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**UNDERSTANDING THE RELATION BETWEEN ADVERSE EVENTS,
PATIENT CHARACTERISTICS, AND RISK FACTORS AMONG HOME CARE
PATIENTS**

**By
Kimberly A. Miller**

**A Thesis
Submitted to the Faculty of Graduate
Studies through the Faculty of Nursing
In Partial Fulfillment of the Requirements for
The Degree of Master of Science
At the University of Windsor**

Windsor, Ontario, Canada

2012

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APPROVALS

“Understanding the Relation Between Adverse Events, Patient Characteristics, and Risk Factors Among Home Care Patients”

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ABSTRACT

Purpose: Explores the relations among patient characteristics, risk factors and adverse events of adult home care patients in Southwestern Ontario.

Significance: Adverse events which occur in home care are different from those that occur in an institutional setting.

Methods: This descriptive study utilized retrospective chart review of 500 episodes of care.

Results: The incidence of adverse events was 9.4%. New emergency room visits, new hospital admissions and new falls were the most common type of adverse events. A decline in physical function and polypharmacy with a history of cognitive impairment were the most frequent risk factors. Self-care and length of stay were significantly associated with adverse events. Patients with acute illness were at decreased risk of falling.

Conclusions: This study identified factors that increase the risk of adverse events, allowing for targeted interventions and contributing to our knowledge and understanding of adverse events in this unique setting.

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UNDERSTANDING THE RELATION BETWEEN ADVERSE EVENTS, PATIENT
CHARACTERISTICS AND RISK FACTORS AMONG HOME CARE PATIENTS

CHAPTER I

INTRODUCTION

Background

Over the past decade, home care has been a critical part of health care restructuring, and has played a key role in primary health care, chronic disease management, and aging at home strategies across Canada (Canadian Home Care Association [CHCA], 2008). Home care programs across Canada have experienced a 51% increase in the number of home care recipients over the past decade (CHCA, 2008). This shift in care delivery requires investigation into how to safely deliver increasingly acute and more complex health care in the home.

Patient safety has emerged as a national priority in Canadian health care. The release of key documents, such as the Canadian Adverse Events Study (Baker, Norton, Flintoft & Blais, 2004) have heightened awareness and increased pressures to improve patient safety within the Canadian health care system.

The Canadian Patient Safety Institute (CPSI) (2003) defines *patient safety* as “the reduction and mitigation of unsafe acts within the health care system, as well as through the use of best practices shown to lead to optimal patient outcomes” (p. 12). It has also been described as the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum (World Health Organization [WHO], 2009). Patient safety considers current knowledge, resources, the context in which care is delivered, and the risk of non-treatment or alternative treatment (WHO, 2009).

Most of the published research on patient safety have been conducted in institutionalized settings (Edwards & Lang, 2006; Madigan, 2007), and there is limited literature on adverse events in home care. Research has identified that adverse event rates in home care vary from approximately 5-23% (Forster et al., 2004; Forster, Murff, Peterson, Gandhi & Bates, 2003; Johnson, 2006; Madigan, 2007; Sears, 2008), but there is limited evidence and understanding about the incidence and impacts of safety problems and adverse events among Canadian home care patients. The purpose of this study is to explore the relations among patient characteristics, risk factors and adverse events of patients in the home environment and contribute to the current knowledge and understanding of adverse events in this unique setting.

Home Care in Ontario

Home care is defined as “an array of services for people of all ages, provided in the home and community setting, that encompasses health promotion and teaching, curative intervention, end-of-life care, rehabilitation, support and maintenance, social adaptation and integration and support for the informal (family) caregiver” (CHCA, 2008, p. viii). For the purpose of this paper, the individual receiving home care will be referred to as the *patient*, which is consistent with language used in most patient safety literature.

In 2008, there were approximately 900,000 individuals receiving home care services in Canada (CHCA, 2008); the majority were seniors aged 65 and over who require long-term supportive care. Home care services are provided in a variety of settings which may include: individuals’ homes, nursing homes, retirement homes, clinics, schools, group homes, hospices, reserves, and on the street for homeless

populations (CHCA, 2008). This research will address only patients receiving care in the home.

In Ontario, 14 Local Health Integration Networks (LHINs) are responsible for the planning, integrating and funding of local health services, including home care services (Ontario Home Care Association [OHCA], 2008). The LHINs work in partnership with 14 Community Care Access Centres (CCACs), who are accountable for the planning, delivery, and ongoing operational management of home care services (OHCA, 2008). Home care provider organizations are selected through an objective procurement process which has been developed through the efforts of home care providers, associations, and government's intent on creating a system that is driven by quality and evaluated on several dimensions (OHCA, 2008). By separating the direct service provision and the service authorization responsibilities of the CCACs, conflict of interest is guarded against (OHCA, 2008).

Patient Safety and Home Care

The provision of health care in the home differs from the institutional setting in several ways. These include the nature of formal service provision, the physical context, and variability of home environments, the role of informal caregivers and specific patient characteristics (Canadian Patient Safety Institute [CPSI], 2010). Patients in the home have significantly less contact with the health care professional than patients in an institutional setting. Therefore, home based patients have more autonomy and may be dependent upon an informal caregiver (Hirdes et al., 2004). A survey completed by Health Canada (2002) determined that approximately four percent of adult Canadians are currently providing care to a family member, suffering from a physical or mental

disability, is chronically ill or frail. Care provided by an informal caregiver influences the quality of care being provided (Hirdes et al., 2004). Home care patients are subject to less intensive monitoring by health professionals than in in-patient settings (Hirdes et al., 2004). Therefore, addressing safety in home care presents challenges that require a unique perspective from that used to examine patient safety in the institutional environment (Edwards & Lang, 2006).

The exploration of safety in home care is complex. It is not limited to only physical safety but also includes the social, emotional, and functional components (CPSI, 2010). There are many variables that cannot be regulated or controlled in the home to the same extent as in institutional settings. The pursuit of a risk-diminished or risk-free environment must be balanced against the realities of the patient's tolerance of risk, preferences, and home life and be respectful of the risks that patients' choices may impose on both formal and informal caregivers. Family/caregiver involvement in care delivery also affects safety. There are very significant differences in training/education and roles and responsibilities within the care teams (including patients, informal caregivers and formal care providers) and how this impacts safety for team communication, handoffs, and knowledge transfer amongst the team. Efforts to examine safety in home care should emphasize the minimization or mitigation of safety risks for patients rather than on discrete events (CPSI, 2010).

Services provided to home care patients have also been influenced by advances in treatment and technology, resource constraints, hospital restructuring, and changes in consumer expectations. These changes have significantly increased the care requirements of individual patients (O'Brien-Pallas et al., 2003). The Ontario Association of

Community Care Access Centres (OACCAC) (2000) has determined that home care patients now have greater physical and mental health care needs than in the past. These needs are less predictable and require intervention over a longer period of time. Patients are being released from hospital into the home earlier, and with a greater need for support (OACCAC, 2002). All of these changes point to a need to improve our understanding of patient safety in this sector.

Adverse events are known to have an economic impact. The To Err is Human Report (Kohn, Corrigan, & Donaldson, 2000) examined the quality of health care in the United States (US), and identified that errors were costly in dollars spent on having to repeat diagnostic tests or counteract adverse drug events and represent money unavailable for other purposes (Kohn, Corrigan, & Donaldson, 2000). Total US national costs (lost income, lost household production, disability, and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion (Thomas et al., 1999). These costs were limited to acute care settings, but Kohn and colleagues (2000) acknowledged that more care and increasingly complex care is being provided in ambulatory settings and medical errors present a problem in any setting, not just hospitals (Kohn, Corrigan, & Donaldson, 2000).

There is a lack of knowledge related to the economic impact of adverse events in health care, in Canada. In an effort to understand the true financial costs, in 2010 the Canadian Patient Safety Institute (CPSI) has funded a research project entitled *The Economic Burden of Patient Safety* to explore the economic implications associated with patient safety in health care. In addition, as well as an economic impact, there is a loss of

trust in the system by patients and diminished satisfaction by both patients and health professionals.

Significance to Nursing

Patient safety has emerged as a priority at the national, territorial, and provincial levels in Canadian health care. Promoting patient safety in the interest of protecting the public is central to the mandate of Canadian healthcare associations at the provincial, territorial, and national levels. The Canadian Patient Safety Institute (CPSI) has a national mandate to build and advance a safer health system for Canadians.

Patient safety has always been important for Canadian registered nurses (RNs) since nurses are involved in the provision of health care in every area of the health care system. Nurses act to keep patients safe, identify areas of risk, and recognize situations in need of improvement (CNA and University of Toronto Faculty of Nursing, 2004). The Canadian Nursing Association (CNA) has declared their commitment to patient safety through the creation and dissemination of a position statement on the importance of patient safety (CNA, 2003). Patient safety is fundamental to health and nursing care across all settings (CNA, 2003). A Registered Nurses Association of Ontario (RNAO) (2004) policy statement envisions RNs as a key link in the health care system, protecting and enhancing the health of patients and creating environments that support patient safety.

Adverse events are not unique to home care patients; it is the environment where the adverse event occurs, which is different from adverse events that transpire in an institutional setting and therefore presents unique challenges. Without an understanding of how and why these adverse events occur in home care, interventions to address the

problem will be unsuccessful. This research will help to increase our understanding of some of the unique factors that contribute to, influence, and therefore possibly may lead to solutions to address the risk for adverse events within home care.

Purpose

There is limited evidence and understanding about adverse events among Canadian home care patients. Gaining insight into risk factors in the context of the home care environment will influence health policy makers and allow organizations to implement strategies and improvement initiatives designed to predict and mitigate these risks.

Doran, Hirdes, White, et al. (2009) completed a secondary analysis of data collected through the Canadian Home Care Reporting System, which utilized the Resident Assessment Instrument - Home Care© (RAI-HC©) assessment tool, to assess the burden of safety problems among Canadian home care patients. The authors explored the role between risk factors and adverse events. A limitation of the study, associated with using only RAI-HC© data, was that it was not possible to validate the occurrence of adverse events because further work, such as chart audits, was needed to validate that the event was associated with home health care management and to identify true positive cases (Doran, Hirdes, White, et al., 2009). The purpose of this study is to expand on the research by Doran, Hirdes, White, and colleagues (2009), specific to risk factors and adverse events in home care, and validate the actual occurrence of an adverse event through chart audits. Additionally, this study will build on current knowledge and understanding of adverse events in home care by exploring the relations among patient

characteristics, risk factors and adverse events at a home care organization in Southwestern Ontario.

CHAPTER II

REVIEW OF THE LITERATURE

Search Strategy

Literature was retrieved from the subsequent databases: Proquest Nursing Journals, Pubmed, Cumulative Index to Nursing and Allied Health Literature, Medline, Ovid Nursing and the Cochrane Database of Systematic Reviews. The key terms utilized in the search process were: adverse events, community health nursing, home care, safety and World Health Organization conceptual framework. The search terms were utilized in different combinations. The literature search covered published literature between 2000 and 2012. Papers included research studies, review articles, policy papers and opinion articles. Reference lists were also examined for any additional relevant studies not identified through the search. Inclusion criteria were: (1) home care services provided in the home (2) adverse events (3) were in English and (4) reported overall rates versus only rates specific to a task or patient population (e.g. sepsis rates in central venous access devices). Studies focusing on a specific type of adverse event, such as urinary tract infections or drug events were excluded since this study is interested in a broader picture of adverse events. *Hospital at Home* programs were also excluded because they provide intensive hospital care in the home, include physicians within the team and, this care delivery model does not exist in Canada. This search strategy generated 10 articles, appropriate for inclusion.

Conceptual Framework

The World Health Organization (WHO) conceptual framework for the International Classification for Patient Safety (ICPS) (WHO, 2009) enables

categorization of patient safety information using standardized sets of concepts with agreed definitions and preferred terms, and provides a way to conceptualize interrelationships among concepts. The framework provides a platform for conceptualizing, organizing, and understanding the interrelationship among patient characteristics, safety risks and adverse events. The conceptual framework for the ICPS was designed so that it can be aggregated and analyzed to:

- Compare patient safety data across disciplines, between organizations, and across time and borders;
- Examine the roles of system and human factors in patient safety;
- Identify potential patient safety issues; and
- Develop priorities and safety solutions (WHO, 2009)

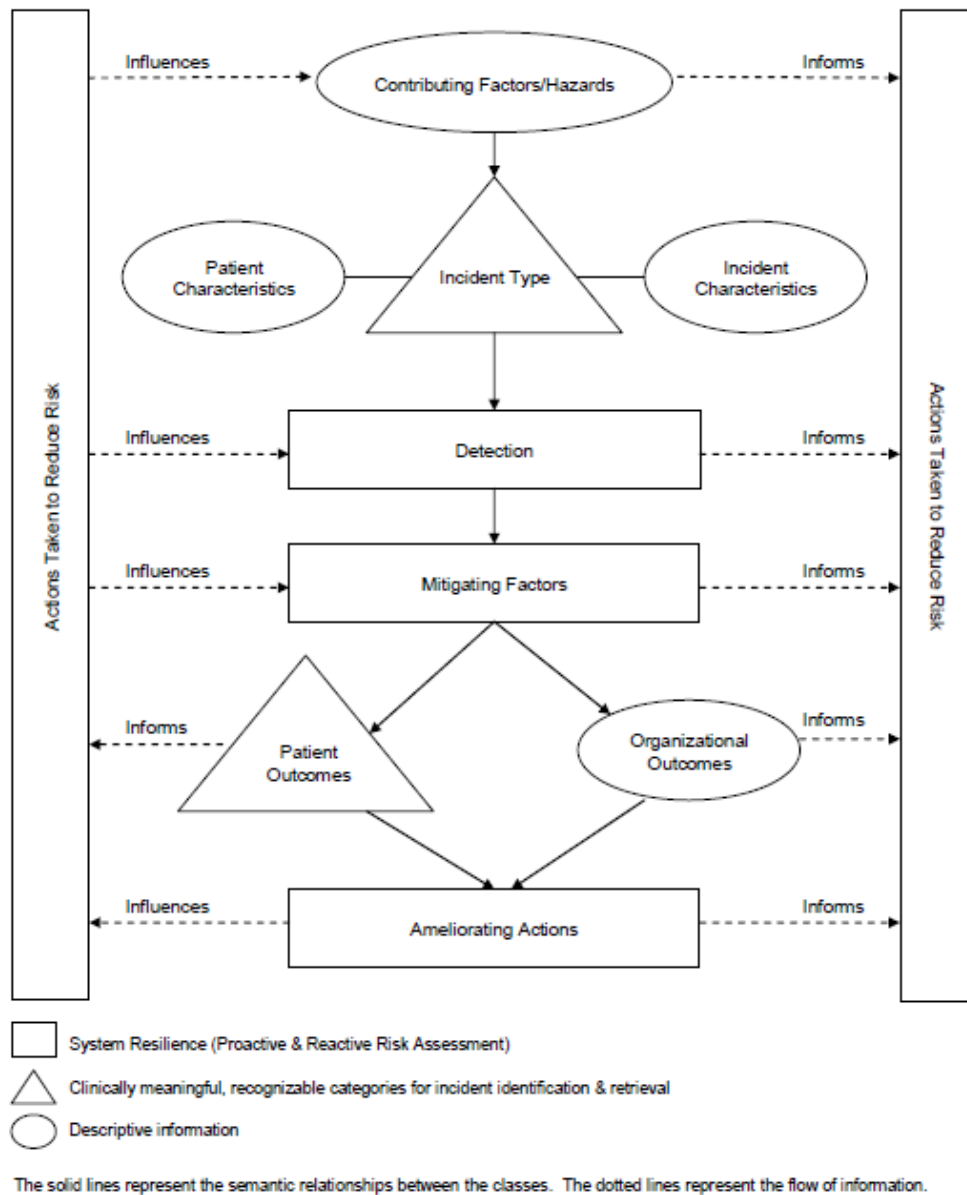
The purpose of the framework is to classify all of the elements of a *patient safety incident*, to enable categorization of patient safety information using standardized sets of concepts with agreed definitions, preferred terms and the relations among them and consists of 10 high level classes: Incident Type; Patient Outcomes; Patient Characteristics; Incident Characteristics; Contributing Factors/Hazards; Organizational Outcomes; Detection; Mitigating Factors; Ameliorating Actions; and, Actions Taken to Reduce Risk (WHO) (see Diagram 1). This focus of this study will be on *patient characteristics*, components of *contributing factors/hazards (risk factors)* and the potential relations among these factors and *patient safety incidents (adverse events)*.

The World Health Organization (2009) Conceptual Framework for the International Classification for Patient Safety is very new. It is not yet the standard for describing and analyzing information about patient safety incidents. The language of the

framework is not yet common or widely understood. For the purpose of this paper the term *adverse events* will be used to describe patient safety incidents. I chose to use this framework in an effort to be consistent with research completed by Doran, Hirdes, White, et al. (2009). The aim of this study is to expand on the research by Doran, Hirdes, White, et al. (2009) specific to contributing factors/hazards and adverse events in home care.

Figure 1

The Conceptual Framework for the International Classification for Patient Safety (WHO, 2009) Reprinted with permission of the WHO.



The framework defines *Contributing Factors/Hazards* as “the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident” (WHO, 2009, p. 11). These contributing actions, circumstances or influences are more commonly referred to as risk factors. The WHO (2009) framework defines *patient safety incident* as “an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient” (p. 131). An incident can be a reportable circumstance, near miss (an error that does not reach the patient; for example, a medication calculation error that is caught through a double check process), no harm incident, or harmful incident (adverse event) (WHO, 2009). In an effort to be consistent with Canadian literature (e.g. Doran, Hirdes, White, et al., 2009) this study will use the term *adverse event* to refer to patient safety incidents.

The WHO (2009) framework is a good choice for home care safety research because it recognizes that health care is not limited to medical care provided by professionals. This is significant in the home care context, where much of the care is independent or provided by informal caregivers, such as family members. Using the WHO conceptual framework for the ICPS (WHO, 2009), with future improvement strategies, will (1) enable accurate translation through standardization; and, (2) provide a clear demonstration of improvement through linkages between patient incidents and detection, mitigation and prevention of safety risks. It is recognized as a limitation that not all components of the framework are being addressed. This study identifies specific risk factors as the contributing factor/hazard and examines the relations among these identified risk factors, patient characteristics, and adverse events.

Literature Review

The findings of this literature review are organized and presented in the following order: (i) adverse event rates and types (ii) patient characteristics and contributing factors, including: causes of adverse events and critical indicators (iii) consequences of adverse events, and finally (iv) gaps in the literature.

Adverse Event Rates and Types

This literature review will examine adverse event rates in Canadian hospitals as well as home care because of the small amount of research available. Additionally, the review of these research reports will provide a rationale for the diversity of the reported rates (approximately 5-23%).

Forster and colleagues (2004) studied 328 patients discharged from a multisite, general internal medicine service of a Canadian hospital and found a 23% adverse event rate (76 adverse events). More than half of the reported adverse events required no additional use of health services. This is significant to the reporting and comparing of adverse events because some authors identify adverse events only through the use of health services.

In a prospective cohort study, evaluating 400 patients for an adverse event three weeks after discharge from a US general medical service, an adverse event rate of 19% (76 patients) was reported (Forster, Murff, Peterson, Gandhi & Bates, 2003). These authors included adverse events which occurred in hospital and after discharge (provided the symptoms continued once the patient went home), versus including only adverse events which occurred in the home. This would theoretically lead to an inflated adverse event rate for home care patients.

A retrospective chart review of 400 Winnipeg home care patients found a rate of 5.5% (26 adverse events in 22 patients) (Johnson, 2006). In this study, both patients and caregivers were included as members of the health care team. This expands on traditional thinking that adverse events are only caused by healthcare management and may more accurately reflect the home care environment.

Sears (2008) conducted a stratified, random sample of 430 patients who had received home care nursing service and were discharged in 2004/05 from three Ontario home care programs. An adverse event rate of 13.2 per 100 home care cases was found (Sears, 2008). This study also included health care interventions carried out by the patient and informal caregivers as well as those by health care professionals. This is important when considering the home care environment; much of the care is completed by the patient or the caregiver. Sears (2008) chose to define adverse event as “(1) an unintended injury or complication (2) which results in disability, death or increased use of health care resources and (3) is caused by health care management” (p. 33). This definition does not however allow for potential harm. Consider a medication error that may have variable outcomes such as an emergency room visit for one patient and no adverse signs or symptoms for another patient. The determination as to whether the medication error was an adverse event is dependent in part on the definition.

Adverse event incidence rates in home care vary significantly. Differences in incidence rates may be partially explained by the lack of a standardized definition of *adverse event*, varying methodology, differences in the patient populations studied and whether the patient and the caregiver are included as health care providers. The limited

amount of data, reporting overall adverse event incidence rates in home care, cannot be compared or generalized because of these reasons.

The purpose of exploring adverse events in home care is to gather knowledge and better understand these events in an effort to implement effective strategies to mitigate or reduce adverse event rates in the home care environment. Considering the types of adverse events that occur will provide information as to whether they are the same as the types of events which occur in an acute environment and will assist us in targeting the areas of most opportunity for improvement.

In a review of the literature, Masotti, McColl, and Green (2010) identify six key categories of adverse events: adverse drug events, line-related adverse events, technology related adverse events, infections and urinary catheter related adverse events, falls and other adverse events. Their review went beyond looking at literature discussing overall adverse events and included research specific to isolated focuses such as adverse drug events. Findings were limited to only four of the above mentioned categories; there were no infusion line related adverse events and no technology related events discovered. Additionally, the authors suggest that incorporation of a wound category would provide sufficient categories to effectively group reported adverse event types.

The most commonly reported and occurring events, found in this literature review, were adverse drug events (16.4-72%) (Forster et al., 2004; Forster, Murff, Peterson, Gandhi & Bates, 2003; Johnson, 2006; Madigan, 2007; Sears, 2008). Infections and urinary catheter related adverse event rates, which also include wound and nosocomial infections, were also frequently reported (Doran, Hirdes, White, et al., 2009; Forster et al., 2004; Madigan & Tullai-McGuinness, 2004; Madigan 2007). Falls were

also a commonly reported adverse event (Doran, Hirdes, White, et al., 2009; Johnson, 2006; Madigan and Tullai-McGuinness, 2004; Madigan, 2007; Sears, 2008). The remaining types of adverse events can be grouped into *other*. These adverse events include mental harm/injury, procedure related injuries, therapeutic errors, procedure-related problems, and discharge to home with problematic behaviours.

Doran, Hirdes, White, et al. (2009) conducted an exploratory study designed to identify the nature and prevalence of patient safety problems among 238,958 Canadian home care patients, using data collected through the RAI-HC© assessment instrument. Doran, Hirdes, White, et al. (2009) differentiate between safety risks and adverse events. Some of the safety risks have been defined by other authors as adverse events; for example, aggressive behaviour. The authors are also original in their classification of adverse events in the context of resource utilization and report adverse event rates for events such as new emergency room visit (8.3% of all potential adverse events) and new hospital visit (7.7% of all potential adverse events). Key to realizing the difference between hospital and home is the recognition by Doran, Hirdes, White, et al. (2009) of caregiver decline (3.3% of all potential adverse events) as an adverse event.

Available literature, specific to research exploring adverse events in home care and reporting types of adverse events, describes adverse event types which can mostly be classified into five categories of adverse events: adverse drug events, wounds, infections and urinary catheter related adverse events, falls and other. Doran, Hirdes, White, et al. (2009) provides a non-traditional classification system that may demonstrate value when evaluating adverse events specific to home care. It is recognized that there is a need to standardize what constitutes an adverse event (Masotti, McColl, & Green, 2010).

Patient Characteristics and Contributing Factors

Characteristics of home care patients associated with an increased risk of adverse events were categorized into two categories: patient-level characteristics such as increased age, co-morbidities or functional status, and healthcare organization and system-level characteristics, such as communication issues and coordination and collaboration (Masotti, McColl, & Green, 2010). Masotti et al. (2010) included home care agencies and their associated staff as well as other clinical providers who work with patients within their definition of the healthcare organization, recognizing the impact of this broader context for increased risk of an adverse event in home care.

Sears (2008) considered patient level characteristics when attributing cause. Factors significantly associated with adverse events included age 65 years or more, living with others, discharge to locations other than home, first languages other than English, cognitively related communication difficulties, certain co-morbidities, a history of falls, psychotropic medication use, short or procedural memory difficulties, lack of ability for independent decision making, depression/anxiety/anger, the need for assistance with a variety of specific activities of daily living and independent activities of daily living, urinary incontinence and bowel incontinence (Sears, 2008).

Forster, Murff, Peterson, Gandhi and Bates (2003) determined that four different aspects of the system require improvement: assessment and communication of unresolved problems at the time of discharge, patient education regarding medications and other therapies, monitoring of drug therapies after discharge, and monitoring overall condition after discharge. They also found that the most common deficit in the provision of discharge care was poor communication between the hospital caregivers and either the

patient or the primary care physician. These identified areas reflect the needs of the post hospital discharge patient populations studied by these authors and further investigation is required before generalizing to all home care patients.

Johnson (2006) and Sears (2008) considered the role of the care provider in adverse events. Johnson (2006) found that multiple contributing providers were involved in 46.2% of the adverse events and 50% of the adverse events were associated with home care providers. Informal caregivers were identified as a contributing to 42.3% of adverse events and patients themselves in 30.8% of events, other healthcare providers identified by chart reviewers as family physicians and hospitals were associated with 42.3% of the adverse events (Johnson). Sears (2008) reported that self-care was rated as a contributing factor in over half (52.6%) of adverse events; self or informal caregiving was rated as a contributing factor in two-thirds of adverse event associated deaths.

Health care professionals were brought together in an effort to determine important issues relating to adverse events in home care (Masotti, Green, & McColl, 2009). They identified factors that contribute to adverse events in home care including: communication problems, formal provider skill mix, patient complexity, home environment, medical procedures, and service delays.

Grouping adverse event etiologies into patient-level and system-level groups without considering the role of the patient or caregiver limits understanding of why adverse events in home care occur and could impair the creation of effective improvement strategies. Systems classification must recognize the home care is unique as care is often delivered by informal caregivers or the patients themselves.

Critical indicator methodology can reliably identify patients who have experienced an adverse event (Sears, 2008). The use of specific critical indicators allows opportunity to measure patient care quality and to design care to improve patient safety and allows for retrospective identification of home care patients who had a higher or lower likelihood of having experienced an adverse event (Sears, 2008). Critical indicators act as a trigger to identify situations in which an adverse event is more likely to have occurred (Sears, 2008). The presence of critical indicator(s) suggest an increased likelihood that an AE occurred, it does not necessarily indicate causality (Sears, 2008).

Sears (2008) identified and validated critical indicators sensitive to identifying home care patients who experience adverse events. A model of five individual critical indicators, developed by Sears reliably identified 67.3% of home care patients with adverse events and 84% of patients without adverse events. The Single Critical Indicators Predictors for Adverse Events (Sears, 2008) includes: recognize actual or potential environmental risks; inappropriate/inaccurate home care case manager or service provider assessment of client; client injury, harm, trauma or complication during home care admission; unplanned visit to hospital emergency department; and, dissatisfaction with care documented or evidence of complaint lodged.

Consequences of Adverse Events

Both health and economic consequences can occur on a continuum that can range from barely observable occurrences to those that have high health and economic costs (Masotti, McColl & Green, 2010). Examples of health consequences include functional loss or decline, illness, temporary injury/pain, permanent injury/harm and death.

Examples of economic consequences include: increased need for treatment or care, increased patient or caregiver time and unplanned hospitalizations.

Johnson (2006) found that 69.3% of adverse events resulted in temporary harm, 4% in permanent harm, 4% in permanent placement and 15.4% resulted in unneeded hospitalizations, premature nursing home placement (3.8%). Forster, Murff, Peterson, Gandhi and Bates (2003) found that 3% of were serious laboratory abnormalities, 65% were symptoms, 30% were symptoms associated with a nonpermanent disability and 3% were permanent disabilities. Forster et al. (2004) ranked adverse event severity, which ranged from laboratory abnormalities (1%) several days of symptoms (68%) or symptoms associated with a non-permanent disability (25%) to permanent disability (3%) or death (3%). Consequences are typically associated with either health or economic impacts.

Gaps in the Literature

A standardized definition of adverse event is required in order to develop benchmark data and reliably compare adverse event rates. Current literature cannot be generalized since a standardized definition of adverse events in home care has not yet been agreed upon and therefore there are multiple differences determining and operationalizing what constitutes an adverse event (Masotti, McColl & Green, 2010).

Differences in methodology and data extraction methods may explain the wide range in reported adverse event rates. Adverse event incidence rates in home care vary from 5.5-23% (Johnson, 2006; Forster et al., 2004; Forster, Murff, Peterson, Gandhi & Bates, 2003; Madigan, 2007; Sears, 2008). Three of the studies reporting overall adverse event rates used critical indicator screening and chart reviews by physicians (Forster et

al., 2004; Forster et al., 2003; Sears, 2008). Johnson (2006) used nurses and social workers to conduct chart reviews. Madigan evaluated the Outcome and Assessment Information Set (OASIS) database for all Medicare and Medicaid home care patients, in the US that includes reporting of 13 adverse event outcomes.

Differences in the patient populations studied may also partially explain variability in reported adverse event rates. Two of the five available studies reporting overall adverse event rates were from the US, where the health care system is very different from Canada (Forster, Murff, Peterson, Gandhi & Bates, 2003; Madigan, 2007). Additionally, two of the studies, one Canadian and one US, examined patients only in the immediate post hospital discharge period (Forster et al., 2004; Forster et al., 2003). The post hospital discharge period may be associated with changes in providers, in therapy and with location of care. These patients may also be more acute. The adverse event rates for these two studies are distinctly higher (19-23%) than the remaining three studies (5.5-13.2%) (Forster et al., 2004; Forster et al., 2003; Johnson, 2006; Madigan, 2007; Sears, 2008). Differences in the patient populations studied may begin to explain the variability of reported overall adverse event rates for home care patients.

Masotti, McColl, and Green (2010) in a review of the literature determined that there does not appear to be a standardized definition for adverse events which occur in home care. Differences in definitions used vary based on outcomes such as increased resource utilization versus the potential for the outcome to occur (Masotti et al., 2010). Definitions also vary in whether it is the consequence or outcome versus the antecedent which is the adverse event (Masotti et al., 2010). For example, death has been identified as both an adverse event and a consequence of an adverse event. Masotti and colleagues

(2010) found that there is a need for clarity and standardization regarding what constitutes an adverse event.

Available literature, specific to research exploring adverse events in home care and reporting types of adverse events, describes adverse event types which can mostly be classified into five categories of adverse events: adverse drug events, wounds, infections and urinary catheter related adverse events, falls and other. Doran, Hirdes, White, et al. (2009) provide a non-traditional classification system that may demonstrate value when evaluating adverse events specific to home care. It is recognized that there is a need to standardize what constitutes an adverse event (Masotti, McColl & Green, 2010).

A lack of a standardized approach to determining what constitutes an adverse event leads to confusion when attempting to identify types of adverse events. For example Madigan and Tullai-McGuinness (2004) report an overall adverse event rate for unexplained death of 1.0%. Madigan (2007) reports an overall adverse event rate for unexpected death of 5.1%. Other authors define death as a consequence of an adverse event (Forster et al., 2004; Sears, 2008). Definitions vary in whether it is the consequence or outcome versus the antecedent which is the adverse event (Masotti et al., 2010).

Masotti et al. (2010) in a review of the literature available (1998-2007), suggest that one should not interpret summaries of the available literature to reflect the true experience of home care patients in multiple home care settings. The authors suggest that differences in definitions used, a lack of large sample cohort studies, minimal research available and the need for some types of adverse events to still be described and defined, influence the generalizability of the literature available to date.

Researchers are only beginning to think about and understand adverse event predictors or risk factors in home care. Forster et al. (2004) found that being female, having type 2 diabetes mellitus or having pneumonia independently predicted adverse event occurrence. Madigan (2007) determined that patients who experienced adverse events were older, had more depressive symptoms, more behavioural problems and higher level of impairment for both ADLs and IADLs. Relative risk was calculated for sex and ethnicity. The results showed that women had a slightly lower relative risk (0.98) and patients of minority ethnicity had a slightly higher relative risk (1.06).

Doran, Hirdes, White, et al. (2009) completed a secondary analysis of data collected through the Canadian Home Care Reporting System, which utilizes the RAI-HC© assessment tool, to assess the burden of safety problems among Canadian home care patients. Findings suggested that home care patients present with multiple risk factors, such as polypharmacy, living alone and no recent medication review (Doran, Hirdes, White, et al., 2009). This research also demonstrated that the studied risk factors were differentially related to potential adverse outcomes, for example, the odds of emergency room visits increased with polypharmacy and decreased with lower self-reliance (Doran, Hirdes, White, et al., 2009). The authors identified adverse events as “potential” because further work, such as chart review, is needed to validate that the events were associated with home health care management.

In summary, there is a gap in Canadian literature because of limited evidence and understanding about adverse events among Canadian home care patients. Gaining insight into adverse events in the context of the home care environment will influence health policy makers and allow organizations to implement strategies and improvement

initiatives designed to predict and mitigate these risks. The purpose of this study is to expand on the research by Doran, Hirdes, White and colleagues (2009), specific to risk factors and adverse events in home care, and validate the actual occurrence of an adverse event through chart audits. Additionally, this study will build on current knowledge and understanding of adverse events in home care by exploring the relations among patient characteristics, risk factors and adverse events at a home care organization in Southwestern Ontario.

Research Questions

1. What is the incidence of adverse events among home care patients in Southwestern Ontario?
2. Are the most common type of adverse events among home care patients new fall, unintended weight loss, new emergency room visit, and new hospital visit (admission)?
3. What are the characteristics (sex, age, primary diagnosis, self-care capabilities, living alone and length of stay) of these patients and is there a difference between those who experience an adverse event and those who do not?
4. Are polypharmacy and a decline in physical function the most common risk factors that occur with home care patients, who experience an adverse event?
5. What are the relations among *types of adverse events* (fall, increased use of health care resources and adverse outcomes) and *risk factors* (client characteristic, client behavioural characteristic, client living situation and health care management factors) and *patient characteristics* (age, self-care capabilities, living alone, length of stay and diagnosis)?

CHAPTER III

METHOD

Population

The study sample consisted of patients discharged from one home care agency, nursing service, between May 1, 2011 and October 31, 2011. This convenience sample consisted of adult patients (greater than 18 years of age) residing in Southern Ontario.

Adverse Events

The WHO (2009) framework defines *patient safety incident* as “an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient” (p. 131). A patient safety incident can be a reportable circumstance, near miss, no harm incident or harmful incident (WHO, 2009). For the purpose of this paper, patient safety incident will be referred to as an adverse event. Adverse event is defined as “an unintended injury or complication that results in disability, death, or increased use of health care resources and is caused by health care management” (Sears, 2008; p. 33). This definition is relevant to the home care environment, recognizes the potential impact of informal caregivers, broad and considers health care management to be critical to the event.

Using RAI-HC© data, Doran, Hirdes, White, et al. (2009) identified three different types of patient safety incidents: fall, increased use of health resources and adverse outcome. These authors suggested that these patient safety incidents be used as screening criteria with investigation undertaken to establish the occurrence of an adverse event. Patient Safety Incidents, as identified through the RAI-HC© Assessment Tool by Doran, Hirdes, White, et al. (2009), is used as an operational definition, for *adverse event*, within this research and is described in Table 1.

Table 1

Adverse Events

Adverse Event	Description
Fall	New Fall
Increased use of health care resources	New emergency room visits New hospital visits (admissions)
Adverse outcome	Cognitive performance decline Unintended weight loss New urinary tract infection New bowel problem New dehydration New caregiver decline

(Doran, Hirdes, White, et al., 2009)

Risk Factors

The WHO (2009) framework identifies contributing factors/hazards that result in a patient safety incident. *Contributing Factors/Hazards* are defined as “the circumstances, actions or influences which are thought to have played a part in the origin or development of an incident or to increase the risk of an incident” (WHO, 2009, p. 11). Doran, Hirdes, White, et al. (2009) defined safety risks as “characteristics of the patient or the living situation that place a patient at risk of adverse outcome” (p. 167). This research identifies risk factors as a component of WHO contributing factors/hazards. Doran, Hirdes, White, et al. (2009) identified *Risk Factors* through the RAI-HC Assessment Tool. These risk factors are provided within Table 2 and are used within this research as an operational definition. Monitoring safety risk factors provides home care organizations and regional health authorities with important information about the profile of their patient population, it provides frontline clinicians with information about individual patients that should be considered when planning health care intervention and they provide individual patients with valuable information for self-care management (Doran, Hirdes, White, et al., 2009). The WHO (2009) framework identifies a link between contributing factors/hazards and patient safety incidents, including adverse events.

Table 2

Risk Factors

	Safety Risk Factor	Operational Definition
Client characteristic	Decline in physical function	Activities of daily living decline compared to status 90 days ago
	Decline in mental function	Sudden or new onset/change in mental function over last 7 days
	Decline in cognitive function	Worsening of decision making as compared to status of 90 days ago
	Hearing deficit	Hearing patterns
	Vision deficit	Ability to see in adequate light and with glasses if used
	Social isolation with distress	Change in social activities compared to 90 days ago
Client behavioural Characteristic	HIV and/or tuberculosis infections and others in the home	HIV infection Tuberculosis infection
	History of two or more falls	Intake history of two or more falls in last 90 days
	Non-adherence to medication	Intake non-adherence to medication
	Substance abuse	In last 90 days client felt the need or was told by others to cut down on drinking, or others concerned with client drinking. Or client had to have a drink first thing in the morning to steady nerves
	Smoking and oxygen in the home and others in the home (exposure second hand smoke)	Smoked daily
	Aggressive behaviour	Socially inappropriate/disruptive behavioural symptoms
	Morbid obesity and requiring weight-bearing assistance for transfer	Morbid obesity and requiring assistance to transfer to/from bed, chair, wheelchair, standing position
Client living situation	Lives alone and decline in physical Function	
	Lives alone and decline in cognition	
	Unsafe housing	Lighting inadequate, flooring and carpeting unsafe, bathroom, unsafe, kitchen (e.g. dangerous stove), heating/cooling, personal safety, difficult access to home, difficult access to rooms
Health care management Factors	Polypharmacy and history of cognitive impairment	Five medications or more
	No medication review for clients with polypharmacy and/or history of cognitive impairment	Physician review of medication as a whole in last 180 days (or since last assessment)

(Doran, Hirdes, White, et al., 2009)

Methodology

Study Design

This descriptive study utilized retrospective chart review to collect data on eligible patients discharged from home care in Southern Ontario. Trained nurse reviewers screened charts for adverse events using Doran, Hirdes, White, et al. (2009) description of adverse events. A nurse reviewer then evaluated the chart to determine if risk factors, as identified by Doran, Hirdes, White, et al. (2009) were present. Additional data collected included: age, sex, primary diagnosis, self-care, living alone, and length of stay. A *Data Collection Form* (Appendix A) containing demographic inquiries, as well as all potential risk factors and adverse events was completed for each episode of care reviewed.

Inter-rater Reliability

Inter-rater reliability was considered, as data were collected by both the primary researcher and a trained nurse reviewer. The nurse reviewer worked in collaboration with the primary researcher. They reviewed charts together until the same decisions, specific to the indicators, had been made on ten consecutive charts. Any indecision resulted in discussion and consensus between the primary researcher and the nurse reviewer.

Quantitative Analysis

Quantitative analysis was performed using IBM® SPSS® Statistics 19. Prior to data analysis, the data were explored for accuracy of entries and missing data (El-Masri & Fox-Wasylyshyn, 2005). Descriptive statistics were used to describe the sample characteristics, the types of adverse events, as well as the incidence of risk factors. Chi-square test of independence and logistic regression was used to explore differences in the

sample characteristics among patients that experienced an adverse event and those who did not as well as to analyze the relations among the types of adverse events and each of risk factors and patient characteristics.

Where there were insufficient data, Fisher's exact test of independence was used. Fisher's exact test of independence is more accurate than the chi-squared test of independence when the expected numbers are small. This test is non-parametric so does not rely on data belonging to any particular distribution.

Sample Size

Based on an estimate of a +/- 5% error margin and a 95% confidence level, with an estimated adverse event incidence of 13%, a sample size of 173 cases (Roasoft Inc. Sample Size Calculator) would be sufficient to establish the incidence of adverse events.

Ethical Considerations

Ethical approval was obtained from the University of Windsor (Appendix B). The participating home care organization has provided a letter granting permission to access discharged client charts, for the purpose of this research (Appendix C). This study was low risk for the patient; with minimal patient vulnerability.

Patient confidentiality was considered. There is no contact with the patient. All data were obtained through retrospective chart review. Only non-identifiable data were collected. Data are only presented in aggregate form. It is possible that, through chart review, an incidental finding, such as a previously unidentified adverse event is identified. In keeping with current practice at the home care organization, any incidental, chart audit finding will be reported to the Regional Director responsible for the Service Delivery Centre.

CHAPTER IV

RESULTS

Missing Data

Missing data were excluded from the analysis accounting for differences in the reported numbers. The fact that for any given variable the largest percent of missing data was 1.6% (length of stay, $n = 8$) it is presumed that the omissions will have little if any influence on the results.

Sample Characteristics

The study sample consisted of adult patients, residing in Southwestern Ontario, discharged from one home care agency, nursing service, between May 1, 2011 and October 31, 2011. Data were collected from chart reviews of 500 episodes of care.

To allow for analysis between patients who experienced an adverse event and those who did not, diagnosis were grouped from 21 categories into four categories (chronic disease, wound, end of life (EOL)/Oncology and acute) (see Table 3).

Table 3

Categorization of Diagnosis

Chronic Disease	Wound	End of life (EOL)/ Oncology	Acute
COPD	Wound	Oncology	Infection
Diabetes		Palliative	Urinary disorder
Stroke			Pancreatitis
Neurological disorder			Clotting disorder
Cardiac disorder			Dehydration
General debility			Surgical wound
Respiratory disorder			Other
Osteoarthritis			
Bowel disorder			
Renal failure			
Mental health care			

A slight majority of home care patients was female (53.4%), independent with self-care (60.8%) and lived with others (71.4%). The average age of the patient was 68 years, *SD*(17.485), and the average length of stay was 53 days, *SD*(96.63). The most common diagnoses were wound (29.4%), urinary disorder (11.8%), oncology (11.4%) and cardiac disorder (10%). Sample characteristics are provided in Tables 4 and 5.

Table 4

Sample Characteristics: Sex, Self-care, Living Alone and Diagnosis

Variable	N (%)
Sex	
Male	232 (46.4)
Female	267 (53.4)
Missing	1 (0.2)
Self-care	
No	193 (38.6)
Yes	304 (60.8)
Missing	3 (0.6)
Living Alone	
No	357 (71.4)
Yes	142 (28.4)
Missing	1 (0.2)
Diagnosis	
Chronic Disease	141 (28.2)
Wound	148 (29.6)
EOL/Oncology	62 (12.4)
Acute	149 (29.8)
Missing	0 (0.00)

Table 5

Sample Characteristics: Age and Length of Stay

Variable	Valid	Missing	Mean	Median	Mode	Standard Deviation	Range
Age (years)	499	1	68.00	71.00	70	17.485	85
Length of Stay (days)	492	8	53.03	22.00	1	96.603	784

Incidence Rate and Type of Adverse Events

Incidence Rate

Trained nurse reviewers screened charts for adverse events, collecting descriptive statistics specific to whether an adverse event had occurred. An incidence rate of 9.4%, ($n = 47$), was found. Trained nurse reviewers identified 51 adverse events in 47 (9.4%) of the 500 episodes of care reviewed. Four patients experienced two adverse events.

Types of Adverse Events

Descriptive statistics were used to analyze data specific to the type of adverse event which occurred. New emergency room visit (51.1%), new hospital admission (38.3%) and new fall (27.7%) were the most common types of adverse events among home care patients in Southwestern Ontario.

Seventy-eight types of adverse events were identified within the 47 episodes of care reviewed and identified as being positive for an adverse event. Often, more than one type of adverse event was relevant; For example, a client may have had a *fall* which led to an *emergency room visit*. This set of results is presented in Table 6.

Table 6

Types of Adverse Events amongst Home Care Patients (n = 47) in Southwestern Ontario

Type of Adverse Event		Frequency
Fall	New Fall	13
Increased use of health care resources	New emergency room visits	24
	New hospital visits (admissions)	18
Adverse outcome	Cognitive performance decline	2
	Unintended weight loss	1
	New urinary tract infection	9
	New bowel problem	5
	New dehydration	4
	New caregiver decline	2
Total		78

Patient Characteristics

Data collected, specific to patient characteristics, included: age, sex, primary diagnosis, self-care capabilities, living alone, and length of stay. Differences in patient characteristics of home care patients who experienced an adverse event and those who do not were explored using chi-square test of independence and logic regression, using an enter method.

To assess whether patient sex (male or female) was related to the experience of an adverse event, a chi-square test of independence was conducted. The test was not significant, indicating that sex did not predict adverse events, $\chi^2(1, N = 499) = .002, p > .05$.

To investigate whether living alone was related to the experience of adverse events, a chi-square test of independence was conducted. The test was not significant, $\chi^2(1, N = 499) = .016, p > .05$. The chi-square test of independence investigating whether diagnosis was related to adverse events was also not significant, $\chi^2(3, N = 500) = 2.79, p > .05$.

Next, a chi-square test of independence was conducted to examine whether self-care status (yes or no) was associated with the experience of adverse events. The chi-square test of independence was significant, $\chi^2(1, N = 497) = 5.14, p = .023$. Individuals who were not independent with self-care were twice as likely to experience an adverse event, $OR = .50, 95\% CI [.27,.92]$.

A logistic regression analysis was performed to determine whether age was related to the occurrence of adverse events. The regression was not significant, age did

not predict adverse events, $\chi^2 = 1.93$, $p > .05$, Hosmer & Lemeshow $R^2 = 12.31$, $p > .05$, .004 (Cox & Snell), .008 (Nagelkerke).

Finally, a logistic regression analysis was conducted to investigate whether length of stay was associated with the experience of an adverse event. This regression was significant, $\chi^2 = 40.64$, $p < .01$, Hosmer & Lemeshow $R^2 = 8.03$, $p > .05$, .079 (Cox & Snell), .171 (Nagelkerke). The longer an individual stayed in care, the more likely they were to experience an adverse event, $OR = 1.01$, 95% CI [1.01,1.01]. For each day that a person is in care, their chance of experiencing an adverse event increases by 1%.

Table 7

*Patients Who Experienced an Adverse Event Compared to Patients Who Did Not**Experience an Adverse Event: Sex, Self-care, Living Alone, Diagnosis*

Variable	Yes Adverse Event N (%)	No Adverse Event N (%)	N (%)	X ²	p value
Sex					
Male	22 (46.8)	210 (46.4)	232 (46.4)	0.002	.964
Female	25 (53.2)	242 (53.4)	267 (53.4)		
Self-care					
No	25 (53.2)	168 (37.1)	193 (38.6)	5.14	.023*
Yes	21 (44.7)	283 (62.5)	304 (60.8)		
Living Alone					
No	34 (72.3)	323 (71.3)	357 (71.4)	0.016	.899
Yes	13 (27.7)	129 (28.5)	142 (28.4)		
Diagnosis					
Chronic Disease	10 (21.28)	131 (28.92)	141 (28.2)	2.79	.425
Wound	14 (29.79)	134 (29.58)	148 (29.6)		
EOL/Oncology	9 (19.15)	53 (11.70)	62 (12.4)		
Acute	14 (29.79)	135 (29.80)	149 (29.8)		

X² Chi square for independence*p value significant at an α of 0.05

Table 8

Patients Who Experienced an Adverse Event Compared to Patients Who Did Not

Experience an Adverse Event: Age and Length of Stay

Variable	Yes Adverse Event Mean (n)	No Adverse Event Mean (n)	Mean (n)	X^2	p value
Age (years)	64.52 (46)	68.35 (453)	68.00 (499)	1.93	.165
Length of Stay (days)	166.0 (46)	41.38 (446)	53.03 (499)	40.64	$p < .01^*$

X^2 Chi square for independence

*p value significant at an α of 0.05

Risk Factors

This section presents the findings concerning the incidence of safety risks among home care clients who experienced an adverse event. Descriptive statistics were used to analyze data specific to risk factors. The most common risk factors were *a decline in physical function* (55.3%), and *polypharmacy with a history of cognitive impairment* (38.3%). Other notable risk factors included: *a decline in cognitive function* (17%), *living alone with a decline in physical function* (17%), and *no medication review for clients with polypharmacy and/or a history of cognitive impairment* (17%). This set of results is presented on the following page within Table 9.

Table 9

Risk Factors Present amongst Home Care Patients in Southwestern Ontario Who Experienced an Adverse Event (n=47)

	Risk Factor	Frequency
Client characteristic	Decline in physical function	26
	Decline in mental function	6
	Decline in cognitive function	8
	Hearing deficit	2
	Vision deficit	7
	Social isolation with distress	3
	HIV and/or tuberculosis infections and others in the home	0
Client behavioural Characteristic	History of two or more falls	6
	Non-adherence to medication	5
	Substance abuse	0
	Smoking and oxygen in the home and others in the home (exposure second hand smoke)	1
	Aggressive behaviour	1
	Morbid obesity and requiring weight-bearing assistance for transfer	2
	Client living situation	Lives alone and decline in physical function
Lives alone and decline in cognition		5
Unsafe housing		0
Health care management Factors	Polypharmacy and history of cognitive impairment	18
	No medication review for clients with polypharmacy and/or history of cognitive impairment	8

Types of Adverse Events, Risk Factors and Patient Characteristics

Chi-square test of independence and logic regression, using the enter method, were used to analyze the relations among the *types of adverse events* (fall, increased use of health care resources and adverse outcomes) and *risk factors* (client characteristic, client behavioural characteristic, client living situation and health care management factors) and *patient characteristics* (age, self-care capabilities, living alone, length of stay and diagnosis). Where there was not enough data to conduct a Chi-square test of independence, Fisher's exact test of independence was used.

The large majority of comparisons were not significant. However, some group differences were found. Fisher's exact test of independence found that patients who had acute illnesses versus all other types of illnesses had less of a chance of a fall ($p = 0.005$). As length of stay increases, the chance of an *adverse outcome* (cognitive performance decline, unintended weight loss, new urinary tract infection, new bowel problem, new dehydration, new caregiver decline) increases, compared to the other two types of adverse events, *falls* and *increased use of health resources*, $\chi^2 = 4.21$, $p = .04$, Hosmer & Lemeshow $R^2 = 12.48$, $p > .05$, .087 (Cox & Snell), .122 (Nagelkerke), $OR = 1.003$, 95% CI [1.000, 1.006]. The remaining risk factors and patient characteristics were not significantly associated with the different types of adverse events.

Table 10

Relations among Types of Adverse Events, Risk Factors and Patient Characteristics

	Fall (n = 13)			Increased Use of Health Resources (n = 42)			Adverse Outcomes (n = 23)		
	χ^2	χ^2	F	χ^2	χ^2	F	χ^2	χ^2	F
		p value	p value		p value	p value		p value	p value
Client Characteristic	NC		.09	1.31	.25		0.25	.61	
Client behavioural Characteristic	NC		.27	NC		1.0	NC		.51
Client living situation	NC		1.0	NC		.70	NC		1.0
Health care management Factors	0.25	.62		2.40	.12		.09	.77	
Age	3.43	.06		3.65	.55		0.74	.39	
Self Care	0.002	.97		1.11	.29		1.36	.24	
Lives Alone	NC		1.0	NC		.74	NC		1.0
Length of Stay	0.224	.64		0.00	.99		4.21	.04*	
Chronic Disease	NC		.11	NC		1.0	NC		.46
Wound	NC		.73	NC		1.0	NC		.32
Palliative/ Oncology	NC		.09	NC		.24	NC		.24
Acute	NC		.01*	NC		.32	NC		.51

X^2 Chi-square test of independence

F Fisher's exact test of independence

*p value significant at an α of 0.05

NC = not calculated

Summary

In summary, chart reviews of 500 episodes of care revealed an incidence rate of 9.4% (n=47). Fifty-one adverse events were identified in 47 (9.4%) of the 500 episodes of care reviewed. Four patients experienced two adverse events. New emergency room visit (51.1%), new hospital visit (admission) (38.3%) and new fall (27.7%) were the most common type of adverse events among home care patients. Seventy-eight types of adverse events were identified within the 47 episodes of care reviewed and identified as being positive for an adverse event.

A lack of independence with self-care and a longer length of stay were significant predictors of an adverse event. The longer an individual stayed in care, the more likely they were to experience an adverse event. For each day that a person is in care, their chance of experiencing an adverse event increases by 1%. Additionally, as length of stay increases, the chance of an adverse outcome (cognitive performance decline, unintended weight loss, new urinary tract infection, new bowel problem, new dehydration, new caregiver decline) increases, compared to the other two types of adverse events. Sex, age, diagnosis and living alone were not significant factors between those patients who experienced an adverse event and those who did not. Patients who had acute illnesses had less of a chance of a fall, compared with the other two types of adverse events.

Risk factors with the highest incidence rates include a decline in physical function (55.3%) and polypharmacy with a history of cognitive impairment (38.3%). Other notable risk factors included: a decline in cognitive function (17%), patients living alone with a decline in physical function (17%), and no medication review for clients with polypharmacy and/or a history of cognitive impairment (17%).

CHAPTER V

DISCUSSION

Adverse Events

The incidence of adverse events, in this study, at 9.4% was higher than the rate of 5.5% found by Johnson (2006) but lower than the rate of 13.2 per 100 home care cases, reported by Sears (2008) and much lower than the rate of 23% reported by Forster et al. (2004).

Forster et al. (2004) were broad in their operational definition of adverse event. They included adverse events such as medication, laboratory and diagnostic errors. Whereas more than half of the adverse events reported by Forster et al. (2004) required no additional use of health services; within this study, only 34% required no additional use of health services. This could suggest that the difference in rate could be explained by adverse events which did not result in an emergency room visit or a hospitalization and were instead managed differently. Given that this study consisted of patients receiving care from a nursing home care organization, it would appear that adverse events not captured within the operational definition used, such as medication errors, may have been followed up by the nurse with a telephone call to the physician or a patient visit to the physician. This study identified additional use of health resources only through emergency room visits or hospitalizations. Additionally, Forster et al. (2004) studied patients in the immediate post hospital discharge period. The post hospital discharge period may be associated with changes in providers, in therapy and with location of care. These patients may also be more acute than the patients included within this study.

In a retrospective chart review of 400 Winnipeg home care patients, Johnson (2006) found an adverse event rate of 5.5% (26 adverse events in 22 patients).

Differences in methodology as well as a difference in the operational definition of the term *adverse event* may partially explain a lower rate of adverse events than what this study reports. For example, Johnson (2006) used key words to screen charts which may have led to the identification of different or fewer adverse events.

Adverse events were described and operationalized as proposed by Doran, Hirdes, White, et al. (2009). Based on findings of Doran, Hirdes, White, and colleagues (2009), this study hypothesized that the most common type of adverse events among home care patients would be new fall, unintended weight loss, new emergency room visit, and new hospital visit/admission. The hypothesis was partially correct; this research determined that new emergency room visit, new hospital visit (admission) and new fall were the most common type of adverse events among home care patients in Southwestern Ontario. Unintended weight loss was only rarely present. The difference with unintended weight loss may be attributed to differences in methodology or to differences in patient populations. Doran, Hirdes, White, et al. (2009) analyzed RAI-HC© data, which is only completed for long stay patients (receiving service greater than 30 days).

Using Doran, Hirdes, White and colleagues (2009) proposed operational definition of adverse event allowed for some level of generalization and standardization of the term. Comparing the types of adverse events measured against what is currently known may suggest that there were some gaps in the definition used. For example, in a review of the literature, the most commonly reported and occurring events were adverse drug events (16.4-72%) (Forster et al., 2004; Forster, Murff, Peterson, Gandhi, & Bates,

2003; Johnson, 2006; Madigan, 2007; Sears, 2008). Unless the adverse drug event led to an emergency room visit or hospital stay, these events were not captured in this research. Given that risk factors with the highest incidence rates included *polypharmacy with a history of cognitive impairment* and *no medication review for clients with polypharmacy and/or a history of cognitive impairment*, adverse drug events should be included within the operational definition of adverse event. An additional omission includes delayed wound healing/new wound. Within this study, a large proportion of the episodes of care reviewed was classified as a wound. Other potential gaps include new infection, technology related events, and inappropriately managed pain.

Contributing Factors

Patient Characteristics

Differences in patient characteristics of home care patients who experienced an adverse event and those who did not were explored in this study. Self-care capabilities and length of stay were significant predictors of an adverse event. The longer an individual stayed in care, the more likely they were to experience an adverse event. For each day that a person is in care, their chance of experiencing an adverse event increases by 1%. As length of stay increases, the chance of an *adverse outcome* (cognitive performance decline, unintended weight loss, new urinary tract infection, new bowel problem, new dehydration, new caregiver decline) increases, compared to the other two types of adverse events. Self-care capabilities and length of stay are concepts that are uniquely associated with adverse events in home care and not typically measured or significant within acute care research. This is critical given that most existing research

about adverse events and improvement strategies has been completed in an acute care environment.

Findings specific to self-care capabilities are consistent with existing home care literature. Sears (2008) identified that the need for assistance with a variety of specific activities of daily living was significantly associated with an adverse event. The acute care setting is an environment where resources are in place to identify and provide or assist with activities of daily living (ADLs), at the press of a button. The same is not true for home care. A patient requiring assistance with all ADLs will only receive about two hours of personal care per day, depending upon where they live and human resource availability. The patient is without personal assistance the other 22 hours of the day. Recognizing that these patients are at risk or more likely to experience an adverse event allows the home care provider to better focus initiatives designed to minimize the occurrence or consequences of adverse events in this unique practice setting.

Sex, age, diagnosis and living alone were not significant factors between those patients who experienced an adverse event and those who did not. Patients who had acute illnesses had less of a chance of a fall, compared with the other 2 types of adverse events. These findings are not all supported by existing literature. Sears (2008) reported that factors significantly associated with adverse events amongst home care clients included age 65 years or more and living with others. Forster et al. (2004) found that being female or having type 2 diabetes or pneumonia independently predicted adverse outcome.

Risk Factors

Risk factors were described and operationalized as proposed by Doran, Hirdes, White, et al. (2009). Based on findings of Doran, Hirdes, White and colleagues (2009),

this study hypothesized that the most common risk factors that occur with home care patients in Southwestern Ontario, who experience an adverse event, will be polypharmacy and a decline in physical function. This study determined that the risk factors with the highest incidence rates include were a decline in physical function and polypharmacy with a history of cognitive impairment. Other notable risk factors included: living alone with a decline in physical function, a decline in cognitive function and no medication review for clients with polypharmacy and/or a history of cognitive impairment. The hypothesis was proven true and supports Doran, Hirdes, White and colleague's (2009) findings,

Identifying personal characteristics and risk factors associated with patients who are vulnerable for an adverse event expands our current knowledge about adverse events in home care. Patient characteristics (self-care capabilities and length of stay) can be used along with risk factors (decline in physical function and polypharmacy) to identify home care patients at risk for an adverse event. This knowledge can assist health care providers with implementing risk mitigation strategies targeted to the right patients in the right practice setting.

Limitations

Data were obtained for this study through retrospective chart review utilizing existing nursing documentation and not intended for research purposes and may be lacking in quality and quantity (Boyd, Pater, Ginsburg & Myers, 1979). Limitations associated with chart review could include incomplete documentation, information that is unrecoverable or unrecorded, difficulty interpreting information found in the documents (e.g. jargon, acronyms, photocopies, and microfiches), problematic verification of

information and difficulty establishing cause and effect and variance in the quality of information recorded by medical professionals (Gearing, Mian, Barber & Ickowicz, 2006).

It is recognized that data were obtained from retrospective chart reviews at one home care agency in Southwestern Ontario. Different agencies may have different documentation forms and styles. Different regions may also have different documentation practices.

Recommendations

Recommendations for Practice

Home health nursing in Ontario operates independent from local hospitals. This creates challenges with communication between hospital and home and gaps or unfinished records of care within the patient's home care chart. Masotti, McColl and Green (2010) determined, through a literature review, that adverse events were commonly associated with communication and/or local system-level integration issues, such as coordination and collaboration, and suggest policy improvements within these areas. These communication challenges impact adverse events through (1) incomplete storytelling and data capture specific to adverse event incidence rates and types, as well as (2) potentially causing adverse events.

The patients chart remains in the patient's home and does not follow the patient to hospital. Charts in the home get lost. Occasionally a patient is discharged from home care without a discharge nursing visit (e.g. with death or when a patient has been in hospital greater than 2 weeks). This means that the chart may not reflect why or even that the patient went into hospital or that death occurred. It is possible that the hospital admission

or death may have been a consequence of an adverse event and not included within incidence rates. A common health record would enable seamless communication between health care providers and practice settings. This has the potential to allow for accurate capturing of adverse events as well as the potential to reduce adverse events. For example, a shared medication record may reduce adverse drug interactions. E-health Ontario (n.d.) states that benefits of electronic health records includes immediate, accurate, secure access to pertinent patient medical information from all relevant sources, including hospital and community care reports and discharge records. Technology is advancing and beginning to come into practice in home care. Thinking about ways we can leverage this technology to learn more about and potentially reduce adverse events is forward thinking and innovative. A shared electronic health record could improve communication, coordination and collaboration; improving data collection specific to adverse events and potentially reducing adverse events such as medication related adverse events. It is recommended that a common chart between the various health care settings would assist with the identification and collection of accurate information specific to adverse event rates.

The findings of this study provide insight into adverse events in the context of the home care environment and can influence health policy makers and allow organizations to implement strategies and improvement initiatives designed to predict and mitigate these risks. Patient characteristics (self-care capabilities and length of stay) can be used along with risk factors (decline in physical function and polypharmacy) to identify patients at risk for an adverse event. This knowledge can assist health care providers with

implementing risk mitigation strategies targeted to the right patients such as screening patients for high risk characteristics and factors for those on service long term.

As length of stay increases, the patient is at a greater risk for an adverse event. Services such as therapies and personal support tend to be front-loaded. The patient receives the services at the initiation of care but is not regularly, purposefully evaluated by the home care agency for further services. The long term patient often receives RAI-HC© assessments by the CCAC; however these are not always shared with the home care agency. We understand from this research that information must be collected from a variety of sources. It is recommended that home care agencies evaluate patients at regular intervals for risk factors specific to adverse events. This includes risk factors identified within this study (self-care, length of stay, a decline in physical function and polypharmacy) as well as RAI-HC© data.

Programs and strategies designed to recognize patients and implement mitigation strategies for home care patients, who have a recent decline in physical function and require assistance with ADLs, may reduce the incidence of adverse events among this population. However, home care patients dependent upon others for self-care receive only minimal formal personal assistance. Unpaid caregivers provide more than 80% of care needed by individuals with long-term conditions (Fast, Niehaus, Eales, & Keating, 2002). Additionally, across Canada there are shortages of health care workers and home care will be disproportionately impacted due to the aging population (CHCA, 2008). Compounding the human resource challenge is the increased demand for home care as a result of our aging population (CHCA, 2008). Given these challenges, patients who

require programs created to support self-care services for patients in their home should either be directed at or include the informal caregiver.

Polypharmacy is the use of 5 or more medications and has been identified as a common risk factor within this study. Statistics Canada (2009) reported that 53% of seniors in health care institutions and 13% of those in private households were multiple medication users (took five or more different drugs in the past two days). People who take several medications at once are more likely to have adverse drug reactions (Statistics Canada, 2009). Patients participating in polypharmacy need to be closely evaluated for appropriateness and effectiveness of the medication and dose, side effects and potential drug interactions. It is recommended that policies be implemented that identify and mitigate the risk for this client population.

This study determined that 51% of adverse events occurring among home care patients included an emergency room visit. Doran, Hirdes, White and colleague's (2009) identified emergency room visits as an area of interest for two reasons: first, visit to the emergency room was among the most common adverse outcomes for home care clients within their research; and second, the Ontario Ministry of Health and Long Term Care has recently invested \$109 Million to reduced wait times in emergency rooms (Ministry of Health and Long Term Care, 2008). The Ontario Home Care Association (OHCA, 2010) states that home care programs need to be supported to provide interventions to circumvent the need for hospitalization and more importantly forestall a health related crisis. This study identifies factors that increase risk of adverse events, which often result in emergency room visits (self-care capabilities, length of stay, decline in physical function and polypharmacy). Additionally, an examination of the specific adverse events

indicates that 28% (n=14) of falls also included an emergency room visit. Strategies to mitigate risk, such as implementation of a new or different falls prevention program which highlights those factors which increase risk, may reduce emergency room utilization by home care clients.

Recommendations for Future Research

Research designed to gather further knowledge about adverse events in home care should include data from a variety of sources, such as from home and hospital or RAI-HC© data. Including hospital admission and emergency room records and/or RAI-HC© data would broaden the patient story and assist with gaining a better understanding of adverse events in home care.

There is a need to broaden and standardize the operational definition of the term adverse events. A lack of a standardized approach to determining what constitutes an adverse event leads to confusion when attempting to identify types of adverse events. Additionally, a standardized definition of adverse event is required in order to be able to develop benchmark data and reliably compare adverse event rates.

Applied research is needed that implements and tests specific initiatives aimed at reducing the risk for patients with decreased self-care capabilities, long length of stays, a decline in physical function and polypharmacy. Risk specific initiatives have the potential to decrease the rate of adverse events and provide safer care for patients receiving home care.

Conclusion

Adverse events, although not unique to home care patients presents unique challenges because of the environment where they occur. The purpose of this study was

to expand on the research by Doran, Hirdes, White, and colleagues (2009), specific to risk factors and adverse events, validating the actual occurrence of an adverse event through chart reviews. Additionally, this study aimed to explore the relations among patient characteristics, risk factors and adverse events at a home care organization in Southwestern Ontario.

Patient characteristics (self-care capabilities and length of stay) can be used along with risk factors (decline in physical function and polypharmacy) to identify home care patients at risk for an adverse event, allowing for targeted interventions to be developed to address these risk factors. Risk mitigation strategies such as supporting patients with self-care limitations and/or a decline in physical function and require assistance with ADLs should either be directed at or include the informal caregiver and may reduce the incidence of adverse events among this population. Communication challenges between health care sectors impacts adverse events through (1) incomplete storytelling and data capture specific to adverse event incidence rates and types, as well as (2) potentially causing adverse events. A shared electronic health record could improve communication, coordination and collaboration; improving data collection specific to adverse events and potentially reducing adverse events such as medication related adverse events. Strategies, such as implementation of a new or different falls prevention program, may reduce emergency room utilization by home care patients.

Research designed to gather further knowledge about adverse events in home care should include data from a variety of sources, such as from home and hospital or RAI-HC© data. A standardized definition of adverse event is required in order to be able to develop benchmark data and reliably compare adverse event rates. Applied research is

needed that implements and tests specific initiatives aimed at reducing the risk for home care patients.

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Appendix A: Data Collection Form

DATA COLLECTION FORM

Demographic Information

Sex (M/F)	
Age	
Primary Diagnosis	
Independent with self-care (Y/N)	
Lives Alone (Y/N)	
Length of Stay (number of days on service with nursing)	

Adverse Events

Adverse Event	Operational Definition	Present*	Absent
Fall	New Fall		
Increased use of health care resources	New emergency room visits		
	New hospital visits (admissions)		
Adverse outcome	Cognitive performance decline		
	Unintended weight loss		
	New urinary tract infection		
	New bowel problem		
	New dehydration		
	New caregiver decline		

*If an *Adverse Event* is present, confirm that the adverse event was “an unintended injury or complication that resulted in disability, death, or increased use of health care resources and was caused by health care management.

- Yes**
 No

**If an Adverse Event has been confirmed as having occurred, complete *Risk Factors*.

Risk Factors

	Safety Risk Factor	Operational Definition	Present	Absent
Patient characteristic	Decline in physical function	Activities of daily living decline compared to status 90 days ago		
	Decline in mental function	Sudden or new onset/change in mental function over last 7 days		
	Decline in cognitive function	Worsening of decision making as compared to status of 90 days ago		
	Hearing deficit	Hearing patterns		
	Vision deficit	Ability to see in adequate light and with glasses if used		
	Social isolation with distress	Change in social activities compared to 90 days ago		
	HIV and/or tuberculosis infections and others in the home	HIV infection Tuberculosis infection		
Patient behavioural Characteristic	History of two or more falls	Intake history of two or more falls in last 90 days		
	Non-adherence to medication	Intake non-adherence to medication		
	Substance abuse	In last 90 days client felt the need or was told by others to cut down on drinking, or others concerned with client drinking. Or client had to have a drink first thing in the morning to steady nerves		
	Smoking and oxygen in the home and others in the home (exposure second hand smoke)	Smoked daily		
	Aggressive behaviour	Socially inappropriate/disruptive behavioural symptoms		

Adverse Events, Patient Characteristics and Risk Factors

	Morbid obesity and requiring weight-bearing assistance for transfer	Morbid obesity and requiring assistance to transfer to/from bed, chair, wheelchair, standing position		
Patient living situation	Lives alone and decline in physical Function			
	Lives alone and decline in cognition			
	Unsafe housing	Lighting inadequate, flooring and carpeting unsafe, bathroom unsafe, kitchen (e.g. dangerous stove), heating/cooling, personal safety, difficult access to home, difficult access to rooms		
Health care management Factors	Polypharmacy and history of cognitive impairment	Five medications or more		
	No medication review for clients with polypharmacy and/or history of cognitive impairment	Physician review of medication as a whole in last 180 days (or since last assessment)		

Appendix B: Research Ethics Board Approval – University of Windsor

Ethics Clearance

Today's Date: December 08, 2011

Principal Investigator: Ms. Kimberly Anne Dalla Bona

REB Number: 29629

Research Project Title: REB# 11-219: Relationship Between Adverse Events and Risk Factors Among Home Care Patients

Clearance Date: December 8, 2011

Project End Date: June 30, 2012

Milestones:

Renewal Due-2012/06/30(Pending)

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

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

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

Investigators must also report promptly to the REB:

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

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

Pierre Boulos, Ph.D.
Chair, Research Ethics Board
301 Assumption University
University of Windsor
519-253-3000, 3948
Email: ethics@uwindsor.ca

Appendix C: Research Approval – Home Care Organization

Saint Elizabeth Health Care
90 Allstate Parkway
Suite 300
Markham, Ontario
L3R 6H3

October 28, 2011

Research Ethics Board
University of Windsor
401 Sunset Ave.
Windsor, Ontario
N9B 3P4

Re) Kim Miller-Dalla Bona Research Project

Saint Elizabeth gives permission for Kim Miller-Dalla Bona to access Saint Elizabeth discharged client charts, for completion of her Masters Thesis research, *Relationship Between Adverse Events and Risk Factors Among Home Care Patients*.

The charts can be accessed and data collection completed between Nov 15, 2011 and June 30, 2012. Kim may access charts stored at the Windsor Service Delivery Centre, for clients discharged between May 1, 2011 and Oct 31, 2011. The charts are not to leave the Saint Elizabeth Windsor Service Delivery Centre and no identifying client information is to be collected.

Thank-you

Nancy Lefebvre
SVP Knowledge and Practice
Chief Clinical Executive
(905)940-9655

VITA AUCTORIS

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