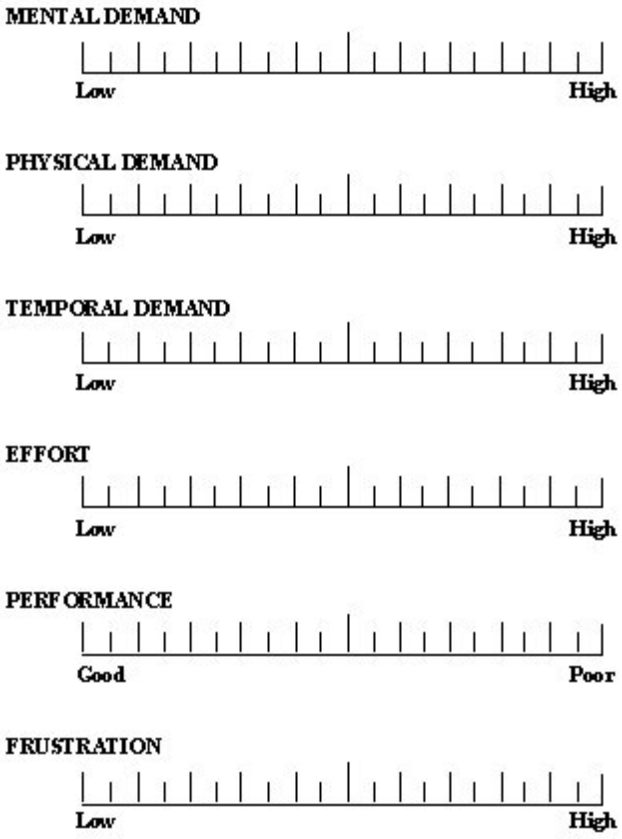
INSTRUCTIONS

One way to find out about workload is to ask people to describe the feelings they experienced. Because workload may be caused by many different factors, we would like you to evaluate several of them individually rather than lumping them into a single global evaluation of overall workload. This set of six rating scales was developed for you to use in evaluating your experiences. Please read the descriptions of the scales carefully. If you have a question about any of the scales in the table, please ask me about it. It is extremely important that they be clear to you.

Rating Scale definitions

Title	Endpoints	Descriptions
Mental Demand	Low / High	How much mental and perceptual activity was required (e.g. thinking, deciding, calculation, remembering, looking, searching, etc.)? Was the task easy or demanding, simple or complex, exacting or forgiving?
Physical Demand	Low / High	How much physical activity was required (e.g. pushing, pulling, turning, controlling, activating, etc.)? Was the task easy or demanding, slow or brisk, slack or strenuous, restful or laborious?
Temporal Demand	Low / High	How much time pressure did you feel due to the rate or pace at which the tasks or task elements occurred? Was the pace slow and leisurely or rapid and frantic?
Effort	Low / High	How hard did you have to work (mentally and physically to accomplish your level of performance?
Performance	Good / Poor	How successful do you think you were in accomplishing the goals of the task set by the experimenter (or your self)? How satisfied were you with your performance in accomplishing these goals?
Frustration level	Low / High	How insecure, discouraged, irritated, stressed and annoyed versus secure gratified, content, relaxed, and complacent did you feel during the task?

Evaluate your workload experience while administering medications by marking each scale with an "X" at the point which matches your experience. Each line has two endpoint descriptors that describe the scale. Please consider your responses carefully in distinguishing among the conditions specifically at during this period. Consider each scale individually. Your ratings will play an important role in the evaluation being conducted, thus your active participation is essential to the success of this experiment, and is greatly appreciated.



Note. From *Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research*. S. Hart, & L. Staveland (1988). In P. A. H. a. N. Meshkati (Ed.), *Human mental workload* Amsterdam: North-Holland.: Elsevier Science Pub. Copyright by Naval Research Laboratory, Code 5513, Washington, DC. Reprinted with permission.

Appendix F Medication Administration Complexity (MAC) scale

MEDICATION ADMINISTRATION COMPLEXITY (MAC) SCALE

ID: _____ Date: _____ DD/MM/YYYY

Section A: Component complexity				Number	Weight	Score
How many patients were administered medications?					3	
How many doses were administered, missing or held?					5	
For each route, indicate how many doses were administered and multiply the number by its weight.						
Oral	Preparation	Tablets	Unidoses		7	
			Stock		20	
		Liquid	Unit-dose		17	
			Stock		5	
	Administration	NG			9	
		Cutting			1	
Topical		Dermal			19	
		Transdermal			17	
		Ophtalmic			22	
		Otic			19	
Parenteral Select a method of preparation and a method of administration for each dose of parenteral medication.	Preparation	Ampoule			16	
		Vial	No mixing		13	
			Mixing required		21	
		Pre-mixed			5	
		Bag dilution			8	
		IV line Assembly			14	
		IV flush	Prepared		5	
			Not prepared		15	
		Prepare label			3	
	Administration	IM /SC			9	
		IV	Gravity		10	
			Pump		12	
			Push		9	
			Mini-infuser		10	
		IV Flush			8	
Mucous membrane		Sublingual	Tablet		20	
			Spray		9	
		Nose drops			13	
		Inhalation	Metered-dose Inhaled		13	
			Aerochamber		20	
			Nebulizer		17	
		Rectal / Vaginal			12	
Controlled substance Double check required					10	
					3	
			Total score section A (Add all scores)			

Version 7

MEDICATION ADMINISTRATION COMPLEXITY (MAC) SCALE						
Section B: Coordinative complexity				# patients	Weight	Score
Part 1: Regular orders Indicate the number of patients with one or more medication administered or held for each of the following class.			AHFS® classes			
Cardiovascular drugs	Antiarrhytmic		24.04.04		5	
	Antihypertensive		24:08-12-20-24-28-32		10	
Anticoagulants			20.12		6	
Antipsychotics			26:16.08		13	
Part 2: Contingent or PRN orders Indicate the number of patients with one or more medication administered or held for each of the following class.						
	Anticoagulants		20:12		8	
	Nitrates and Nitrites		24:12.08		8	
	Nonsteroidal Anti-inflammatory Agents and anti-pyretics	Analgesic purpose	28:16.04		6	
		Antipyretics			10	
		Non-specific				
	Opiate Agonist		28:08-10		25	
	Anxiolytics, Sedatives, and Hypnotics		28:24		4	
	Bronchodilators		48:12		19	
	Antiacids and Adsorbents		56:04		8	
	Cathartics and Laxatives		56:12		16	
	Antiemetics		56:20		13	
	Antidiabetics Agents		68:20		12	
	Antipsychotic		28:16.08		6	
			Total			
						X 2
			Total score section B			
			Total score section A			
			Medication Administration Complexity Score: (Total A + Total B)			

Appendix G Control Variables Questionnaire

Participant ID: Date:
Observation number:

System-related nurses' characteristics

Please complete the following questions by filling in the blanks.

1. Did you work overtime in the last seven days prior to the current work shift? ❑ Yes ❑ No
2. How many hours did you work in last seven days prior to current work shift? _____ hours
3. How many hours did you work in last 24 hours prior to current work shift? _____ hours
4. Number of consecutive days of work _____ days
5. How many admissions did you have since the beginning of the shift? _____ admissions
6. How many patients are you caring for at the time you were observed? _____ patients
7. How would you rate the amount of care required by your patients in the current shift compared to the last 5 shifts?

□	□	□	□	□
Definitely less	Slightly less	same	Slightly more	Definitely more

8. How would rate the severity of your patients' medical condition in the current shift compared to the last 5 shifts?

□	□	□	□	□
Definitely less	Slightly less	same	Slightly more	Definitely More

Your collaboration to this research project is greatly appreciated.

Appendix H Demographic Questionnaire

Nurses' work environment and medication administration practices

Participant ID: _____ Date: _____

YYYY/MM/DD – (e.g. H3X) YYYY/MM/DD

Father's DOB and first 3 digits of postal code

Demographic Information Form

Please complete the following questions by checking off the response that corresponds to you or, where indicated, fill in the blanks.

Please note that your responses will not be used to describe you as an individual but only to describe the characteristics of the group that participates in this study.

1. Gender:
   - ❑ Female
   - ❑ Male
2. How many years of experience in nursing do you have? _____ years _____ months
3. How many years of experience on the current unit do you have? _____ years _____ months
4. Highest level of education:
   - ❑ CEGEP
   - ❑ Baccalaureate
   - ❑ Master
   - ❑ Post RN Certification
5. Type of shift work:
   - ❑ Days only
   - ❑ Rotation (days and night)
6. What position do you hold?
   - ❑ Full time
   - ❑ Part time
   - ❑ Availability

Your collaboration to this research project is greatly appreciated.

Appendix I Ethic Certificate

Centre universitaire de santé McGill
McGill University Health Centre
Les meilleurs soins pour la vie
The Best Care for Life

March 19, 2007

Mr. Alain Biron
School of Nursing
McGill University
Montreal General Hospital

RE: **GEN#06-055 entitled "Nurses" Work Environment and Medication Administration Practices."**

Dear Dr. Biron:

The research proposal entitled above received Full Board review at the convened meeting of the MUHC-Montreal General Hospital Research Ethics Committee on February 20, 2007, and was entered accordingly into the minutes of the Research Ethics Board (REB) meeting.

We are writing to inform you that the above referenced study was found ethically acceptable for conduct at the McGill University Health Centre, and we hereby grant you full approval for the revised research protocol (14 March 2007), and the revised English and French Consent Documents (dated 19 March 2007), via review by the Co-Chair on March 19, 2007.

At the MUHC, sponsored research activities that require US federal assurance are conducted under Federal Wide Assurance (FWA) 00000840.

All research involving human subjects require review at a recurring interval and the current study approval is in effect until **February 19, 2007**. It is the responsibility of the principal investigator to submit an Application for Continuing Review to the REB prior to the expiration of approval to comply with the regulation for continuing review of "at least once per year".

It is important to note that validation for the translated version of the consent document has been certified by an MUHC translator. Any further modification to the REB approved and certified consent document must be identified by a revised date in the document footer, and re-submitted for review prior to its use.

The Research Ethics Boards (REBs) of the McGill University Health Centre are registered REBs working under the published guidelines of the Tri-Council Policy Statement, in compliance with the "Plan d'action ministériel en éthique de la recherche et en intégrité scientifique" (MSSS, Qc) and the Food and Drugs Act (17 June, 2001); and acting in conformity with standards set forth in the (US) Code of Federal Regulations governing human subjects research, functions in a manner consistent with internationally accepted principles of good clinical practice.

We wish to advise you that this document completely satisfies the requirement for Research Ethics Board Attestation as stipulated by Health Canada.

RE: GEN#06-055 entitled "Nurses" Work Environment and Medication Administration Practices."

The project was assigned MUHC Study Number GEN#06-055 that is required as MUHC reference when communicating about the research.

Should any revision to the study, or other unanticipated development occur prior to the next required review, you must advise the REB without delay. Regulation does not permit initiation of a proposed study modification prior to REB approval for the amendment.

Good luck with your study.

Sincerely,

Denis Cournoyer, M. D.
Co-Chairman
GEN Research Ethics Board
MUHC-Montreal General Hospital

Cc: GEN#06-055

Appendix J Main study English consent form

NURSES' WORK ENVIRONMENT AND MEDICATION ADMINISTRATION PRACTICES

CONSENT FORM

Principal investigator

Alain Biron, N., PhD student
School of Nursing
McGill University, MUHC FERASI Fellow

Thesis co-supervisors

Carmen G. Loiselle, N., PhD
Assistant Professor, McGill University School of Nursing
Mélanie Lavoie-Tremblay, N., PhD
Assistant Professor, McGill University School of Nursing

INTRODUCTION

You are being invited to participate in this study because you are a nurse working on medical unit who administers medication as part of your work.

Before you decide to participate, you should clearly understand its requirements, risks and benefits. This document provides information about the study. It may contain words you do not fully understand. Please read it carefully and ask the study staff any questions you may have. They will discuss the study with you in detail. You may take this form with you and discuss the study with any one else before making any decision. If you decide to participate, you will be asked to sign this form and a copy will be given to you.

STUDY DESCRIPTION

Nurses work environment is being increasingly recognized as playing an important role in ensuring high quality care. However, little is known about the influence nurses' work environment may have on nurses' medication administration practices.

PURPOSE OF THE STUDY

The purpose of this study is to describe features of nurses' work environment and its influence on nursing medication administration practices. This study is being conducted at the Montreal General Hospital and the Royal Victoria Hospital. Approximately 17 participants will be enrolled in this study.

STUDY PROCEDURES

If you agree to take part in this study, you will be observed for a maximum of one hour during the administration of medication on six different occasions while wearing an audio recording device. After each observation, you will be asked to complete a questionnaire requiring approximately 5 minutes. You will also be asked, prior to the first observation, some questions on your background such as your years of professional experience that requires approximately 3 minutes of your time. Your participation will take a total of approximately 35 minutes over a six-week period.

MEDICATION INCIDENT PROCEDURE

Because of the nature of the study, there is a possibility that medication administration incidents will be noted. If medication incidents are noted during the analysis of the results, an *anonymous* report based on all incidents identified will be sent to the quality management team to conform to Quebec's legislation on incident reporting. It is unlikely that the observer will notice a medication incident during the observation. It is unlikely because the observer will not know what medication the patient should be receiving. In a situation where a nurse is clearly making a harmful error, the observer will ask tactfully the nurse participant to recheck the medication. If the nurse does not detect the potentially harmful incident, the observer will stop the administration.

POTENTIAL BENEFITS

You should not expect any direct benefit from participating in the study. However, knowledge gained through this study will provide a more precise account of the influence nurses' work environment along with potential indications for actions to improve care.

POTENTIAL RISKS

Although this study would not foreseeably create any risk or liability for your employment, the results of this study could lead to hospital programs aimed at improving nursing care.

CONFIDENTIALITY

All information obtained during the course of the study will be kept strictly confidential in a locked filing cabinet in a locked office at the School of Nursing, McGill University. Confidentiality will be maintained by using a code number consisting of your father's date of birth along with the first three digits of your postal code to identify questionnaires. This code will be subsequently changed by a serial number to further protect your confidentiality. Any names that may appear on the audio recordings will be removed

when coded. The audio recordings will be transcribed and subsequently destroyed within 5 years upon study completion.

The information from the study may be published, and other investigators participating in this research may have access to data; however, your identity will not be revealed in the combined results. In order to verify the study data, monitors from one of the McGill University Health Centre (MUHC) Research Ethics Boards may review these records.

By signing this consent form, you give us permission to release information regarding your participation in this study to these individuals. Your confidentiality will be protected to the extend permitted by applicable laws and regulations.

COSTS AND COMPENSATION FOR PARTICIPATION

You will not be compensated for your participation in this study.

INDEMNIFICATION

The MUHC, the MUHC Research Institute, and investigators would not be able to offer compensation in the unlikely event of any injury resulting from your participation in this research study. However, you are not giving up any of your legal rights by signing this consent form and agreeing to participate in this study.

VOLUNTARY PARTICIPATION AND/OR WITHDRAWAL

Your participation in this study is strictly voluntary. If you decide not to participate, or if you discontinue your participation, you will forseeably suffer no prejudice regarding your work or your participation in any other studies. You may refuse to participate or may discontinue your participation at any time without explanation. By accepting to participate in this study, you do not waive any rights, nor do you release named investigators involved in this study of their legal and professional liabilities.

QUESTIONS AND CONTACT INFORMATION

If you have any questions regarding the study, the investigators can be reached at the following numbers:

Alain Biron, N. “page number will be inserted here when available”

If you have any questions regarding your rights as a study participant, the patient representative can be reached at: MGH (514) 935-8306, RVH: tel: (514) 934-1934 ext; 35655.

DECLARATION OF CONSENT

I have read this consent form, and I agree to participate in this study. I have had the opportunity to ask questions and my questions have been answered to my satisfaction. I have been given sufficient time to consider the above information and to seek advice if I choose to do so. I understand that I will be given a signed copy of this consent form. I have not given up any of my legal rights.

Participant signature: _____ Date: _____
Print name of participant: _____ Yr/ Mo/Day

To the best of my knowledge, the information in this consent form, and the information that I have provided in the response to any questions, represents the project fairly. I am committed to conducting this study in compliance with all the ethical standards that apply to projects that involve human subjects. I will ensure that the participant receives a copy of this consent form.

Investigator signature: _____ Date: _____
Print name of investigator: Alain Biron Yr/ Mo/Day

Appendix K Main study French consent form

L'ENVIRONNEMENT DE TRAVAIL INFIRMIER ET LES PRATIQUES MEDICAMENTEUSES

FORMULAIRE DE CONSENTEMENT

Chercheur principal
Alain Biron, inf., PhD étudiant
École des sciences infirmières
Université McGill, Boursier FERASI / CUSM

Directrices de thèse
Carmen G. Loiselle, inf., PhD
Professeur adjoint, École des sciences infirmières, Université McGill
Mélanie Lavoie-Tremblay, inf., PhD
Professeur adjoint, École des sciences infirmières, Université McGill

INTRODUCTION

Vous êtes invité à participer à cette étude parce que vous êtes une infirmière oeuvrant en médicine et que vous avez à administrer des médicaments dans le cadre de votre travail.

Avant de prendre une décision, il est important de connaître ce que l'on attend de vous, les risques et avantages éventuels associés à la participation à cette étude. Il peut contenir des mots difficiles à comprendre. Veuillez lire attentivement ce formulaire et n'hésitez pas à poser des questions pour clarifier certains éléments au besoin. Vous pouvez apporter avec vous ce formulaire et discuter de son contenu avec quiconque avant de prendre une décision. Si vous décider de participer à cette étude, il vous sera demandé de signer ce formulaire.

DESCRIPTION DE L'ETUDE

L'environnement de travail des infirmières est de plus en plus reconnu comme jouant un rôle significatif dans la prestation de soins de qualité. Cependant, l'influence de l'environnement de travail infirmier sur les pratiques reliées à l'administration des médicaments est peu connue.

OBJECTIF DE L'ÉTUDE

Cette étude vise à décrire l'environnement de travail des infirmières et son influence sur les pratiques infirmières reliées l'administration des médicaments. Cette étude se déroulera à l'Hôpital Général de Montréal et l'Hôpital Royal-Victoria. Approximativement 17 infirmières participeront à cette étude.

PROCÉDURES

Si vous acceptez de faire partie de cette étude, une personne vous observera administrer des médicaments pour une période maximale d'une heure et ce, à six reprises au cours des six prochaines semaines tout en ayant une enregistreuse audionumérique sur vous. Après chaque observation, il vous sera demandé de compléter un questionnaire requérant environ 5 minutes de votre temps. De plus, il vous sera demandé de compléter un questionnaire sociodémographique au début de l'étude nécessitant environ 3 minutes. Votre participation nécessitera un total de 35 minutes de votre temps sur une période maximale de 6 semaines.

PROCÉDURE LORS D'UN INCIDENT MÉDICAMENTEUX

De par la nature de l'étude, il est possible que des incidents médicamenteux soient identifiés. Si des incidents médicamenteux sont identifiés lors de l'analyse des données, un rapport *anonyme* basé sur tous les incidents identifiés sera acheminé au département de la qualité afin de se conformer à la législation relative à la déclaration d'incident au Québec. Il est peu probable que des incidents soient identifiés lors de l'observation. Cela est peu probable car l'observateur ignorera quels médicaments le patient devrait recevoir. Dans la situation où une infirmière commet une erreur évidente pouvant avoir des conséquences pour le patient, l'observateur demandera avec tact à l'infirmière de vérifier de nouveau les médicaments. Si l'infirmière ne détecte pas l'incident avec cette intervention et procède, l'observateur stoppera l'administration.

AVANTAGES EVENTUELS

Vous ne tirerez aucun avantage direct de votre participation à cette étude. Cependant, les résultats de cette étude permettront de mieux connaître l'influence de l'environnement de travail afin de dégager des pistes d'actions.

RISQUES

Même si cette recherche ne comporte aucun risque connu pour votre emploi, les résultats pourraient être à l'origine de programmes visant l'amélioration des soins infirmiers.

CONFIDENTIALITÉ

Toutes les informations recueillies lors de cette étude sont strictement confidentielles et seront conservées dans une filière fermée à clef dans endroit barré à clef à l'école des sciences infirmières de l'Université McGill. La confidentialité sera protégée par l'utilisation par les participants d'un code formé par la date de naissance du père et les trois premiers caractères du code postal pour identifier les questionnaires. Ce code sera subséquemment changé par un code numérique afin de protéger davantage la

confidentialité. Les noms contenus dans les enregistrements audio seront exclus lors de la transcription. Les enregistrements audio-numérique seront transcrits et détruits à l'intérieur d'une période de 5 ans une fois l'étude complétée.

Les résultats de cette étude peuvent être publiés et les autres chercheurs participant à cette recherche pourrant avoir accès aux données ; cependant, aucune information pouvant mener à l'identification de participants ou de l'unité de soins ne sera divulguée. Il est possible qu'un représentant du comité d'éthique de la recherche du Centre universitaire de santé McGill (CUSM) revoie les documents afin de vérifier que ce projet respecte les règlements relatifs à la conduite de recherche.

En signant ce formulaire de consentement, vous autorisé la divulgation d'information concernant votre participation à ces individus. Votre confidentialité sera assurée à l'intérieur des limites prescrites par les lois.

COÛT ET COMPENSATION

Aucune indemnisation ne sera offerte pour la participation à cette étude.

INDEMNISATION

Le CUSM, l'Institut de recherche du CUSM, et les chercheurs ne pourrait offrir une indemnisation dans la situation peu probable où vous seriez victime de préjudice découlant de la participation à cette étude. Cependant, vous renoncer à aucun de vos droits légaux en signant ce formulaire et en participant à cette étude.

PARTICIPATION VOLONTAIRE ET / OU RETRAIT

Votre participation est entièrement volontaire. Quelle que soit votre décision, elle n'entraînera aucune pénalité ou perte de bénéfices auxquels vous avez autrement droit. Votre refus de participer ou votre retrait de l'étude n'affectera en rien votre emploi ou toute évaluation de votre rendement.

QUESTIONS ET INFORMATION

Si avez des questions au sujet de cette étude, les chercheurs peuvent être contacté au numéro suivant :

Alain Biron, N. « PAGE NUMBER TO BE ADDED ONCE KNOWN »

Si vous avez des questions au sujet de vos droits en tant que participant à cette étude, vous pouvez contacter l'ombudsman du Centre universitaire de santé McGill (MUHC) au numéro : HGM (514) 935-8306, HRV : tel : (514) 934-1934 poste: 35655.

DECLARATION DE CONSENTEMENT

Je reconnais avoir lu ce formulaire de consentement et j'accepte de participer à cette étude. J'ai eu la possibilité de poser des questions et mes questions ont été répondues à ma satisfaction. J'ai disposé de suffisamment de temps pour réfléchir à l'information présentée et de consulter au besoin. Je comprends qu'une copie signée de ce formulaire me sera remis. En signant ce formulaire de consentement, je comprends que je conserve tous mes droits légaux.

Signature du participant: _____ Date: _____
Nom en lettres moulées: _____ Année/ Mo / Jr

Au meilleur de mes connaissances, l'information figurant sur ce formulaire de consentement et l'information que j'ai fournie en réponse à toute question décrivent de manière équitable le projet. Je m'engage à procéder à cette étude conformément à toutes les normes éthiques qui s'appliquent aux projets comportant la participation de sujets humains. Je m'engage à m'assurer que le participant recevra un exemplaire de ce formulaire de consentement.

Signature du chercheur: _____ Date: _____
Nom en lettres moulées Alain Biron inf. PhD ét. Année/ Mo / Jr

Appendix L Waiver of consent

Centre universitaire de santé McGill
McGill University Health Centre

DEMANDE D'ACCÈS AU DOSSIER MÉDICAL / *REQUEST TO ACCESS HEALTH RECORD*

☐ HME MCH ☒ HGM MGH ☒ HRV RVH ☐ HNM MNH ☐ ITM MCI

Date: 2006/12/15

But de l'accès au dossier medical / *Purpose of Access to Health Record:*

Recherche / Research	☑ Nurses' work environment and medication administration practices
Assurance de la qualité */Quality Assurance*	☐
Enseignement / *Teaching*	☐
Vérification / Audit	☐
Autre / *Other*	☐

Critères de sélection pour les dossiers médicaux / *Criteria for Health Record Selection*

Diagnostic / *Diagnosis*	
Procédure chirurgicale / *Operative Procedure*	
Âge / *Age*	
Sexe / *Sex*	
Période */Time Frame*	
Numéro de dossier/ *Health Record Number*	
Autre / *Other*	*Admitted on a medical unit, receiving medication from a nurse participating in the study*

Période visée pour l'accès au dossier médical / Health Record Access *Time Frame*

2007/01/31 2008/01/31

Nombre approximatif de dossiers requis : maximum of 550
Estimated Quantity of Health Records to be Accessed:

Résumé du projet / *Summary of Project*: (joindre un résumé / *attach a separate summary*)

Contact avec les usagers? / *Will the patients be contacted?* ☐ Oui / *Yes* ☑ Non / *No*

Consentement des usagers pour accéder au dossier? / *Have the patients consented to the access of their record?* ☐ Oui / *Yes* ☑ Non / *No*

Projet approuvé par un CÉR? / *Project approved by a REB?* ☑ Oui / *Yes** ☐ Non / *No*
Si oui, # de projet du CÉR de McGill ou CUSM/ *If yes, McGill or MUHC project #*
**Submitted.*

Financement du projet/ *Project Funding*: Industrie/ Industry ☐, Interne/ Internal ☐,
Aucun/ None ☐ Subvention/ Grant ☑ (FRSQ and FERASI Doctoral fellowships)

N° de subvention / *Grant #*: Centre de coût / *Cost Centre #*:

Je déclare être au courant qu'en vertu de la *Loi sur les services de santé et les services sociaux*, tous les renseignements contenus dans les dossiers des usagers seront gardés strictement confidentiels de même que les renseignements colligés dans le cadre du projet de recherche. Des mesures appropriées seront prises quant à l'entreposage et à la destruction des informations recueillies au cours de la présente recherche. Aucun nom ou aucun autre renseignement personnel concernant les patients n'apparaîtront lors de la divulgation des résultats de la recherche. Si les sujets doivent être contactés dans le contexte de cette recherche, l'approbation du comité d'éthique de la recherche sera obtenue au préalable. J'ai lu la politique et procédure du CUSM relative à la demande d'accès au dossier médical et suis au courant des frais encourus pour la sortie de dossiers. Les dossiers seront consultés au service des archives.

I acknowledge that the information contained in health records as well as other information collected for this research project will be kept strictly confidential in accordance with An Act Respecting Health Services and Social Services. Appropriate security measures will be used in regards to the storage and disposal of the information gathered during this research. In reporting the results of the research, the patients' name or other identifying information will remain confidential. If subjects will be contacted for the purposes of this research, approval from a MUHC Research Ethics Board (REB) will be obtained before conducting this study. I have read the MUHC Policy and Procedure for Access to Health Records and am aware of the fees for health record access. Health records will be reviewed in the Medical Records department.

Demandeur / *Applicant*: Alain Biron N.PhD(c) Signature:

Département / *Department* : McGill School of Nursing Téléphone / *Phone* : (514) 398-2478

Télécopieur / *Fax*: (514) 398-8455 Téléavertisseur / *Pager* : None

Bureau ou adresse postale / *Room or Postal Address*: 3506 University Ave., H3A 2A7

Courriel / *Email Address*: alain.biron@mail.mcgill.ca

Collaborateurs / *Collaborators*: Dr Carmen G. Loiselle Signature
(Doctoral Supervisors)

Dr Mélanie Lavoie-Tremblay Signature

Autre personnel autorisé à accéder au(x) dossier(s) / *Other Staff Authorized to Access Health Record(s) for this Request: Two health care professionals will be recruited to review patients' charts.*

Approbation du chef de Service: Dr Hélène Ezer SIGNATURE:
Head of Service approval:

Accès approuvé par le DSP / *Access Approved by DPS* SIGNATURE:

DATE 07/01/11

Appendix M Quality and risk management support letter

Centre universitaire de santé McGill
McGill University Health Centre

December 6th, 2006

Denis Cournoyer, MD
Director, Research Ethics Office
McGill University Health Center

Dr Cournoyer,

As the director of Quality and Risk Management of the McGill University Health Center, I am writing to indicate my full support for this study on the influence of nurses' work environment on medication administration practices. The McGill University Health Center has made a major investment in the area of quality and safety and this project adds to the current efforts deployed. It will provide new evidence on the influence of nurses' work environment on medication related practices and valuable information on current medication administration practices within our organization. Both are key elements to effectively intervene to reduce medication error occurrences.

It is believed this project merits support considering its contribution to quality while ensuring that, through collaboration, ethical standards are met.

Sincerely,

M. Kaplow BSc PT, M Sc(A), MBA Director, McGill University Health Center Quality and Risk Management and Administrative Director, Neurosciences Mission, Montreal Neurological Hospital

HÔPITAL ROYAL VICTORIA HOSPITAL
687, av. des Pins O., Montréal (Québec) H3A 1A1, Tél.: (514) 842-1231

Appendix N Director of nursing support letter

Centre universitaire de santé McGill
McGill University Health Centre

March 8, 2007

Dr. Denis Cournoyer
Director, Research Ethics Office
McGill University Health Center
Montreal, Quebec

Dr. Cournoyer,

As the Director of Nursing of the McGill University Health Centre, I am writing to indicate my full support to this study on the influence of nurses' work environment on medication administration practices.

Mr. Alain Biron is a FERASI / McGill University Health Centre (MUHC) doctoral fellow. The FERASI Center draws upon close partnerships with decision makers to train a new generation of nursing administration researchers. Decision-makers from the MUHC have collaborated in the development of this research project from its early stages. This partnership has resulted in a project that addresses both our need for evidence related to safe medication use while contributing to knowledge development in patient safety.

The MUHC has a long history of supporting nursing research. This project is another example of this support and I strongly recommend it for approval.

Sincerely,

Diane Borisov

Diane Borisov
Director of Nursing
McGill University Health Centre

DB/dmcn

1650 Cedar, Montréal (Québec) Canada, H3G 1A4 (514) 934-1934

Appendix O Manuscript #4 acceptance letter

Alain Biron

From: onbehalfof@scholarone.com on behalf of jns@stti.org
Sent: 26 mai 2009 21:40
To: Alain Biron
Cc: melody@stti.iupui.edu; patrick.dillon@gmail.com
Subject: Journal of Nursing Scholarship - Decision on Manuscript ID JNU-02-09-037.R1

26-May-2009

Dear Mr. Biron:

Manuscript ID JNU-02-09-037.R1 entitled "Characteristics of work interruptions during medication administration" which you submitted to the Journal of Nursing Scholarship, has been reviewed and I am pleased to accept it for publication, pending some revisions.

The comments of the reviewer(s) were positive, but also suggest some minor revisions to your manuscript. The comments of the reviewer(s) are included at the bottom of this letter. I invite you to respond to the reviewer(s)' comments as you revise your manuscript.

To revise your manuscript, log into http://mc.manuscriptcentral.com/jnu and enter your Author Center, where you will find your manuscript title listed under "Manuscripts with Decisions." Under "Actions," click on "Create a Revision." Your manuscript number has been appended to denote a revision.

Once the revised manuscript is prepared, you can upload it and submit it through your Author Center.

You will be unable to make your revisions on the originally submitted version of the manuscript. Instead, revise your manuscript using a word processing program and save it on your computer. Please remember that changes made to revise your manuscript may not substantially increase the overall page count. Once the revised manuscript is prepared, you can upload it and submit it through your Author Center.

When submitting your revised manuscript, you will be able to respond to the comments made by the reviewer(s) in the space provided. You can use this space to document any changes you make to the original manuscript. In order to expedite the processing of the revised manuscript, please be as specific as possible in your response to the reviewer(s).

IMPORTANT: Your original files are available to you when you upload your revised manuscript. Please delete any redundant files before completing the submission.

Because we are trying to facilitate timely publication of manuscripts submitted to the Journal of Nursing Scholarship, your revised manuscript should be uploaded as soon as possible. If it is not possible for you to submit your revision in a reasonable amount of time, we may have to consider your paper as a new submission.

Once again, thank you for submitting your manuscript to the Journal of Nursing Scholarship and I look forward to receiving your revision.

Sincerely,
Susan Gennaro, RN, DSN, FAAN
Editor, Journal of Nursing Scholarship
jns@stti.org

Reviewer(s)' Comments to Author:
Reviewer: 1
Comments to the Author
I see that the needed corrections were substantially completed. There are still two tables missing (page 10). I think the editor can address those needs. Also, provide a reference for the assertion on page 12, line 34/35. I think it would be better to substantiate this claim.
"Improvement in the efficiency of medication administration systems is clearly needed as