

ADVERSE EVENTS AMONG WINNIPEG HOME CARE CLIENTS

BY

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the Faculty of Graduate Studies
in Partial Fulfillment of the Requirements for the Degree of**

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“Adverse Events Among Winnipeg Home Care Clients”

BY

Keir Johnson

**A Thesis/Practicum submitted to the Faculty of Graduate Studies of The University of
Manitoba in partial fulfillment of the requirement of the degree
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MASTER OF PUBLIC ADMINISTRATION**

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Abstract

The topic of patient safety has recently received considerable attention in Canada, the United States, and several other countries. Most studies in this area, however, focus exclusively on hospitals, with few investigating the safety of other health care sectors, such as home care. The integrating theme for this study is that no part of the health care system, including home care, is free of adverse events (AEs). Before measuring patient safety in home care, this study sought to translate hospital-centric patient safety concepts to the home care environment. A context-appropriate approach to measure AEs in home care was developed—this used chart reviews prompted by a mixed screening process—and these methods were applied to a sample of clients from the Winnipeg Health Region to describe the incidence, type, severity, cause, preventability and ameliorability of AEs in home care.

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Abbreviations

ADE	Adverse Drug Event
ADL	Activities of Daily Living
AE	Adverse Event
CMS	Centres for Medicare and Medicaid Services (U.S.)
CTS	Community Therapy Services
DSS	Direct Service Staff
HMPS	Harvard Medical Practice Study
IADL	Instrumental Activities of Daily Living
IHI	Institute for Healthcare Improvement
IOM	Institute Of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MDS-HC	Minimum Data Set for Home Care
OASIS	Outcome and Assessment Information Set
OBQM	Outcome-Based Quality Monitoring
OT	Occupational Therapy
PCH	Personal Care Home
PHIA	Personal Health Information Act
PHIN	Personal Health Identification Number
PT	Physical Therapy
RAI-HC	Resident Assessment Instrument for Home Care
WRHA	Winnipeg Regional Health Authority

1. INTRODUCTION

The topic of patient safety has recently received considerable attention, with prominent studies in Canada,¹ the United States^{2,3} and other countries examining this critical health care issue. A recent Canadian study found that 7.5% of hospital admissions resulted in an adverse event (AE)—defined as “unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management”⁴ and not the patient’s underlying condition. This study estimates that in Canada between 9,000 and 24,000 hospital patients die each year due to preventable medical errors.⁵ These types of studies have drawn public attention to the issue; governments have taken action by creating patient safety institutes to improve the situation.⁶ However, these studies capture only part of the picture since hospitals are only part of the broader health care system. The well-known Canadian Adverse Event Study notes that “[a]dditional research is also needed into the incidence and types of AEs beyond the acute care hospital setting.”⁷ The pivotal American report *To Err is Human* by the Institute of Medicine

¹ Ross Baker et al., “The Canadian Adverse Event Study: the incidence of adverse events among hospital patients in Canada,” *Canadian Medical Association Journal* 170(11) (2004): 1678-86.

² TA Brennan et al., “Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I,” *New England Journal of Medicine* 324 (1991): 370-7.

³ Eric J. Thomas et al. “Incidence and types of adverse events and negligent care in Utah and Colorado,” *Medical Care* 38 (2000): 261-71.

⁴ Baker et al.

⁵ Medical errors are not only caused by physicians; indeed, all health care staff can cause a medical error.

⁶ The federal government created the Canadian Patient Safety Institute (see <http://www.hc-sc.gc.ca/english/care/cpsi.html>) in 2002 and the Manitoba government established the Manitoba Institute for Patient Safety in 2004 (<http://www.mbips.ca/>).

⁷ Baker et al., 1685.

(IOM) notes that “with the exception of medication-related events... little if any research has focused on errors or AEs occurring outside the hospital setting.”⁸ Indeed, little if any research has been done on AEs in physician’s offices, clinics, public health, mental health, long term care, or home care.

Home care is an integral and growing component of the universal health care system in Manitoba. Its broad aims are to maintain independent living at home and to prevent, delay or shorten institutionalization (both hospital and long term care).⁹ Approximately 16% of seniors in Winnipeg use home care services.¹⁰ With an aging population, the numbers using this program will continue to grow.¹¹ A literature search, the results of which are included in chapter two, found that few studies have looked at home care client safety. Of the studies that examine AEs or errors outside of hospital, some focus on hospital patients after discharge who may or may not have been receiving home care. Others look at home care clients but examine only medication-related events—this is only one type of AE. Only one study considered a variety of AEs in the home care setting, but the study reported *potential* adverse events for American home care agencies that typically serve clients for short periods of time (i.e. post-acute). Furthermore, it was conducted in the United States, which has quite a different health care system than Canada. Clearly, there is a gap in research and knowledge about the safety of home care.

⁸ Linda T. Kohn, Janet Corrigan, and Molla S. Donaldson, eds., *To err is human: building a safer health system* (Washington, DC: National Academy Press, 1999), 29.

⁹ Noralou P. Roos et al., “A Look at Home Care in Manitoba” Manitoba Centre for Health Policy and Evaluation, August 2001. Retrieved 25-SEP-2004 at <http://www.umanitoba.ca/centres/mchp/reports/pdfs/homecare.pdf>

¹⁰ Ibid., based on 1998/99 population data.

¹¹ By 2026, seniors will account for 21% of the population, compared to 13% in 2000 (Statistics Canada, “Population projections: 2000 to 2026,” *The Daily*, Tuesday, Mar 13 2001).

This thesis seeks to fill that gap by examining data from the Home Care program delivered by the Winnipeg Regional Health Authority (WRHA).

Patient safety studies have been invaluable in advancing quality improvement in hospitals; hopefully the results of this investigation will have a similar impact on home care. The integrating theme for this study is that no part of the health care system, including home care, is free of adverse events. In order to minimize potential harm to home care clients, policy makers and care providers need valid and reliable evidence on the frequency, types, severity, causes and preventability of events that harm clients.

The study has three goals. First, it will attempt to tailor patient safety concepts and terms to the home care context. The traditional concepts may not directly translate to home care given that it is quite different from hospital care—care is less controlled, delivered in varying unfamiliar environments, and relies heavily on client and family action as well as other health care providers (i.e. family physicians). Clear, unambiguous definitions are critical to developing an appropriate methodology and to interpreting results.

Second, the thesis will develop a methodology to screen and measure AEs in the home care setting. While chart reviews are the “gold standard” for screening and determining AE rates in the hospital—this approach has also drawn strong criticism—many other approaches have been employed, including patient and provider interviews, voluntary incident reporting and observation studies. Moreover, some studies are prospective in design while others are retrospective. Just as appropriate definitions must be established

for the home care context, an appropriate methodology must be developed to identify and describe AEs in home care.

The third and final goal of this thesis is to apply the methodology and collect, measure and analyze data to determine the incidence, type, severity, preventability and ameliorability (severity of could have been reduced through better care) of AEs in home care. This information will be useful to improving the safety and quality of care for home care clients.

To accomplish these three goals, the study will proceed as follows. Chapter two reviews relevant literature in this field of study. Specifically, this chapter explores the more well-known hospital-focused patient safety studies and relevant non-hospital studies, and considers methodological approaches to measuring adverse events and errors. This chapter is important to ground the study and understand both the broader body of work, the need for this study, and discuss key patient safety concepts. Chapter three is devoted to examining these key concepts in more detail and seeks to meet the first goal of the study—translating hospital-centric patient safety concepts to the home care context. This topic requires the attention of an entire chapter as a clear and appropriate definition is critical to a successful study. Drawing on both secondary sources and the results of qualitative research, this chapter develops a definition for “adverse event” that is more appropriate to home care and grounds the rest of the study.

The final three chapters are dedicated to measuring home care client safety. Based on the review of methodological approaches in the literature review, Chapter four begins with a

discussion of the potential methods and which is most suitable for this study. The remainder of this chapter describes the methodology that is used for this study, meeting the second goal of developing a home care-specific method for measuring adverse events. Chapter five presents the results of the investigation and reports any methods-related issues. The sixth and final chapter offers a discussion of the results and methods, and final comments. Together, the final two chapters meet the third goal of the thesis—collecting, measuring and analyzing data to determine the incidence, type, severity, cause preventability and ameliorability of AEs in home care.

ABOUT HOME CARE

In the City of Winnipeg, Manitoba, the Winnipeg Regional Health Authority (WRHA) oversees the operation of a range of health services, including six hospitals, 39 personal care homes and 20 community health offices.¹² The WRHA is responsible for the delivery of acute care, long-term care, public health, primary care, mental health, and home care to approximately 750,000 people.

As part of the WRHA portfolio, the Home Care program is provincially mandated and seeks to “help people live at home, remaining independent for as long as possible, thereby avoiding or delaying the need for individuals to go into long term care facilities.”¹³ Home Care’s mandate is to “provide effective, reliable and responsive

¹² Winnipeg Regional Health Authority. “About Us.” Web site, accessed 20-JAN-05, <http://www.wrha.mb.ca/aboutus/>

¹³ Winnipeg Regional Health Authority. “Home Care.” Web site, accessed 15-NOV-04, http://www.wrha.mb.ca/findcare/careincom/home_care.php. Also, see Noralou Roos *et al.* “A Look at Home Care in Manitoba” Manitoba Centre for Health Policy and Evaluation, August 2001. Available online at <http://www.umanitoba.ca/centres/mchp/reports/pdfs/homecare.pdf>

community health care services to support independent living, develop appropriate care options with clients and/or family and facilitate admission into long term care facilities when living in the community is no longer possible.”¹⁴ Home Care was established in Manitoba in 1974, and “is the oldest comprehensive, province-wide, universal home care program in Canada.”¹⁵

The WRHA Home Care program has two main components: nursing-coordinated, which typically focuses on clients with a short term, nursing-only need, and community-coordinated, which accounts for the vast majority of clients who generally use the service for an extended period. This study focuses only on community-coordinated Home Care. The program offers a variety of services to meet the needs of its clients, including assistance with some instrumental activities of daily living (IADLs, including household maintenance, laundry and cooking), activities of daily living (ADLs, including bathing, personal hygiene, dressing, locomotion, transferring, toileting, and eating), and nursing services (such as medication administration, wound care, etc).

Home Care services are based on assessed need and are offered to supplement supports available to the client through their informal network (i.e. family and friends) and other community organizations; thus provision of services is fragmented and often shared among several of these providers. Appropriately, coordination, information and referral are important services delivered by Home Care. Various other services, such as

¹⁴ Ibid.

¹⁵ Manitoba Health. “Manitoba Home Care Program.” Retrieved 25-FEB-2005 from <http://www.gov.mb.ca/health/homecare/index.html>

occupational and physical therapy and social activities, are also available and delivered through partner organizations. When community-based care is no longer a viable option for the client, Home Care facilitates nursing home placement, generally referred to as *personal care homes* (PCHs) in Manitoba.¹⁶

The WRHA Home Care program has used the standardized comprehensive assessment tool, called the MDS-HC (Minimum Data Set for Home Care), for over three years.¹⁷

This assessment tool was developed by interRAI, a non-profit organization of researchers from over 20 countries dedicated to improving the care of the elderly, frail, and disabled. InterRAI has developed tools for a variety of care settings, including home care, long term care, mental health, and palliative care. The assessment and its associated indicators undergo rigorous research and testing to ensure reliability and validity.¹⁸

The MDS-HC is not simply an assessment tool, but also promotes evidence-based decision-making at both the practice and organizational planning level by including care planning protocols, outcome measures, quality indicators and resource utilization groups—the assessment and these indicators are collectively referred to as the RAI-HC (Resident Assessment Instrument for Home Care). These indicators are all calculated using data collected in the assessment tool.

¹⁶ Case Coordinators complete an Application and Assessment for Personal Care Home (PCH). This application is reviewed at “panel” to ensure that placement in a PCH is the most appropriate option for the individual. For a brief but complete overview of the services of Home Care see the Guide to the Manitoba Home Care Program at <http://www.gov.mb.ca/health/homecare/guide.html>

¹⁷ MDS-HC was implemented regionally after a one-site pilot project. An evaluation report that led to the selection of this tool is available at <http://www.gov.mb.ca/health/homecare/assessment.html>

¹⁸ Visit interRAI’s web site at <http://www.interrai.org>

2. REVIEW OF THE LITERATURE

A search for relevant journal articles was conducted using PubMed, CINAHL, and Google Scholar. A general Internet search was performed as several web sites have been created for patient safety-related organizations that contain invaluable resources. The review also included some previously-known sources, such as major books and web sites. The search, which had no date restrictions, was conducted in late 2004 and continued, ongoing, until May, 2005.

The general literature review is separated into three sections. The first section presents the most significant patient safety studies; these studies focus on adverse events exclusively in the hospital setting. The next section reviews relevant studies that examine AEs outside of hospital. Finally, the last section will review various patient safety methods drawing on literature that evaluates relevant measurement methodologies.

PATIENT SAFETY LITERATURE

As discussed earlier, the majority of adverse event and medical error research concentrates on hospitals. Patient safety research really began with a now well-known study published in 1991.¹⁹ This study, commonly referred to as the Harvard Medical Practice Study (HMPS), reviewed about 30,000 randomly selected patients discharged in 1984 from 51 randomly selected New York state hospitals. The charts were screened by

¹⁹ Brennan et al.

nurses and medical records analysts for potential AEs using a set screening criteria. Physicians then reviewed the screened in charts. This study revealed that 3.7% of admissions suffered an AE and that 58% of those were due to negligence or substandard care; in other words 58% of the adverse events were preventable. This study is referenced often for the results, and just as often for its methods. It has been noted that "this review process has become the benchmark method for research on adverse events in hospitals."²⁰ Indeed, the methods were used in a study of AEs in Colorado and Utah hospital patients discharged in 1992.²¹ This study sampled about 15,000 discharges and found that 2.9% of patients experienced an AE, with 53% of those rated as preventable.

While these studies' findings are clearly important, they were largely ignored until the pivotal IOM report *To Err is Human*. Based on the two studies mentioned above, the report estimates that in the United States 44,000-98,000 hospital patients die each year due to preventable AEs, noting that even if one considers the low estimate of 44,000, it still outnumbers deaths from either motor vehicle accidents or breast cancer.²² The IOM report drew widespread attention to the issue of patient safety and research in this area subsequently exploded, with several researchers replicating the American studies in other countries and exploring ways of improving the situation. Most recently, the Institute for Healthcare Improvement (IHI) launched its "100K campaign," seeking to sign up hospitals to commit to six interventions known to reduce preventable hospital deaths.²³

²⁰ Ross Baker, "Commentary: Harvard Medical Practice Review," *Quality and Safety in Health Care* 13 (2004): 151-152.

²¹ Thomas et al.

²² Kohn, Corrigan, and Donaldson, 26.

²³ Visit IHI's web site at <http://www.ihi.org> for more information. Since the campaign was launched in late 2004, over 2,000 American hospitals have signed up for the campaign, as well as hospitals around the

Ultimately, the campaign seeks to save 100,000 lives. A similar campaign, Safer Healthcare Now!, was recently launched in Canada, replicating the six strategies proposed by IHI.²⁴

The methods used in the HMPS have certainly served as a gold standard, with studies in Britain, Australia, New Zealand, Denmark, and more recently in Canada utilizing a very similar approach. The Canadian Adverse Events Study sampled 4,164 discharges from 20 hospitals in five provinces in 2000 (British Columbia, Alberta, Ontario, Quebec and Nova Scotia).²⁵ The study discovered that 7.5% of hospital admissions suffered an AE. They also found that 41.6% of AEs were preventable, meaning that overall, between 2.5% and 3.3% of admissions had a preventable AE. The researchers estimate that between 9,250 and 23,750 hospital deaths in 2000 are associated with a preventable AE. It is important to note that the chart review method used in these studies have been criticized for several reasons, which will be discussed in the methodology section of the literature review.

RELEVANT NON-HOSPITAL LITERATURE

Of the studies focusing on adverse events outside of the hospital setting, a few focused on hospital patients after discharge.²⁶ These studies conducted a telephone interview with

World. Winnipeg's St. Boniface Hospital and Health Science Centre are among the international hospitals who have committed to the IHI campaign.

²⁴ Visit the web site for Safer Healthcare Now! at <http://www.saferhealthcarenow.ca> to learn more about the Canadian campaign, which was launched in April, 2005.

²⁵ Baker et al., "The Canadian Adverse Event Study."

²⁶ Alan J. Forster et al., "Adverse events among medical patients after discharge from hospital," *Canadian Medical Association Journal* 170(3) (2004): 345-9, and Alan J. Forster et al., "The Incidence and Severity of Adverse Events Affecting Patients after Discharge from the Hospital," *Annals of Internal Medicine* 138 (2003): 161-167.

patients discharged during a specific follow-up time-period. The results of the interviews, combined with data from electronic health records, were reviewed independently by two physicians using a technique similar to the HMPS review approach. One study found an AE rate of 19.0%, with 30.5% of AEs rated as preventable and 31.6% rated as ameliorable (severity could have been reduced through better care).²⁷ The other study, sampling discharges from a Canadian hospital, found an AE rate of 23.2%, with 27.6% of AEs rated as preventable and 22.4% rated as ameliorable. In both studies, the most common type of AE was an adverse drug event (ADE). These two studies offer important information about patient safety in the home environment, although the AEs resulted from the care received during hospital stay or the discharge planned by the hospital. While these results cannot be relied upon to estimate the home care AE rate—a recent study discovered that only 20% of long stay hospital discharges in Winnipeg receive home care²⁸—the definitions and approaches are useful to this investigation.

Of the studies that examined home care clients, the vast majority focus specifically on medication-related events. One study focused on ADEs in elderly home care patients following hospital discharge.²⁹ This study used methods similar to the post-discharge investigations mentioned earlier, conducting telephone interviews with patients to determine if an AE had occurred, but was limited to those hospital discharges who

²⁷ Forster et al., "Incidence and Severity..."

²⁸ Anita Kozysrjy et al., "Discharge Outcomes for Long-Stay Patients in Winnipeg Acute Care Hospitals," Manitoba Centre for Health Policy, January 2003. Retrieved 24-SEP-2004 at http://www.umanitoba.ca/centres/mchp/reports/pdfs/lstay_03.pdf

²⁹ Shelly L. Gray, Jane E. Mahoney, and David K. Blough. "Adverse Drug Events in Elderly Patients Receiving Home Health Services Following Hospital Discharge," *Annals of Pharmacotherapy* 33 (1999): 1147-53.

received home care. The researchers found that 20.1% of participants experienced an ADE. Most ADEs affected the gastrointestinal system (symptoms of nausea, diarrhea, constipation) and the central nervous system (symptoms of dizziness, fatigue, confusion).

Another home care ADE study surveyed direct service nurses in six American states to determine the prevalence of ADEs.³⁰ Focus groups with nurses revealed that patients do not always take prescribed medications, or may not follow the prescription directions correctly; the results of these focus groups were used to create the survey. This study found that five percent of patients experienced an ADE. This number is significantly lower than other studies, possibly because it was based on a general retrospective survey of direct care nurses asked to recall ADEs. Many of the ADEs affected the gastrointestinal system and the central nervous system, as was noted in the previous study. Nurses' responses to the survey revealed two broad categories of ADE causes. The first category was system issues, such as poor communication, inadequate hospital discharge preparation, and the number of providers involved. The other category was the nature of the patient (or client), including variables such as the presence of a family caregiver, cognitive abilities of the patient, ability to afford medications, knowledge about prescriptions, and choice to follow or not follow drug regimens.

Several studies were located that looked at *potentially* inappropriate medication use among the elderly. All of these studies employed one or more of several explicit criteria

³⁰ Carol Hall Ellenbeker, Susan C. Frazier, and Sharon Verney, "Nurses' Observations and Experiences of Problems and Adverse Effects of Medication Management in Home Care," *Geriatric Nursing* 25, no. 3 (2004): 164-170.

that have been developed to identify potentially inappropriate medications with a high risk for adverse events. Before discussing these studies, a brief introduction to these protocols will be provided. The Beers Criteria, first developed by Dr. Mark Beers et al. in 1991, has twice been updated to reflect changes in both drugs (i.e. new drugs) and research about medications that may discover harmful drug-related affects.³¹ The Criteria lists medications that are themselves potentially inappropriate and medications that are inappropriate when a specific disease or condition is present. The medication list was developed using a consensus panel (a modified Delphi approach) of pharmacy, medicine and gerontology experts. A Canadian Criteria (or McLeod Criteria) has also been developed, modeled after the Beers Criteria.³² Using a consensus panel approach similar to Beers et al., the Canadian Criteria includes drugs that are generally contraindicated for seniors, potential drug-disease interactions and potential drug-drug interactions. Finally, the Home Health Criteria, which was also developed by an expert panel, identified patterns of medication use combined with relevant signs and symptoms that suggest a potential ADE.³³ There are numerous studies that have employed one or more of these criteria; the most relevant are presented below.

³¹ Mark H. Beers et al. "Explicit Criteria for Determining Inappropriate Medication Use in Nursing Home Residents." *Archive of Internal Medicine* 151 (1991): 1825-1832; Mark H. Beers. "Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly." *Archive of Internal Medicine* 157 (1997): 1531-1536; Donna M. Fick et al. "Updating the Beers Criteria for Potentially Inappropriate Medication Use in Older Adults." *Archive of Internal Medicine* 163 (2003): 2716-2724.

³² Peter J. McLeod et al. "Defining inappropriate practices in prescribing for elderly people: a national consensus panel." *Canadian Medical Association Journal* 156, no. 3 (1997): 385-391.

³³ Nancy J. Brown et al. "A Model for Improving Medication Use in Home Health Care Patients." *Journal of the American Pharmaceutical Association* 38, no. 6 (1998): 696-702.

Sarah Meredith et al. studied 6,718 home care clients aged 65 and over from two of the largest home healthcare agencies in the United States.³⁴ The researchers used two sets of criteria to identify potentially inappropriate medication use—the Beers Criteria (1997) and the Home Health Criteria. Thirty percent of the study subjects were taking potentially inappropriate medications according to either criteria; 19% of all clients were identified using the Home Health Criteria and 17% using the Beers Criteria (some clients were identified by both). The study also found that the prevalence of possible medication errors increased with the number of medications taken.

The 1997 Beers Criteria was also used to study a sample of 2,193 home care clients in the Miami, Florida area.³⁵ This home care sample was part of a Medicaid-supported managed care program and all clients had to be eligible for nursing home placement. This home care program acted to avoid or delay institutionalization by providing many of the same services as Home Care in Winnipeg. Using the Beers Criteria, the researchers found that 39.7% of clients were taking at least one potentially inappropriate medication, and 10.4% were prescribed two or more.

The 1997 and 2003 Beers Criteria and Canadian Criteria were used to study potentially inappropriate medication use among European home care clients.³⁶ This study used only the contraindicated medications for the elderly from both Criteria, excluding the sections

³⁴ Sarah Meredith et al. "Possible Medication Errors in Home Healthcare Patients," *Journal of the American Geriatric Society* 49 (2001): 719-724.

³⁵ Adam G. Golden et al. "Inappropriate Medication Prescribing in Homebound Older Adults." *Journal of the American Geriatrics Society* 47, no. 8 (1999): 948-953.

³⁶ Daniela Fialová et al. "Potentially Inappropriate Medication Use Among Elderly Home Care Patients in Europe." *Journal of the American Medical Association* 293, no. 11 (2005): 1348-1358.

of the criteria related to drug-drug and drug-disease interactions. The study included clients from eight European countries: the Czech Republic, Italy, Finland, Norway, Iceland, the United Kingdom, The Netherlands, and Denmark. Considering all explicit criteria, 19.8% of clients in the sample were identified as taking at least one potentially inappropriate medication. The 2003 Beers Criteria seemed to work best, identifying 85.6% of clients identified using all three criteria.³⁷

It is important to remember that medication-related events are only one type of adverse event. Certainly, there are many non-medication-related events, such as physical injury, which could occur often among home care clients. A study by Madigan, Schott and Matthews examined a different aspect of potential adverse events among Home Care clients—rehospitalization.³⁸ This study was American and focused on patients who became home care clients after their hospital discharge. Rehospitalization, therefore, is an important outcome measure for this type of home care client. This study sought to measure the rate of rehospitalization, determine if the hospital admission was preventable, and if rehospitalization can be predicted at admission to home care. The researchers employed a prospective research method to capture as much data as possible surrounding a rehospitalization; retrospective studies can be limited because researchers are constrained by the information available on study subjects. The study found a rehospitalization rate of 24% in the 12 weeks following home care admission and

³⁷ This was calculated using numbers presented in the study. 535 of the sample (n=2707) were identified using all three of the criteria, while 458 were identified using the 2003 Beers Criteria alone – $458/535 = 85.6\%$.

³⁸ Elizabeth A. Madigan, Donna Schott, and Carol R. Matthews. "Rehospitalization Among Home Healthcare Patients: Results of a Prospective Study." *Home Healthcare Nurse* 19, no. 5 (2001): 298-305.

determined that 73.3% of the hospitalizations were not preventable. The most critical period for rehospitalization is the first three weeks of home care service. The researchers were unable to predict rehospitalization based on data collected on home care admission.³⁹

Only one study was found that investigated AEs generally in home care.⁴⁰ This study reviewed adverse event reports from home care agencies in Michigan and Ohio. The study used data collected using the Centers for Medicare and Medicaid Services (CMS) Outcome and Assessment Information Set (OASIS).⁴¹ OASIS is a standardized data set used in home health agencies reimbursed by CMS. The OASIS package supports Outcome-Based Quality Monitoring (OBQM); part of OBQM is an adverse event outcome report, which reports on thirteen *potential* adverse events.⁴² The study reports each of the potential adverse events based on the aggregate data from two states. No overall rate of potential adverse events is reported. Rather, rates for each of the thirteen types of events are provided individually; the most frequent AEs reported were an increase in the number of pressure ulcers (1.9%), development of a urinary tract infection (1.4%), emergent care for injury caused by falls at home (1.4%), emergent care for wound infections and deteriorating wound status (1.4%), and unexplained death (1.0%). These results are difficult to interpret and compare to other studies because the study reports on *potential* adverse events based on routine assessment data and only the

³⁹ Data was collected using the standardized American OASIS assessment tool.

⁴⁰ Elizabeth A. Madigan and Susan Tullai-McGuinness, "An examination of the most frequent adverse events in home care agencies," *Home Healthcare Nurse* 22(4) (2004): 256-262.

⁴¹ Visit CMS' OASIS web site at <http://www.cms.hhs.gov/oasis/>

⁴² Health Care Financing Administration. *Quality Monitoring Using Case Mix and Adverse Event Outcome Reports*. United States, Department of Health and Human Services, 2001. Retrieved 23-JAN-2005 from <http://www.cms.hhs.gov/oasis/obqm.asp>

incidence of each individual AE is reported, rather than an overall AE rate as is standard in most studies. Despite these shortcomings, the study does offer some very important and relevant information to this investigation.

One additional study was located that examined “operation failures” in home care. Bruno and Ahrens discuss home care errors rather than adverse events.⁴³ Errors can be simple mistakes or accidents that have no harmful impact, whereas adverse events cause some level of harm but may or may not result from errors. The article recounts a recent case study in which a home care nurse was shadowed for a day by a researcher who observed and recorded any operational failures.⁴⁴ A very interesting aspect of this study was the researcher’s classification of the sources of errors. Sources of failure were categorized by patient/family, home health care agency, or the overall health care system. The study found 23 operational failures in the seven visits shadowed on a single day. The source was identified as patient/family for 52% of the failures, and 39% and 9% respectively for home health care agencies and the broader health care system.⁴⁵

The discussion that follows in the article by Bruno and Ahrens examines another important consideration to home care safety—challenges. The authors describe three challenges to home care safety: (1) staff work in multiple environments (i.e. different clients’ homes), which makes it difficult to standardize practices; (2) home care is

⁴³ Lori Bruno and Joann Ahrens. “Examining ‘Operational Failures’ to Reduce Home Care Errors.” *Caring* 24, no. 2 (2005): 34-35, 37, 39.

⁴⁴ A. L. Tucker. “A Case Study of Operational Failure in Home Health Care.” *Journal for Healthcare Quality* 26, no. 3 (2004): 38-43.

⁴⁵ Bruno and Ahrens, 35.

affected by players not under home care's jurisdiction (i.e. physicians, hospitals, pharmacies, clients and their families); and (3) that clients receive care from multiple home care providers. While the third challenge is not exclusive to home care, the other two help in understanding the unique nature of providing and receiving care in the home.

METHODOLOGICAL REVIEW

Many different methods have been used to study patient safety issues. Chart reviews are the so-called "gold standard" for adverse event studies. This process was used in the groundbreaking HMPS, as well as subsequent studies in Colorado and Utah, Australia, Britain, New Zealand and most recently in Canada. This approach involves sampling the general patient population, then screening the sample for potential AEs—in these studies the screening was done by nurses and medical records analysts. Any potential AEs are then reviewed by physicians who rate the likelihood that an AE occurred, determine the type and severity, and judge the preventability of the AE. The chart review method is often employed as it uses readily available data. Table 2-1 provides the rating scales used in the Canadian Adverse Event Study.

While the chart review method is the most widely used approach, it has been criticized for several reasons. The most commonly discussed weakness of the chart review is inter-rater reliability—the level of reviewer agreement. Thomas et al. sampled 500 cases from the Utah/Colorado study and found that the AE rate changed substantially if cases were independently reviewed by one, two, or three reviewers.⁴⁶ They concluded that the

⁴⁶ Eric J. Thomas et al. "The Reliability of Medical Record Review for Estimating Adverse Event Rates," *Annals of Internal Medicine* 136 (2002): 812-816.

Table 2-1 Chart Review Rating Scales Used in the Canadian Adverse Events Study

Rating if Adverse Event occurred	Rating if AE is Preventable
1. Virtually no evidence of management causation	1. Virtually no evidence of preventability
2. Slight to modest evidence of management causation	2. Slight to modest evidence of preventability
3. Management causation not likely (less than 50/50, but "close call")	3. Preventability not quite likely (less than 50/50, but "close call")
4. Management causation more likely (more than 50/50, but "close call")	4. Preventability more than likely (more than 50/50, but "close call")
5. Moderate to strong evidence of management causation	5. Strong evidence of preventability
6. Virtually certain evidence of management causation	6. Virtually certain evidence of preventability

Source: Ross Baker et al., "The Canadian Adverse Event Study: the incidence of adverse events among hospital patients in Canada," *Canadian Medical Association Journal* 170(11) (2004): 1678-86.

reliability of the chart review method is questionable, although they note this research does uncover important quality improvement opportunities. A study by Localio et al. also found wide disagreement among reviewers.⁴⁷ Several other commentary pieces have discussed the reliability weakness.⁴⁸ To address this concern, the major studies report on inter-rater reliability using the Kappa statistic and the level of agreement among reviewers. Moreover, each chart is usually independently reviewed by two reviewers; if there is disagreement, a third reviewer breaks the tie.

⁴⁷ A. Russell Localio et al. "Identifying adverse events caused by medical error: degree of physician agreement in a retrospective chart review," *Annals of Internal Medicine* 125(6) (1996): 457-464.

⁴⁸ See David Birnbaum and William Scheckler, "Beware of the patient safety juggernauts," *British Journal of Clinical Governance* 7(4) (2002): 282-285; Ross Baker, "Commentary"; and The Doctors Company, "An 'Epidemic' of Medical Malpractice? A Commentary on the Harvard Medical Practice Study," The Doctors Company, obtained online 20-SEP-2004 at <http://www.thedoctors.com/advocacy/outcause/harvardstudy/commentary.asp>

There are other criticisms of the chart review method. Reviewer bias, both conscious and unconscious, is another concern. Incomplete documentation⁴⁹ and loss of context⁵⁰ could impair the reviewer from coming to an accurate conclusion. Also, the sampling approach used by most studies has been another source of criticism as they often only include inpatient cases, likely the sickest and most complex patients with riskier treatments.⁵¹ The “denominator” is often not sufficiently defined, which means the population to whom the AE statistics apply is not clearly described.⁵² A final criticism of this method is the poor predictive value of the screening process, which means the reviewers must evaluate a large number of false-positive charts.⁵³

Chart review is not the only approach to studying patient safety; in fact researchers have used a variety of methods. Murff et al. provide an excellent review of methodologies, looking at voluntary and involuntary manual methods, as well as combined modalities, a mix of electronic and manual review.⁵⁴ Voluntary systems include incident or occurrence reporting systems that encourage professionals to report errors and/or adverse events. However, Murff et al. report that some research studies have found this method to greatly underreport errors.⁵⁵ Underreporting could be attributed to a number of factors, including fear of blame and punitive action or simply forgetting to report an incident. This

⁴⁹ Baker, “Commentary”; Eric J. Thomas and Laura A. Peterson. “Measuring Errors and Adverse Events in Health Care.” *Journal of General Internal Medicine* 18 (2003): 61-67.

⁵⁰ Birnbaum et al.

⁵¹ The Doctors Company.

⁵² Birnbaum et al.

⁵³ Murff, Harvey J., et al. “Detecting adverse events for patient safety research: a review of current methodologies,” *Journal of Biomedical Informatics* 36 (2003): 131-143.

⁵⁴ Ibid.

⁵⁵ They refer to studies that compared AE detection through incident reporting and chart reviewing; these studies found only 1.5% of AEs and 6% of ADEs are reported through incident reports. See *ibid.*, 132.

underreporting problem can be improved through various continuous prompting techniques explored by the authors.

Involuntary reporting includes chart reviews, described earlier, direct observation, and patient interviews. Direct observation—data is collected by observing the patient's care and interviewing providers as care is provided—is more accurate at detecting errors, but nearly eight times more expensive than chart reviews. Alternatively, patient interviews can also be used to determine the prevalence of adverse events. This approach, combined with chart reviewing, was used by Forster et al. while studying post discharge AEs.⁵⁶ This method is much more resource-intensive than chart reviews, though less so than direct observation.

The combined modalities approach uses electronic screening which may possibly trigger a manual chart review to detect adverse events. The authors note that electronic methods could be used ongoing by organizations to measure adverse events. A number of promising approaches are discussed, such as using diagnosis codes or searching electronic narrative for key trigger words that indicate a potential AE, like "agitation." Several studies were located that used this approach.⁵⁷ Electronic screening has been used by researchers studying ADEs in home care, but the results were reported as possible or

⁵⁶ Forster et al., "Adverse events among medical patients"; Forster et al., "Incidence and Severity of Adverse Events."

⁵⁷ Harvey J, Murff et al. "Electronically Screening Discharge Summaries for Adverse Medical Events." *Journal of the American Medical Informatics Association* 10 (2003): 339-350; Alan J. Forster, Jason Andrade, Carl van Walraven. "Validation of a Discharge Summary Term Search Method to Detect Adverse Events." *Journal of the American Medical Informatics Association* 12, no. 2 (2005): 200-206. David Bates et al. provide an excellent overview of electronic AE detection, including a detailed review of several studies, in "Detecting Adverse Events Using Information Technology," *Journal of the American Medical Informatics Association* 10, no. 2 (2003): 115-128.

potential ADEs; manual review is required to confirm the presence of an adverse event. Another study was located that reviewed various AE and error detection methods and came to similar conclusions as Murff et al.⁵⁸

Some studies have compared different AE detection methods by reviewing the same cases using different approaches. O'Neil et al. compared voluntary physician reporting with chart review to uncover AEs and found that both systems detected about the same number of AEs, but only half were detected by both methods.⁵⁹ The researchers concluded that voluntary reporting caught more preventable ADEs and was consequently more useful to quality improvement. These results stand in contrast to the 1.5 - 6.0% of AEs caught by incident reporting noted earlier. Reporting is likely dependent on the organizational culture and varies from site to site. Another study compared three methods for estimating AE rates in hospitals: cross-sectional, prospective (similar to direct observation), and retrospective (chart review).⁶⁰ This study found the retrospective and prospective approaches were much better than the cross-sectional study at identifying adverse events. The prospective method was much more sensitive to detecting preventable adverse events.

There are several methods for measuring adverse events and medical errors. While chart reviewing seems to be the most common approach, it has several disadvantages that can

⁵⁸ Thomas and Petersen.

⁵⁹ O'Neil et al., "Physician reporting compared with medical record review to identify adverse medication events," *Annals of Internal Medicine* 119 (1993): 370-376.

⁶⁰ Michel, Philippe et al. "Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals." *British Medical Journal* 328, no. 7433 (2004): 199-204.

diminish the reliability of the results. There are several other methods, including patient observation (prospective), patient interviews, and electronic measurement. Some studies have mixed methods, such as combining patient interviews or electronic screening with chart reviews.

3. LOST IN TRANSLATION: APPLYING THE PATIENT SAFETY CONCEPT TO THE HOME CARE CONTEXT

The vast majority of patient safety literature focuses on hospitals; this is, however, only one part of the broader health care system. Consequently, the core concepts of patient safety—the very definitions and concepts that guide research—were developed to fit the hospital environment. As mentioned earlier, a review of the literature found only one article that studied adverse events in home care.⁶¹ This study used the U.S. Centers for Medicare and Medicaid Services (CMS) definition, which describes an adverse event as a “low-frequency-negative or untoward event that potentially reflects a serious health problem or decline in health status for an individual patient.”⁶² A CMS quality monitoring manual further describes adverse events:

Adverse events serve as markers for potential problems in care because of their negative nature and relative low frequency. It is important to emphasize the word ‘potential’ in this definition. Whether or not an individual patient situation results from inadequate care provision can only be determined through investigation of the care actually provided to specific patients.⁶³

As this article used the CMS definition and a CMS-mandated data collection tool, the adverse events reported in this study are *potential* AEs, which perhaps should be interpreted more like quality indicators. While this study is important to understanding

⁶¹ Madigan and Tullai-McGuinness.

⁶² Qtd. in Madigan and Tullai-McGuinness, 257.

⁶³ Health Care Financing Administration.

quality in home care, the definition is not similar to most adverse event studies. No other home care-specific definition for the term adverse event was located.

Clear, unambiguous definitions are critical to developing an appropriate methodology and to interpreting results. The traditional hospital definition and concepts may not directly translate to the home care context given that it is quite different from hospital care. Therefore, in the absence of an adequate home care definition, this chapter intends to translate the term to home care by considering existing hospital-centric definitions and by contrasting care in the home with hospital care. To strengthen this intention, consultation sessions were conducted with home care staff and the results of this qualitative research are presented to help in establishing a home care definition. Finally, these components lead to a definition of “adverse event” and a description of its underlying concepts.

CONCEPTS IN THE LITERATURE

To begin examining the concept of patient safety in the home care context, a review of the literature was conducted and relevant definitions and concepts were collected. As discussed in the previous chapter, patient safety studies generally examine either errors, which may or may not result in harm, or adverse events, which cause harm but may or may not be the result of an error. The former focuses primarily on providers of care while the latter is more concerned with outcomes. This study is interested in outcomes and will thus concentrate only on the term adverse event and its underlying concepts. The term “adverse event” has been used by several patient safety researchers to ground their

investigations. All of the major hospital studies include a definition early in their publication, which reinforces the importance of a clear definition. The definitions from the major studies are presented in table 3-1.

Table 3-1 Adverse Event Definitions in Major Patient Safety Studies

	Definition of Adverse Event	Study/Source
1	"[A]n injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both" (370).	T. A. Brennan et al. "Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I." <i>New England Journal of Medicine</i> 324, no. 6 (1991): 370-377.
2	"[A]n injury caused by medical management (rather than the disease process) that resulted in either a prolonged hospital stay or disability at discharge" (263).	E. J. Thomas et al. "Incidence and types of adverse events and negligent care in Utah and Colorado." <i>Medical Care</i> 38, no. 3 (2000): 261-271.
3	"AEs are unintended injuries or complications that are caused by health care management, rather than by the patient's underlying disease, and that lead to death, disability at the time of discharge or prolonged hospital stays" (1678).	Ross Baker et al. "The Canadian Adverse Events Study: the incidence of events among hospital patients in Canada." <i>Canadian Medical Association Journal</i> 170, no. 11 (2004): 1678-1686.
4	"Unintended injuries caused by medical management rather than the disease process" (517).	Charles Vincent, Graham Neale, Maria Woloshynowych. "Adverse events in British hospitals: preliminary retrospective record review." <i>British Medical Journal</i> 322, no. 7285 (2001): 517-519.
5	"An adverse event was operationally defined as: 1) an unintended injury; 2) resulting in disability; and 3) caused by healthcare management rather than the underlying disease process. Each of these criteria had to be fulfilled."	Davis P, Lay-Yee R, Briant R et al. "Adverse events in New Zealand public hospitals I: occurrence and impact." <i>New Zealand Medical Journal</i> 115, no. 1167 (2002): U271.

These definitions are all quite similar and generally include three central components, or concepts: (1) an incident, (2) harm to the patient, and (3) caused by care rather than underlying disease. First, an adverse event involves some type of incident, event or circumstance. Second, the event involves some type of negative impact, harm, injury or complication, often described as prolonged hospital stay, temporary or permanent disability at the time of discharge, or death. Third, the event is caused by health care management rather than the underlying disease or condition. Health care management can include both actions (something was done and caused the AE) and/or inactions (something was not done and this inaction caused the AE).

The Canadian Patient Safety Dictionary reviewed some common definitions of adverse event and recommended it be defined in one of three ways:

1. An unexpected and undesired incident directly associated with the care or services provided;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.⁶⁴

This specialized patient safety dictionary also cautioned that “it is essential that the context be described whenever the term ‘adverse event’ is used.”⁶⁵ Understanding the home care context is important to effectively define the term adverse event in home care, not to mention put it to use.

⁶⁴ National Steering Committee on Patient Safety. *The Canadian Patient Safety Dictionary*, October 2003: 40. Retrieved 05-JAN-2005 from http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf

⁶⁵ *Ibid.*, 40.

CARE IN THE HOSPITAL VERSUS CARE IN THE HOME

There are several differences between care in the hospital and care in the home. In a hospital, the environment is relatively controlled—hospitals are responsible not only for all medical interventions, but also for many other aspects of care, such as administering all medications, ensuring patients receive adequate meals (perhaps “adequate” is a contentious issue from the patient’s perspective), and maintaining a safe environment (i.e. continuous sanitization). In home care, on the other hand, care is less controlled, delivered in varying unfamiliar environments, and relies heavily on client and family action, not to mention the health and social services delivered by professionals who are not part of home care.

Caring for a client in home care is less controlled than in a hospital. For example, direct service staff—both professional nurses and non-professional staff such as aides and home support workers—deliver care in varying environments as they visit clients in their own homes. Bruno and Ahrens noted that this unique aspect of community care makes it difficult to standardize practices.⁶⁶ Moreover, making practice changes can be difficult as staff are rarely in the same physical location.⁶⁷ They also note that most home care staff work alone in clients’ homes and when problems arise, staff tend to “work around” the problem themselves rather than call in to report the issue.

Another difference between home care and the hospital is the great impact on care by providers who are not part of the program. Physicians, pharmacists, psychologists,

⁶⁶ Bruno and Ahrens, 2005.

⁶⁷ In Winnipeg, Direct Service Staff have quarterly meetings and occasional workshops.

hospitals, clinics, and facility respite centres play a major role in providing care for home care clients, but these providers are not part of the home care team. Home care, therefore, relies on the actions of non-home care health professionals to deliver services to home care clients. Furthermore, patients are in the hospital for the entire episode of care; this is twenty-four hours a day for in-patients. Home care staff are rarely in a client's home around the clock; rather they are in the home for portions of the day, and in many cases are in the home only a few days per week or less.

Similarly, clients themselves play a major role in their care, as do their informal caregivers (family or friends who help provide care). In a hospital, activities such as managing and administering medications, cooking and providing meals, and ensuring patients maintain proper hygiene, are all the responsibility of the hospital. In home care, clients and their informal caregivers play a major role in the execution of these types of activities. Furthermore, clients are highly involved in care delivery and play a vital role in its outcome. They must communicate with providers about their health and well-being, they must make decisions about their care, and in most cases, client action is simply part of the care plan (i.e. taking medications appropriately, maintaining hygiene, using assistive devices like a walker to reduce risk for falls, etc.). Informal caregivers are also highly involved in these areas.

An article by Bitner et al. examines the contribution and role of customers in service delivery, identifying three levels of customer participation: low, in which only the customer's presence is required; moderate, in which customer inputs, generally

information, are required; and high, in which the customer co-creates the service.⁶⁸ Home Care should be classified as high level because clients and caregivers essentially co-create the service—they are involved in the design of the care plan and participate in the provision of care. One source referenced by Bitner et al. in their literature review encourages viewing the customer as a “partial employee.”⁶⁹ They find that effective customer involvement will impact on the quality of the service and the customer’s satisfaction. While this article focuses on improving the effectiveness of customer involvement to increase the customer’s satisfaction, they also note this can have a positive effect on quality—patient safety is one dimension of health care quality.

Clearly, client and caregiver decisions and actions are import factors in the quality and success of home care services. In home care, a client may occasionally decide to remain at home and live at risk. For example, consider a client who is unsteady on their feet and at risk for falls but dislikes using a cane or walker and refuses an assessment by an occupational therapist. Despite the hard work of home care professionals to encourage the client to address this potentially injurious risk, the client refuses. Alternatively, perhaps the caregiver for this client has been told that the scatter mats in the home are putting the client at risk for falls; despite home care’s suggestion to remove the mats, the caregiver decides against it. These are examples of client and caregiver decisions and actions that can result in harmful events that impact on the overall quality of receiving care in the home rather than in an institution.

⁶⁸ Mary Jo Bitner et al. “Customer contributions and roles in service delivery.” *International Journal of Service Industry Management*, 8(3) (1997), 193-205.

⁶⁹ Mills, Chase and Margulies (1983), referenced in Bitner et al., page 196.

Informal caregivers, the family and friends who provide unpaid assistance to clients, are also involved in providing care for home care clients—some have estimated that seventy to ninety percent of care for community-dwelling elderly is provided by informal caregivers⁷⁰—and this care is critical to maintaining a client in the community. Furthermore, caregivers also act as decision-makers for clients unable to do so themselves. In Winnipeg, a 2002 analysis of client data found that 96.2% of caregivers provide emotional support and companionship to clients, 85.0% provide IADL care and 35.3% provide ADL care.⁷¹ Many informal caregivers help in managing clients' medications. A study by Smith et al. investigated the number and type of medication management problems experienced by informal caregivers.⁷² Several problems were identified, including maintaining continuous supplies of medication, reminding the client to take their medication, opening containers for client, assisting client in taking or using medications, and noticing and managing client's side-effects to medicines. While informal caregivers provide a substantial amount of care for clients, they are generally not health care professionals and do not possess the professional knowledge to manage medications and provide personal ADL care (i.e. safely bathing or transferring a physically impaired client).

⁷⁰ Health Canada, "The Future of Caregiving," *Seniors Info Exchange* (Winter, 1997-98); Sherri Torjman, "R-e-s-p-i-t-e Spells Respect" Caledon Institute of Social Policy, May 2004.

⁷¹ Hirdes, John, Jeff Poss and Dawn Dalby. "Report on Home Care: Winnipeg Regional Health Authority (WRHA)." Waterloo, Ontario: University of Waterloo and Homewood Research Institute (Resident Assessment Instrument – Health Informatics Project), October, 2002.

⁷² Felicity Smith et al. "A multi-centre survey among informal carers who manage medication for older care recipients: problems experienced and development of services." *Health & Social Care in the Community* 11, no. 2 (2003): 138-145

Providing care in the home is certainly different from care provision in the hospital, for a number of reasons. Varying environments, the reliance on other providers and the actions of clients and informal caregivers make the home care environment unique.

UNDERLYING CONCEPTS AND HOME CARE

Armed with a better understanding of both the home care context and the underlying concepts of the term adverse event, as defined in major studies, it is now possible to examine adverse events in the home care context. As mentioned, the term “adverse event” has three underlying concepts: (1) some type of incident or circumstance, (2) some level of harm to the patient or client, and (3) the event is the result of care rather than the underlying disease or condition. The first concept is more straightforward while the other two concepts require careful consideration about how they apply to home care. The third concept, resulting from care, really involves the cause of the event. This could include individuals as well as systems, policies and procedures. Both of these underlying concepts—harm and cause—need to be examined more thoroughly and their applicability to home care must be considered.

An article by researchers from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), an American health care accreditation body, introduces the JCAHO Patient Safety Event Taxonomy.⁷³ This article was published after the initial literature review but is very relevant to this chapter, so it was incorporated into the final

⁷³ Andrew Chang et al. “The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events.” *International Journal for Quality in Health Care* 17, no. 2 (2005): 95-105.

examination of the two underlying concepts. Seeking to develop a multidimensional taxonomy for patient safety concepts that could be applied to all health care settings and be used to classify events, the researchers assembled and analyzed an extensive list of concepts and definitions. Five conceptual categories were established: (1) impact, or the outcome or harm of a medical error; (2) type, to explain the process(es) that were responsible; (3) domain, the setting and/or individuals involved; (4) cause, which describes the structures and/or human error associated with the event; and (5) prevention and mitigation, to explain how to reduce the incidence and effects of events. All five classifications include categorized examples to better understand the meaning of each classification. While these are important considerations when coding incidents in a health care organization, the taxonomy is too broad for this study. However, it does further develop the concepts of harm and cause, both of which will now be discussed in more detail.

Harm

Considering the JCAHO taxonomy, the thirteen CMS *potential* adverse events, and the discussion of delivering care in the home, a more thorough, home care-focused description of harm can be developed.

In terms of harm, or impact, the JCAHO taxonomy categorizes two broad types. The first, medical impacts, accounts for the psychological or physical harm that a patient or client can suffer. Non-medical impacts, the second broad type, includes legal, social and economic effects. This is important as it recognizes that the impact of adverse events is

not simply limited to physical harm but encompasses other elements. For example, an elderly home care client may have a non-injurious fall; there is no physical harm but non-physical impacts, such as psychological or social, may occur (i.e. client limits leaving home for fear of subsequent falls).⁷⁴

Several of the CMS *potential* adverse events can also help to understand harm in the home care setting, including: injuries related to falls or accidents in the home; wound infections or an increase in the number of pressure ulcers; medication side effects; unexpected nursing home admission; and unexpected death.⁷⁵ While unexpected nursing home admission and death are defined as adverse events by CMS, these outcomes are not necessarily caused by care. For example, an unexpected death could be related to the client's condition (i.e. heart attack) or a misfortunate event (i.e. traffic accident), and not related to care. Similarly, a client's medical or family situation may suddenly deteriorate, unexpectedly, to a point where the client requires admission to a nursing home. While this is unexpected, it may not be the result of care but rather is related to the client's condition or disease. However, there is the possibility that a client may be placed in a nursing home prematurely or inappropriately. Part of WRHA Home Care's mandate is to prevent or delay institutionalization. There is the possibility that a client may be placed in a nursing home but could have remained at home if a different care plan was developed. This could be an adverse event if the client's desire was to remain at home.

⁷⁴ M. Lange. "The challenge of fall prevention in home care: a review of the literature." *Home Healthcare Nurse* 14, no. 3 (1996): 198-206.

⁷⁵ Health Care Financing Administration

In the major hospital studies, harm generally includes death, disability and injury, and prolonged hospital stay. This study is limited to community-coordinated home care clients who are more likely long-term users, so prolonged home care use is most likely not related to an adverse event as clients will likely use the service for as long as they can remain at home. However, clients may require hospital care to address the harm caused by an adverse event (i.e. a client who falls and breaks a hip will require medical attention); so hospitalization could be associated with an adverse event.

To summarize, in home care, harm could include a number of areas, such as physical, psychological, legal, social and economic impacts. It may also include premature or inappropriate placement in a nursing home, or unneeded or unplanned hospitalization. Of course, it could also include death.

Cause

Considering the JCAHO taxonomy and the discussion of delivering care in the home, the cause of adverse events in home care can also be examined in more detail. The JCAHO taxonomy separates cause into two broad categories, systems and human. The systems side of cause includes both structure and process, and account for factors such as management and oversight, training, organizational culture (i.e. a culture of safety), protocols and processes, facilities, and equipment. Human cause can involve the practitioner and/or the patient.

Causation can be difficult to determine, and sometimes there is a tendency to associate an adverse event with human factors rather than system factors, leading to what is often called a “culture of blame.” The Canadian Patient Safety Dictionary notes that “[a]ssigning blame to an individual for an error or adverse event does not recognize the complexity within the health-care system and the impact of latent conditions.”⁷⁶ The patient safety community has encouraged a move towards a culture of safety, where the emphasis is placed on examining potentially faulty systems that cause AEs. In fact, the Canadian Patient Safety Dictionary lists blame in the “Terms best avoided” section.

There are a number of considerations in defining AE cause in home care. Like hospitals, home care events could be the result of system or human factors. Home care likely faces similar system causes, such as challenges with training, policies and protocols. Human factors could include a variety of practitioners; in WRHA Home Care, these can be categorized into two groups. The first is Direct Service Staff, which includes non-professional staff who assist with household maintenance and personal care, and professional staff such as nurses and occupational and physical therapists. Coordinators make up the other group and include Case Coordinators who assess clients and develop care plans, and Resource Coordinators and Nursing Resource Coordinators who schedule and supervise Direct Service Staff and fill service requests. As service delivery is shared and somewhat fragmented in home care, cause could also be attributed to other providers, such as hospitals, family physicians, other programs and non-governmental organizations. As discussed, clients and informal caregivers are highly involved in care and, consequently, could also be the cause of an adverse event.

⁷⁶ National Steering Committee on Patient Safety, 44.

CONSULTATION SESSIONS

The applicability to home care of the term “adverse event” (AE) and its underlying concepts of harm and cause are still unclear. To better understand the home care environment and the perspectives of those working in home care, consultation sessions were conducted with home care staff. The objectives of these sessions were to discuss the types and causes of AEs in home care and their harm and impact on clients. They were used to help solidify the concepts of AE harm and cause as they relate to home care and establish a definition for “adverse event” to be used for this study.

Two consultation sessions were held with WRHA Home Care employees. The first session included management and program planning staff, including Home Care Directors, Team Managers, Specialists, a Quality Improvement Manager, and a Policy Analyst, while the second session included coordinators (both Case Coordinators and Resource Coordinators). The investigator for this study also worked with the WRHA, so participants were recruited via email.⁷⁷ As there are few staff involved in management and program planning, these employees were individually invited to attend. All coordinators were sent a generic email invitation to participate, indicating that participants would be randomly selected if there was a surplus of volunteers. All participants provided informed consent by signing a consent form at the session; consent

⁷⁷ It is important to note that the investigator, Keir Johnson, worked with the WRHA as a student at the time the sessions were conducted. He was not in a position of power or authority over any of the participants.

forms were included in the recruitment email and consent was discussed at the beginning of the session.

Regarding anonymity and confidentiality, participants were advised that job titles would be included in the report of findings. For coordinators, this is not an issue as dozens of employees share the same title. For managers, directors, specialists, the quality manager, and the policy analyst, anonymity could not be guaranteed as there are often less than five people who share a job title, and in some cases only one person with a specific job title.

The participants were made aware of this prior to providing consent. All notes from the sessions that included the names of participants were locked in a filing cabinet that only the investigator had access to, and were destroyed following analysis. No compensation or honorarium was offered to participants, although lunch was provided as the two-hour sessions ran over the lunch hour.

A session leader's guide, or protocol, was developed for use in the consultation sessions.

After greetings and introductions, some ground rules were set to ensure participants were comfortable with sharing their personal opinions. Participants were then introduced to the study in more detail and existing definitions and concepts for the term adverse event were presented by the moderator. Two broad questions followed relating to the types of adverse events that might happen in home care and to the cause of these events. The session then revisited the definition of adverse event and participants were invited to vote on different elements of both harm and cause. Table 3-2 shows the elements for which participants voted.

Table 3-2 Concepts Voted on by Consultation Session Participants

Elements related to <u>Harm and Impact</u> of adverse event		Elements related to <u>Cause of</u> adverse event	
Health and well-being harmed	Physical injury / disability	While Home Care was on site	Any time
	Psychological injury / disability	Coordinators (Case Coordinator, Resource Coordinator, Nursing Resource Coordinator)	
	Emotional injury / disability	Direct Service Staff (Home Support Worker, Home Care Attendant, Nurse, Occupational / Physical Therapist)	
	Financial injury / disability	Policies / procedures	"Systems" (Structure and Process)
Unnecessary / unplanned hospitalization	Training / education		
Premature or inappropriate nursing home placement		Other non-home care providers (hospitals, family physicians, other programs / agencies / etc.)	
Death		Informal caregivers (family or friends)	
More care*			

* "more care" was added by the program management and planning group

The concepts were posted on the wall and participants attached sticky dots to a concept if they agreed it should be part of the definition. If two concepts were side-by-side, participants could vote for either concept, but not both. For example, under Cause, participants could vote for either "while on site" or "any time", but not both. Under Harm and Impact, participants could vote for either "health and well-being" or any of physical, psychological, emotional, or financial injury / disability. A discussion of the dot voting

followed to help understand any differences that emerged. The session concluded with a methodology-related question, which will be discussed in chapter four. The sessions were moderated by the study investigator.

Ethics approval for the consultation session methods was obtained from the University of Manitoba Joint-Faculty Research Ethics Board. Copies of the consent form and the session leader's guide are included in the appendix. WRHA access approval was received from the WRHA Research Access Committee.

Sessions were not electronically recorded, but rather extensive notes were taken. The results were analyzed systematically. Notes were categorized and labeled; themes were identified and interpreted. Results were analyzed as soon after the sessions as possible—within one week. Peer debriefing was used to ensure the results were logical and clear. Participant verification, or member checking, was also completed to ensure results reflected the perspectives shared in the sessions. This involved an oral summary of some of the key points at the session and the distribution to all participants, via email, of an interim draft of the findings for review and feedback.⁷⁸

Consultation Session Findings

The manager and program planning staff session was held on April 20, 2005. The session included Directors, Team Managers, Home Care Specialists, a Quality Improvement

⁷⁸ The following texts were used to assist in consultation session planning, conduct, and analysis: John W. Creswell. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*, 2nd ed. (Thousand Oaks, California: Sage Publications, Inc., 2003); and David L. Morgan and Richard A. Krueger. *The Focus Group Kit* (Thousand Oaks, California: Sage Publications, Inc., 1998).

Manager and a Policy Analyst. There were fifteen participants, a number higher than anticipated. The large group, however, did not seem to diminish the quality of the discussion, probably because participants were all well acquainted. During introductions, participants were invited to share the number of years they had worked in home care. Collectively, the group had over 160 years of home care experience, and several of the participants indicated they had additional health care experience in other sectors, such as acute and long-term care. The group was very engaged and seemed quite comfortable from the beginning, probably because all participants had established working relationships. There was some concern about the level of comfort to freely share opinions due to superior-subordinate dynamics (several of the participants supervised other participants), but this did not appear to be an issue.

The coordinator session included Case Coordinators and Resource Coordinators and was held on April 21, 2005. This session was much smaller, with seven participants. Collectively, this group had over 50 years of home care experience. This group was more subdued and less engaged at first, possibly because not all participants knew each other. Also, the topic of patient safety and adverse events may have been unfamiliar to some of the participants in this session. The atmosphere warmed up shortly after group introductions and opening remarks about the study.

A great deal of very useful information was collected during the consultation sessions. Some of the discussion confirmed much of the preliminary research surrounding AEs in home care, while other comments helped to uncover new knowledge or understanding.

The sessions had three main components: types of adverse events, harm and impact, and cause. Accordingly, the findings of the session are organized into these categories.

Participants in both sessions mentioned several types of AEs that can occur in home care. For the most part, both groups identified the same types; the most common responses were falls, pressure ulcers, medication-related events, and other physical injuries. These types of events are consistent with the limited home care AE literature that was found. A few participants in both groups noted that many falls do not result in physical injury, but can negatively impact on a client's emotional and social functioning. All references to medication-related events were limited to medication errors—participants in both groups mentioned double doses and missed doses, for example. There was no discussion around ADEs, or the negative reactions that clients can have to medications. Other physical injuries included burns, bruises, and scratches.

As no one mentioned premature nursing home placement, this issue was raised by the moderator. At first, both groups seemed reluctant to consider this an AE. For example, one participant in the coordinator group stated that “unneeded personal care home placement is unlikely due to the panel process” (nursing homes are generally referred to as personal care homes, or PCHs, in Manitoba). After some discussion, however, nearly all participants in both groups seemed to agree that the possibility exists that clients could be placed in a nursing home prematurely and unnecessarily. A participant in the management and planning group noted that while helping with training in a Winnipeg PCH, she questioned why a couple of the residents were in the PCH given their high level

of independence; she believed they could manage in the community and still live at home. Another participant in the coordinator group noted that some clients may be placed in a PCH as a result of an AE. For example, a client's functioning may decline rapidly due to an AE which results in a need to admit the client to a nursing home. A couple of participants noted that, similarly, an AE may cause an otherwise unneeded or unplanned hospitalization (i.e. hospitalization due to a broken hip that was caused by a preventable fall). The otherwise unneeded hospitalization may, itself, be an adverse event as it negatively affects an individual's independence.

One participant in the management and planning group also thought that social and emotional distress could be a type of adverse event. This provoked a rather lively discussion about what should be considered an adverse event. The intensity and varied perspectives during this portion clearly demonstrates the challenge in translating the term "adverse event" to the home care environment. The discussion seemed to centre on the underlying concepts of harm and cause, both of which will now be discussed.

Discussion around the harm, impact or outcome of an adverse event surfaced in the management and planning session. As mentioned, a rather lively debate about what should and should not be considered an adverse event arose during this session. One participant mentioned that social and emotional distress should be considered an adverse event. Several participants seemed uncomfortable with this as defining social and emotional distress could be highly subjective and problematic. One participant questioned the difference between social and emotional distress and dissatisfaction and

complaints. For example, perhaps a changed schedule or worker results in client dissatisfaction and results in a complaint. This may cause the client some level of social or emotional distress, but one might question if this should be considered an AE. In the discussion that followed, this question was not resolved. This issue did not arise in the coordinator session.

As mentioned, participants had the opportunity to vote on the two major underlying concepts of harm and cause. Table 3-2 lists the elements of the concept of harm or impact for which participants could vote. Participants were introduced to the various elements, which were posted on the wall, and were instructed on the dot voting procedure. Before voting, participants were asked if they wanted to add any elements to the concept lists. In the management and planning group, one participant added "more care," arguing that this was similar to the concept of prolonged hospital stay used in hospital studies. This participant noted that an event might involve more care to address complications from an AE. "More care" was added by the moderator in the coordinator session to seek their opinion on this additional aspect of harm and impact.

First, participants had to choose whether to vote for the more broad and conceptual term "health and well-being" or to vote for the more specific elements of harm, including physical, mental, emotional, and financial. Both groups were split between health and well-being and some or all of the other terms. Both groups were asked to explain why they were divided. Just over half of the coordinator group seemed to prefer the more broad and conceptual term of "health and well-being" because they felt the more specific

terms were too narrow and there could be additional aspects not included (i.e. spiritual); the health and well-being term was less specific and could, therefore, be interpreted to include any missing elements. The majority of management and planning participants preferred the more specific terms because they were measurable, whereas they felt health and well-being was not as measurable. Among those who opted for the more specific terms, nearly all agreed that physical, mental and emotional impacts should be included in defining harm, but less than half felt financial liability should be considered.

Next, groups voted on whether they agreed that the following elements should be included: unnecessary/unplanned hospitalization; premature/inappropriate PCH placement; death; and more care. All participants in both groups agreed that the first three of these elements should be included in defining harm. The last aspect, more care, was a more contentious issue. As mentioned, a participant in the management and planning group added this aspect to the list. While the majority of both groups agreed this should be included, those who did not vote for this element were quite vocal in describing their opposition. They felt that more care may not be negative. Indeed, many clients, they believed, would welcome more care and service. Both groups remained divided on this issue.

The other concept that was discussed and voted on was cause. There was much more discussion around this concept. Many of the participants in both groups identified a wide range of "system" causes, such as: communication; organization change; equipment issues (i.e. using lawn chair to bathe because there was no bath stool); lack of resources,

specifically Direct Service Staff; scheduling problems that result in a missed call; competency of staff; training and education; and excessive workload. Several participants noted that the transition points—when a client moves from hospital to home care, or coordination of the case changes between offices—leaves clients particularly vulnerable due to “holes in the system.”

The majority of the discussion about cause in both groups related to the individuals and organizations that could be responsible for adverse events. Much of this discussion confirmed the literature review and discussion about the reality of providing care in the home. For example, “client choice” surfaced as an issue in both sessions and the perspectives seemed to be common among both the coordinator and management and planning groups. Some participants recounted situations where a client refused to seek medical attention, refused or limited home care service, or refused to comply with medication prescriptions. A Case Coordinator recalled a client who had a female worker come in to administer medications. Something arose which required a change in worker, and the client refused the new worker because he was male. Consequently, the client did not have medication administered as prescribed. In this situation, the client ended up in hospital because the medication was not administered. Many participants noted that, at times, clients decide to live at risk by making these types of decisions. Clearly, client choice has a dramatic impact on the quality of home care.

The majority of participants in both groups recognized that informal caregivers (i.e. family and friends) are also responsible for clients care, and that these caregivers can be

responsible for adverse events. A handful of participants in both groups raised the issue of abuse, arguing that abuse from caregivers should be considered an adverse event. One participant noted that caregivers often become stressed by their caring role and this can, occasionally, result in abuse towards the client. While no one disagreed with this argument, no participants voiced their support.

The possibility of other non-home care providers causing adverse events was also discussed; this issue was raised by the moderator in both groups. The management and planning group, at first, was divided on whether it was relevant or appropriate to consider events not caused by home care. Several participants shared examples and opinions about whether to consider all providers; table 3-3 includes a few of these comments.

Table 3-3 Management and Planning Group Comments about Considering All Providers

Comments Supporting the Consideration of All Providers
<p>“What about when doctors don’t provide a timely medical when we initiate PCH placement? This delay leaves the client in the community longer and could cause an event.”</p> <p>“Any provider could cause harm. It shouldn’t matter who causes it.”</p> <p>“A lot of the issues home care deals with are caused by other players. Sometimes clients come out of (a two-week facility) respite or hospital with a pressure ulcer.”</p>
Comments Opposing the Consideration of All Providers
<p>“That (considering other providers) could be difficult. We could have little to no role in the event aside from referring the client.”</p> <p>“I’m more interested in only considering home care and not others unless they are partners.”</p>

After some discussion, the moderator asked if participants would be more comfortable if the provider/organization responsible for cause was identified and included in reporting the results (this was the original intent of the study). This seemed to address the concerns of those participants initially opposed to considering other providers and nearly all participants then agreed with considering all providers. The coordinator group was not divided on this issue and all participants in this group seemed to agree with the need to consider all providers. One participant noted that "home care is not its own entity; it relies on other providers."

Like the concept of harm, dot voting was also used to focus the discussion and determine the support for the various potential causes of adverse events in home care. Table 3-2 lists the elements related to cause for which participants voted. First, participants had to decide if they only wanted to include events that occurred while home care was on site, or events that occurred any time. All participants in both sessions agreed that AEs that happen any time should be considered. Similarly, all groups agreed that both staff involved in coordinating clients' care (Case Coordinators and Resource Coordinators) as well as Direct Service Staff could cause an adverse event. Next, participants voted on whether they preferred the term "systems" or the more specific terms "policies/procedures" and "training/education." Both groups were divided with their responses, with almost equal numbers preferring one option or the other. When asked why their votes were divided, about half of the participants in both groups felt that the more specific elements were not comprehensive enough, so they opted for systems. The other half preferred the more specific terms because they were just that, more specific.

During this discussion, some of the participants who voted for the more specific elements indicated they would change to systems because they now preferred this more “all-encompassing” term. Finally, all participants in both groups agreed that events could be caused by clients, informal caregivers, or other providers and agencies.

TOWARDS A DEFINITION

The consultation sessions were extremely helpful in translating the term “adverse event” to home care. The concepts of harm and cause were thoroughly discussed and nearly all participants in both groups agreed on the elements of each concept that should be included. There were a few issues and concerns that remained unresolved and warranted further exploration after the consultation sessions. The first issue was whether “more care” should be considered harm. As mentioned, the majority of participants agreed that more care should be included, perhaps because it is viewed as synonymous with prolonged hospital stay. However, the concerns expressed by the opposing minority could not be ignored and, as such, more care was excluded from the concept of harm.

Also, both groups were divided on whether to include health and well-being or the more specific physical, mental and emotional injury in defining harm. Again, the reasons expressed by participants were reviewed to resolve this issue. Health and well-being was favoured by some because it was broader and didn’t exclude any elements whereas the specific aspects listed were not viewed as inclusive and comprehensive. Those who voted for physical, mental and emotional injury did so because they were viewed as more measurable. As this study intends to measure AEs, it was decided to utilize the more

specific, measurable elements rather than the broader, more subjective health and well-being.

The final outstanding issue concerned whether or not emotional and social distress should be considered an AE, if caused by care. There was some concern in the management and planning group that this was closely related to client dissatisfaction and complaints and, therefore, should not be included in the concept of harm. Looking at emotional and social distress separately, emotional distress seems to be relevant as nearly all of the participants who voted for the more specific elements voted for emotional injury. Social distress, on the other hand, is more difficult to include or exclude in defining harm because it was not voted on; no participant added social distress to the list. Perhaps participants viewed social and emotional as synonyms, so did not see the need to add a seemingly repetitive element to the list. Furthermore, perhaps participants felt that if someone was sufficiently socially distressed, he or she would also be emotionally distressed. Ultimately, the investigator decided to include emotionally distressed but exclude socially distressed as the latter seems to be more contentious and dissatisfaction is not intended to be included in the definition of harm.

To further address the participants' concerns about ensuring the exclusion of dissatisfaction and complaints, harm was more explicitly defined to indicate that it must affect a client's overall health and/or functioning. By specifying health and/or functioning, only events that significantly and negatively impact the client are included.

By examining existing definitions, contrasting care in the home with hospital care, and considering the findings of the consultation sessions and resolving the few outstanding issues, it is now possible to translate the term adverse event to home care, compose the highly-anticipated definition and describe the underlying concepts. Based on all of this information and for the purpose of this study, the term adverse event will be defined as:

Harm to the client that negatively affects their overall health and/or functioning and is the result of care actions and/or inactions rather than the client's underlying condition.

“Harm” can include physical and mental injuries, emotional distress, unneeded or unplanned hospitalizations, premature or inappropriate PCH placement, and death.

“Result of care,” or cause, includes a number of different providers, such as: the WRHA Home Care program (coordinators, direct service staff, “systems”); other providers (WRHA programs, family physicians, hospitals, other agencies and organizations, etc.); clients (self care); and informal caregivers. This definition attempts to translate the hospital-centric terms by integrating the unique characteristics of home care and the perspectives of home care professionals.

4. METHODS

With a definition of adverse event appropriate to the home care environment, it is now possible to develop a methodology for measuring the incidence of adverse events among Winnipeg Home Care clients, the second goal of the study. The chapter begins by revisiting the various methods that could be used in this study. There are several potential approaches to measuring patient safety, which were introduced in the literature review in chapter two. Based on the various advantages and limitations of the various approaches, the following discussion contrasts the potential methods with the resources available to conduct this study in order to select a feasible methodology. This discussion leads to the selection of a method for this study. Based on the general approach selected, a more detailed and thorough methodology is formulated to measure adverse events among Winnipeg Home Care clients.

POTENTIAL METHODS

Chapter two introduced a variety of methods that have been used, or could be used, to measure patient safety; this section recapitulates these approaches. Most patient safety studies assume either a retrospective or prospective design and utilize a variety of information sources. Retrospective studies examine existing secondary health information to determine if an AE occurred. Reviewing patient charts, or chart reviewing, is the most common retrospective approach and, perhaps, the most common approach in general. Other retrospective studies have used voluntary reporting of AEs, also called

incident or occurrence reporting, while others have interviewed patients and staff or examined administrative databases.

Chart reviewing is certainly the “gold standard” method used in patient safety studies, having been used in studies in the United States, Canada, the United Kingdom, Australia, and New Zealand among other nations. This method involves a screening and review stage. Generally, nurses or medical records analysts review patient charts for selected screening criteria that could indicate the presence of an adverse event. All charts that screen positive then advance to the review stage in which physicians review the chart to determine if an AE has occurred. In most studies, charts are independently reviewed by two physicians. If there is disagreement between the two reviewers, they discuss the situation. If the discrepancy cannot be resolved through discussion, a third physician reviewer will break the tie. Reviewers generally determine if an AE occurred, identify the type of event, its harm to the patient and judge its preventability.

While the most common approach, chart reviewing is also the most criticized. Several reasons were discussed in chapter two, including concerns about inter-rater reliability (agreement between reviewers), incomplete documentation, and reviewer bias. A retrospective study is limited to the information that is available which can, consequently, result in a loss of context. The approach is also criticized as the screening stage can be somewhat inefficient due to its poor predictive value. Other retrospective approaches include reviewing voluntary incident reporting and interviews with patients and staff. Incident reporting has been found to catch a small percentage of adverse events due to

underreporting. This issue, of course, is dependent on the organizational culture, among other factors.

Prospective studies collect data during clients' hospital stays, as possible AEs unfold. This can be achieved by prompting reporting when certain events happen, interviewing staff and patients as care is delivered, or directly observing the provision of care. Direct observation can involve shadowing a patient or staff person and observing the care provided or received. Comparison studies have found prospective observational studies to cost up to eight times the amount of chart review studies.⁷⁹

Both retrospective and prospective designs can use manual or electronic methods, or a combination of both. Traditional chart reviews, for example, have been exclusively manual in design; both the screening and review stages are completed by hand. Most studies that rely solely on electronic methods often report findings as *potential* adverse events, as harm and cause are difficult to determine using automated electronic approaches. For example, the home care study discussed in the literature review reported *potential* adverse events and several medication-related studies reported *potentially* inappropriate medication use. These are reported as potential events or potentially inappropriate because the cause and/or harm have not been clearly identified—computerizing the review stage is extremely challenging as cases must be individually reviewed to determine cause and harm.

⁷⁹ Murff et al. "Detecting adverse events for patient safety research."

It is also possible to combine different approaches. Forster et al., for example, used patient telephone interviews with chart reviews to determine if an adverse event occurred after hospital discharge.⁸⁰ Some have suggested computerizing the screening portion of chart reviews to improve the use of often expensive expert chart reviewers.⁸¹ This allows automated searching of patient records for specific coding (i.e. ICD-9-CM diagnosis codes) or for key words that might indicate the presence of an AE.

CONSIDERING RESOURCES AND CHOSING AN APPROACH

Selecting an approach to measure adverse events in home care requires careful consideration of resources, sources of information, and potential weaknesses of each approach. In terms of resources, this study was limited in several areas: the study has no funding, limited human resources, and a tight schedule. While prospective studies have been shown to be more effective at identifying adverse events, especially preventable AEs, it is also more costly and requires a longer time span to follow, track and observe clients. A participant observation approach has been used in home care to study operational failures, or errors; this study shadowed a home care nurse for a day to observe and identify operational failures. While following a nurse is effective for identifying errors, it is likely not as successful for observing adverse events in home care—AEs can happen when home care is not on site and can be caused by other providers. A more effective observer approach would be to follow a client, but this would be quite costly

⁸⁰ Forster et al., "Adverse events among medical patients"; Forster et al., "Incidence and Severity of Adverse Events."

⁸¹ Harvey J. Murff et al. "Electronically Screening Discharge Summaries for Adverse Medical Events." *Journal of the American Medical Informatics Association* 10, no. 4 (2003): 339-350; and Forster, Andrade, and van Walraven.

and likely quite challenging logistically. Therefore, prospective approaches were not considered for this study.

Retrospective studies have used a number of approaches. Chart reviewing is certainly the most common approach. Other methods include reviewing incident reports or interviewing staff and/or clients. The WRHA collects incident reports, called occurrence reports, for all programs. However, the reports themselves do not contain all of the information needed to determine cause and harm. Further, occurrences are not reported for non-WRHA providers. While these contain invaluable information, occurrence reports alone are not sufficient. Interviews were discounted because the study does not have sufficient resources to effectively complete interviews and these alone may not provide sufficient information. Chart reviewing is the last option, and is perhaps the most appropriate considering its strengths, weaknesses, convenience, resources, and data availability.

During the consultation sessions, which were described in the previous chapter, participants were asked about potential sources of information. Aside from interviews and surveys with staff and clients, the following sources of information were identified: Occurrence Reports (would need to access original copies as no client data is saved electronically); MDS-HC database (case coordination software, including client assessments, notes and care plans); scheduling database (records of visits from Direct Service Staff); complaints (formal complaints are handled by a single Client Relations Manager); Appeals (clients and families can appeal decisions made about eligibility and

care plans to a provincial appeal panel); and the nursing home placement database (includes a record of all clients placed in nursing homes). There is clearly a great deal of information already collected about clients, both electronically and in hard copy, which could include clues about adverse events. Due to the high level of data already collected in the WRHA Home Care program, as well as considering the resources and thesis deadline, the chart review approach was selected for this study. While this approach requires human resources to actually review the charts, it can be completed in a relatively short timeframe. Several Home Care employees (Specialists and Team Manager) volunteered to assist with the study and could be used for the chart review process.

Determining which data sources to access is also important. While all sources contain valuable information, it was decided to focus on the most comprehensive and relevant sources. Of the various data sources mentioned earlier, two were selected to support this study. The MDS-HC database stores all data relating to case coordination, including: intake information; assessments that use standardized coding; care plans, which should include all care providers, not just Home Care providers; and ongoing notes about the client's situation.⁸² Several participants in the consultation sessions noted that if clients suffer any injuries or harm, are hospitalized, placed in a nursing home, or die, it should be noted in this software. As this data is all stored electronically, it is possible to complete a computerized screen, which should eliminate the need for additional human resources

⁸² The standardized assessment, called the Minimum Data Set for Home Care (MDS-HC) was developed by interRAI, an international organization dedicated to improving care for the elderly and disabled. The MDS-HC assessment items are used to calculate care plan protocols, outcome measures and other decision-support tools intended to improve care by using standardized data and incorporating best practice. The MDS-HC assessment form uses standardized quantitative coding.

during the screening stage. The second source of information is the WRHA occurrence reports. One participant noted that occurrences are probably dramatically underreported, but those that are reported could provide very useful information. Unfortunately, client information for occurrence reports is not stored electronically; therefore a manual search for reports is required.

Based on careful consideration of resources, timeframe and the various measurement approaches, the chart review method was selected for this study. More specifically, this can be described as a chart review prompted by a mixed (electronic and manual) screening method.

DATA COLLECTION METHODS

The chart review method requires historical client data to review and determine if an adverse event occurred. A one-year period was selected to search for adverse events—this allows for easier analysis and reporting (i.e. incidence of adverse events over a one year period). The data collection methodology has four stages: (I) sampling, (II) screening, (III) reviewing, (IV) analysis. Figure 4-1 illustrates the methodology. The data collection methods received ethics approval from the University of Manitoba Joint Faculty Research Ethics Board and organizational approval from the WRHA Research Access Committee. There were two changes to the data collection methods, which are noted in the following section; amendments were approved by both the University and the WRHA.

Stage I - Sampling

To determine an appropriate sample size, it was necessary to first establish the population size over a one year period; this timeframe was selected to allow for annual incidence reporting. For the calendar year of 2004, there were a total of 14,624 clients open to the community-coordinated Home Care program. This number includes all clients open at the beginning of 2004 and the number of intake in the following twelve months.⁸³ To calculate an appropriate sample size when measuring a nominal variable (i.e. incidence of AEs), an estimation of the expected results is required; in the absence of any comparable home care-based studies to rely on, an estimate was calculated by averaging the rates from two Canadian studies. The Canadian Adverse Event Study, which focused on hospitals, found an AE rate of 7.5% and a post hospital discharge study by Forster et al. found an incidence of 23%.⁸⁴ Therefore, the estimated incidence of AEs for this study, used solely to determine an appropriate sample size, is 15%. Based on this estimate, a 95% confidence limit and an accepted error margin of +/- 3.5%, it was determined that a sample size of 400 clients is required.⁸⁵ This sample size is appropriate as it balances the ability to generalize to the home care population with the anticipated chart review resources.

⁸³ This information was obtained from the monthly statistics collected by the Home Care program.

⁸⁴ Baker et al., "Canadian Adverse Event Study"; Forster et al., "Adverse events among medical patients"; Forster et al., "Incidence and Severity of Adverse Events."

⁸⁵ See Winston Jackson. *Methods: Doing Social Research* 3rd ed. Toronto: Prentice Hall, 2003, p. 441 for calculating a sample size for estimating a nominal variable. Formula used:

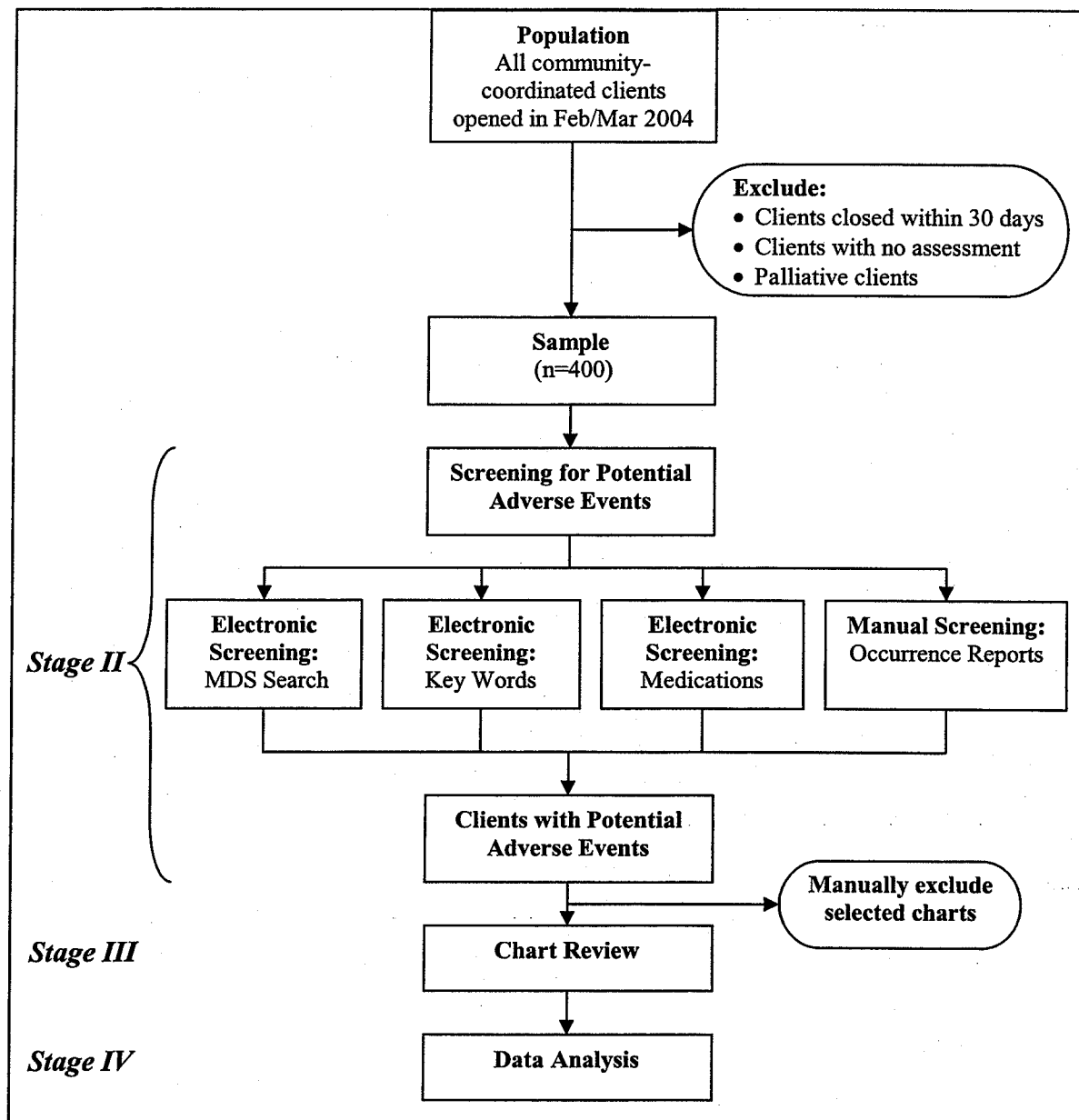
$$\text{Sample size} = \frac{(\text{success}) \times (\text{failure}) \times (\text{confidence limit Z value})^2}{(\text{accuracy})^2}$$

success = estimated proportion exhibiting the variable; failure = 1 – success

confidence limit Z value = 1.96 for 95% confidence

accuracy = range within which estimate should be, or margin of error.

Figure 4-1 Illustration of Methods



A random sample of clients opened in February and March, 2004 was pulled from the MDS-HC database using SPSS for Windows. Clients were excluded if they were closed within 30 days of being opened. Only clients with a completed MDS-HC assessment were included as the assessment contains critical information to describe the sample, screen for potential AEs and review the file. Any palliative care clients were also

excluded. Thirty days is too short a timeframe to study AEs and palliative clients' conditions are highly unstable and they are likely in receipt of comfort care. To determine if clients are open less than thirty days, the date of home care opening was subtracted from the date of closing (if client has been closed to home care). The date that the electronic client file was opened was used as the opening date for community clients. For hospital clients, the date the file was transferred from the hospital to the community office was used.⁸⁶ Palliative clients are identified in the MDS-HC assessment (item K8e = 1, or item CC3f = 1).

Originally, the study intended to sample clients opened in February, 2004; as there was an insufficient number of clients opened in this month, the timeframe was expanded to include clients opened in both February and March, 2004.

Stage II - Screening

Stage two involves screening the sample for *potential* adverse events. Based on the home care definition of adverse event established in chapter three and description of its underlying concepts, there are several types of AEs in home care, including: injurious and non-injurious falls, pressure ulcers, ADEs, other physical injuries, emotional distress, or mental harm or injury. These events can result in temporary or permanent injury,

⁸⁶ Home Care has two sources of intake, community or hospital. Community intakes are received through a central intake office which sends client files to community offices for further assessment. Alternatively, clients can be opened to the program through the hospital. As clients' electronic files are opened in hospitals when first referred to hospital home care, files can be opened for weeks or months before the patient is ready for discharge. Therefore, the date of discharge—when the file is transferred from the hospital to the community office—was selected to reflect the home care opening date. Client files are generally closed within 30 days if clients are found to be ineligible for home care or if they were in need of short-term home care only (usually post-acute home care).

otherwise unneeded hospitalization, premature nursing home placement, or death. To enable a chart review, all clients must be screened for these circumstances. Because WRHA Home Care utilizes an electronic health record that includes client assessments, continuation notes and care plans, an electronic screen was selected as it is likely the most efficient and effective approach. As mentioned earlier, the major hospital studies utilized a manual screening process. Electronic screening has recently emerged as a potential replacement for this approach and has been used in several studies. The WRHA has implemented a standardized occurrence reporting system, similar to incident reporting. Cross-referencing the sample with occurrence reports could uncover AEs. This mixed screening process was used to identify clients that possibly had an AE. Only potential AEs that occurred in the year following opening to home care were included as this study seeks to establish an annual incidence of AEs.

The electronic screen used three approaches. First, clients' MDS-HC assessment and discharge records were searched for items that may identify an adverse event.

Community-coordinated clients are supposed to be assessed upon opening to the Home Care program and assessed at least annually thereafter. Only clients with at least one assessment were included in the sample, and it was expected that some clients would have multiple assessments. MDS-HC items were selected based on the adverse event types included in the study. Items are generally time framed to a specific period prior to assessment (i.e. number of falls in 90 days prior to assessment (item K5), or medications administered in the 7 days prior to assessment). Table 4-1 lists the search parameters for this screening method.

Table 4-1 Electronic Screening Criteria for MDS-HC and Discharge Assessment

Screening For	Screening Criteria (with MDS-HC item)
MDS-HC Assessments	
Falls	<ul style="list-style-type: none"> One or more falls in 90 days prior to assessment (K5 ≥ 1)
Other injuries	<ul style="list-style-type: none"> Presence of any of the following: Hip fracture (J1n=1 or 2); other fractures (J1o=1 or 2); unexplained injuries (K9c=1); or second or third degree burns (N3a=1)
Abuse	<ul style="list-style-type: none"> Potential physical, emotional or financial abuse (K9d=1)
Pressure ulcer	<ul style="list-style-type: none"> Stage 1 - 4 pressure ulcer present (N2a = 1-4)
Other skin problems	<ul style="list-style-type: none"> Troubling skin conditions, such as burns, bruises, rashes, itchiness, body lice, or scabies (N1 = 1) OR second or third degree burns (N3a = 1)
Urinary Tract Infection AND indwelling catheter	<ul style="list-style-type: none"> Urinary Tract Infection (J1w = 1 or 2) AND use of indwelling catheter (I2b = 1)
Hospitalization	<ul style="list-style-type: none"> Visited ER, accessed emergent care, or had an overnight stay in 180 days prior to assessment (P4a, P4b, P4c ≥ 1)
Discharge Records	
Hospitalized	<ul style="list-style-type: none"> Client hospitalized for extended period, closed to home care (MDS discharge reason = 8)
PCH (Nursing Home) Placement	<ul style="list-style-type: none"> Client placed in PCH, closed to home care (MDS discharge reason = 5 or 7)
Deceased	<ul style="list-style-type: none"> Client deceased, closed to home care (MDS discharge reason = 6)

The second method searched the continuation notes for key words or phrases that could indicate the presence of a *potential* adverse event. The key word list was created based on past studies⁸⁷ and feedback obtained from staff during the coordinator consultation session. Words were selected that coordinators felt might be documented in clients' electronic files. Common synonyms for key words were also identified. When searching

⁸⁷ Murff et al. "Electronically Screening Discharge Summaries"; and Forster, Andrade, and van Walraven.

for key words, the search was case insensitive and looked for any words or phrases that contained the key word to ensure singular and plural forms of words were included (i.e. notes will be searched for “fall” which could yield matches such as “falls” and “fallen”).

Table 4-2 lists the search parameters for this electronic screening method.

Table 4-2 Electronic Screening Criteria for Key Word Search

Key Words	Example / Description
Fall, fell	“Client had a fall last night and broke her hip.”
Slip	“Client slipped out of wheelchair and couldn’t get up”
Distress	“Client is distressed by decline in social activities, referral to Adult Day Program completed.”
Abuse, abusing	“Client has broken pelvis, possible spousal abuse”
Nosocomial	Hospital-acquired infection
Adverse	Could indicate adverse event, adverse reaction or adverse effect
Ulcer, sore	“Client now has two pressure ulcers” or “client developed bed sore in hospital”
Occurrence, incident	May indicate the an occurrence report or a harmful incident.
Rhabdo	The breaking down of muscle fibers, which can have severe or sometimes fatal outcomes. One could develop rhabdomyolysis, sometimes referred to as rhabdo, after a prolonged period of lying on the floor, possibly after a fall.
Accident	“Client had an accident last night while getting into bed.”
Death, deceased, die	“Daughter phoned to inform that client died last night”
Injur	Could indicate “injury” or “injured”
Fracture	“Client fractured her ankle last week”
Error	“Nurse made an error while administering medication”
Overdose, double dose	May indicate medication administration error that could result in adverse reaction
Reaction	“Client had a reaction after medication changed last week”
Infection	“Client developed a infection...”
Admitted	“Client was admitted to hospital with a fever”
Victoria, VGH Health Science, HSC Seven Oaks, SOGH Grace, GGH St. Boniface, SBGH Concordia, CGH ER Hospital	Only the “hospital track” notepad, which is used to track clients’ hospital use, will be searched for these terms. Any matches would indicate a visit or admission to any of Winnipeg’s tertiary or community hospitals.

The third electronic method searched for potentially inappropriate medications. Searching for ADEs was a major challenge for this population as medication-related issues are generally reported to physicians, not to home care, or the adverse reactions are discovered in hospital. Moreover, assessments are completed infrequently, so symptoms of ADEs may not be captured by the assessment. Consequently, it was decided to use established expert criteria to identify clients who take potentially inappropriate medication. This method only applied to clients aged 65 years and older; this age cohort was expected to account for the vast majority of the sample. This approach has been used by several studies, noted in chapter two, to investigate potentially inappropriate medication use or prescribing; no articles were found that used the expert criteria as a screening technique to trigger a more thorough review as it was used in this study.

One study reviewed in chapter two used portions of multiple expert criteria to identify potentially inappropriate medication use among European home care clients; medication data was collected using the MDS-HC assessment tool.⁸⁸ This study searched for medications using the same search criteria as the European study, which used portions of both the Canadian Criteria and two versions of the Beers Criteria, all of which were described in chapter two. Clients' MDS-HC records were searched for all medications considered potentially inappropriate. The search was also expanded to include a medication notepad used for those clients whose medications change frequently. While the names of medications, dosage, route, and frequency are noted in WRHA Home Care client files, Drug Identification Numbers, or DINs, are not consistently recorded.

⁸⁸ Fialová et al.

Consequently, the medication search was limited to searching for the names of medications, which could exclude some clients due to incorrect spelling; where possible, clients' files were searched for portions of the potentially inappropriate medications identified by the expert criteria; all matches were scanned by the investigator to exclude any false matches. The medication search cross-referenced the MICROMEDEX database for all Canadian and American listings for noted medications.⁸⁹

The final search technique cross-referenced WRHA occurrence reports with clients in the sample. As occurrences are not saved electronically with client-identifying information, this search could not be performed electronically. An Administrative Assistant in the WRHA Quality and Decision Support Department was supplied with a list of all clients in the sample and manually searched through all occurrences reported between February, 2004 and March, 2005 for any matches. If any matches were found, all relevant information was noted and the complete list returned to the investigator. Occurrences not related to adverse events (i.e. theft or property damage) were excluded. A copy of a WRHA Occurrence Report Form is included in the appendix.

An anonymized database was created using a random study code to identify clients. The code list, which matches study codes with client names and personal health identification numbers, was printed and maintained in hard copy only —no client-identifying information was saved electronically. All printed material was kept locked in a drawer in a WRHA office. The database included study codes and the results of all screens. All

⁸⁹ Micromedex® Healthcare Series, Thomson Micromedex, Greenwood Village, Colorado (Edition expires 2005).

clients identified as possibly having had an adverse event were printed individually with their screen results. A sample "screen sheet" is included in the appendix. All screen sheets were reviewed by the investigator who determined if any could be excluded; it was anticipated that some screens would be excluded. For example, a client is screened in because there is a match for the key word "fall," but the note uses the word to describe the season, like "will call client in the fall" rather than to describe the action. Other events may be excluded because they happened prior to opening to home care or beyond the one-year time frame. Only screens that clearly were not an AE were excluded.

Stage III - Reviewing

All clients who screened positive were subsequently reviewed by a trained chart reviewer. There were four chart reviewers, three WRHA Home Care Specialists and one Team Manager, who have each worked in Home Care for at least fifteen years. The reviewers are all exceedingly familiar with Home Care policies and guidelines and best practices in caring for clients, and highly experienced in interacting with other parts of the health care system. The reviewers volunteered their time after regular work hours to assist with the study. Three of the reviewers are social workers and one is a nurse. Most of the major hospital studies used physicians as chart reviewers; it was decided for this study that social workers and nurses are most appropriate as they are the professionals who coordinate care for Home Care clients in Winnipeg. All chart reviewers attended a half-day training session to ensure they were familiar with the concepts used in this study, the screening process, and how to complete a chart review. The chart reviewers received a definition and instruction sheet, an inappropriate medications list, and a list of

study codes matched with client information to enable the reviewers to look up the client and review the file. A few clients from the sample were reviewed by the group during training to ensure everyone was comfortable with chart reviewing. Chart reviewers were instructed to keep all study-related information locked in a drawer in their office to ensure confidentiality.

Initially, it was planned that all clients who screened positive would receive two independent reviews, with a third conducted if there was irreconcilable disagreement between the original two reviewers. However, due to limited chart review resources, the methods were amended to include only one chart review for each client who was screened in. To report on inter-rater reliability—this is a common criticism of this approach—at least fifteen percent of the sample was to be randomly selected and independently reviewed by two chart reviewers. If chart reviewers agreed less than 75% of the time or if the Kappa statistic,⁹⁰ used to rate inter-rater reliability, was less than 0.41 (fair to poor), chart reviewers would receive additional training. The remainder of the sample were distributed among the four chart reviewers and received only one review. The methods amendment, from a full double review to the modified single review process, was reported to the University of Manitoba Joint Faculty Research Ethics Board and received ethics approval.

Chart reviewers determined if an adverse event had occurred, based on the definition developed in chapter three. If an AE occurred, chart reviewers indicated the date of the

⁹⁰ Jacob Cohen. "A coefficient of agreement for nominal scales." *Educational and Psychological Measurement* 20 (1960): 37–46.

AE, the type of AE, level of harm or impact to the client, the cause or domain, and if the AE could have been prevented or ameliorated. Finally, reviewers reported on the adequacy of the record. The chart review form, a copy of which is included in the appendix, was developed using existing scales where possible with modifications as needed. The form was designed to collect the required data to measure and describe adverse events among home care clients and incorporates a variety of existing measurement methods. The scale for rating if an adverse event occurred was borrowed from the Canadian Adverse Events Study⁹¹ (see table 2-1), and modified slightly for this study. The wording was slightly altered to better fit the home care context (i.e. from “management causation” to “caused by care”) and an additional score was added to the scale to make it a seven-point AE rating scale (“0 - No event occurred” was added). For a discussion on the development of the types of adverse events, levels of harm or impact, and cause (or domain), see chapter three.

While all of the major hospital studies only measured preventability, it was anticipated that some events may not be viewed as preventable, but rather seen as potentially ameliorable. This means the event could not have been prevented but the harm or impact could have been lessened. Rating an event as preventable or ameliorable was used by Forster et al. in their study of adverse events occurring after discharge from hospital.⁹² The rating scale for preventability was borrowed from the Canadian Adverse Event Study and was used to rate both preventability and ameliorability in this study.

⁹¹ Baker, “Canadian Adverse Event Study.”

⁹² Forster et al., “Adverse events among medical patients”; Forster et al., “Incidence and Severity of Adverse Events.”

The adequacy of records was also noted as the level of documentation in the home care electronic file was a concern, especially for AEs not caused by home care. The rating scale for record adequacy was borrowed from the modular review form.⁹³ Chart reviewers also recorded the start and end time of the review to allow for a cost estimate of the chart review process, had the chart reviewers not been volunteers.

Stage IV - Analysis

For the sample, descriptive statistics were provided to allow comparison to the general Home Care population. This includes demographic information (i.e. gender, age, geographic distribution) as well as functional information, such as cognition, depression and physical functioning, among others. This data is included in clients' MDS-HC assessments. Completed chart reviews were data entered twice into a computer database to assure accuracy; any discrepancies were verified and corrected as needed. The first fifteen percent of the sample that was reviewed independently by two reviewers was analyzed first. If agreement between reviewers was not sufficient, chart reviewers would receive additional training. Reporting inter-rater reliability is one method of analyzing the overall reliability of the study.

After the remaining chart reviews are completed and entered into the database twice, the full analysis could proceed. The incidence of adverse events among the sample was first

⁹³ M. Woloshynowych, G. Neale and C. Vincent. "Case record review of adverse events: a new approach." *Quality and Safety in Health Care* 12, no. 6 (2003): 411-415. See specifically web-only appendix "Modular Review Form 2 for Retrospective Case Record Review."

determined. For the AEs that did occur, the type, level of harm, cause, and the preventability or ameliorability was calculated. If AEs were rated as preventable or ameliorable, the reviewer described how the event could have been prevented or ameliorated. The results from this open-ended question were also analyzed and reported.

Addressing Chart Review Weaknesses

Several weaknesses of the chart review method were discussed earlier, namely incomplete documentation and loss of context, inter-rater reliability, inefficient screening, and reviewer bias. The methods developed for this study attempt to address all of these common sources of criticism.

Incomplete documentation is a concern, as the home care file does not include a comprehensive account of all interactions with all parts of the health care system—it is a Home Care file, not a central electronic health record. Incomplete documentation is, perhaps, the most challenging of the weaknesses to address as gaining access to and linking client files with databases external to home care is difficult, especially when this data would have to be reviewed by an individual who would not otherwise have access. Rather than attempt to gain access to external health files, this study relies on information noted in clients' Home Care files. Generally, it was expected that any significant interactions with non-home care health services would be noted in the client's Home Care file as this will likely impact on Home Care services (i.e. if client is admitted to hospital for several days, home care services must be put on hold).

Ensuring inter-rater reliability is a challenge in any study using the chart review approach. In this investigation, reviewers all attended a half-day training session and completed a few chart reviews as a group to ensure consistency in the information and demonstrations provided to reviewers. The first charts independently reviewed by two reviewers represented a sub-sample of at least fifteen percent of the clients identified as requiring a review. Inter-rater reliability was assessed by measuring the percentage of cases on which reviewers agree and calculating the Kappa statistic to score the level of agreement between reviewers; if the scores on either of these two measures were unsatisfactory, reviewers would receive additional training.

Chart review studies are sometimes criticized for using an inefficient screening process. In most of the major hospital studies, the screening stage has been completed manually and often produces many false positive matches that are advanced to the chart review stage—screening can itself be inefficient if done manually or can make inefficient use of chart reviewers if there are numerous patients who are screened in inappropriately. This study attempted to develop a more efficient screening approach by developing an electronic screening process; rather than manually examining all 400 clients in the sample for the screening criteria, this was completed electronically. Occurrence reports were manually searched. It was difficult to predict how many clients would match the screening criteria and proceed to the chart review stage.

The last criticism of chart reviewing this study attempted to account for was reviewer bias. By using employees as chart reviewers, there was the potential that these reviewers,

as Home Care employees, would be biased towards not rating a questionable event as an AE. However, reviewers also had a professional and ethical responsibility to clients' interests. Moreover, the individuals recruited as reviewers for this study are known for their dedication to consistently considering the client's perspective and situation, both on an individual case level and at a program planning and policy development level. During their chart review training, the reviewers were instructed to consider the client's perspective when in doubt about judging if harm had occurred.⁹⁴

Ethical Considerations

The development of this methodology included several ethical considerations. Informed consent was not obtained from the study subjects because the study involves a retrospective review of secondary data (client home care file). Subjects were unaware that their health information was being reviewed for this study. No deception was employed as no direct or indirect contact with study subjects occurred. Furthermore, subjects were not placed at any risk. However, it was anticipated that during the chart review stage, reviewers may find cases in which the home care client is unnecessarily at risk at the time of the review due to substandard care, abuse or neglect. In these situations, the reviewer can contact the client's Case Coordinator and discuss the situation if deemed necessary, as it would be ethically and professional irresponsible not to address the situation.

⁹⁴ This approach of considering the situation from the client, or patient, perspective was adapted from an adverse event training package developed by the Institute for Healthcare Improvement. See "Global Trigger Tool Kit" ver 6. Boston: Institute for Healthcare Improvement, 2005. Retrieved 03-APR-2005 from <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/GlobalTriggerToolforMeasuringAEs.htm>

Clients' personal health information was accessed and reviewed for the purpose of this study. All individuals involved in the study (primary investigator and chart reviewers) work with the WRHA and have signed their PHIA (Personal Health Information Act) pledge. All of the personal health information reviewed is information the investigator and chart reviewers would normally have access to during their usual work duties (i.e. staff development activities). Several measures were taken to ensure the confidentiality and anonymity of the participants were maintained and that the research methods adhered with the Personal Health Information Act of Manitoba.⁹⁵ The sample was extracted and each client in the sample assigned a study code. The sample extract and electronic screening were completed on a single day to ensure that no client data has to be stored electronically; all of the screening criteria were programmed in advance to support the single day sample and screen. Once the screening was complete, all client identifiers were removed from the computer database. The age of the client at March 31, 2005 was calculated and stored electronically; the clients' date of birth was not retained as this was considered a client identifier. Similarly, clients' geographic locations in one of Winnipeg's twelve Community Areas were determined using the 2002 Postal Code Conversion Database; postal codes were not retained as this is considered a client identifier.⁹⁶ Client assessment data was retained to allow for description of the sample; this data does not contain any client-identifying information. A hard copy file was maintained matching clients' names and personal health identification numbers (PHINs)

⁹⁵ Manitoba Health. "The Personal Health Information Act: A Brief Summary for Health Researchers." Manitoba Health: date unknown. Retrieved 15-OCT-2004 from http://www.gov.mb.ca/health/legislation/Summary_Researchers.pdf

⁹⁶ For a description of Winnipeg's twelve community areas, see Manitoba Centre for Health Policy, "Winnipeg Area Definitions," February, 2001, available online at http://www.umanitoba.ca/centres/mchp/concept/dict/wpg_area/wpg_area.html

with the study code. Any information with client-identifying data (i.e. hard copy matching clients with study code) was stored in a locked drawer in a WRHA office. All client-identifying data was destroyed following the review stage.

The principal investigator (KJ) extracted the sample and completed the electronic screen of clients as he was the only WRHA employee capable of completing such a request (i.e. if a similar request came to Home Care to access any information from the MDS-HC database, the primary investigator would be tasked with completing the request).

5. RESULTS

The results of the study are presented in four sections. The first three sections describe the data collection methods and results, including describing the sample, the screening techniques and the results of the chart review. Figure 5-1 illustrates the data collection methods and notes the number of clients associated with each step or approach. The final section includes data to support evaluating the methods, including inter-rater reliability, record adequacy, and the cost of the chart review approach.

Sample

There were 663 clients opened in the MDS-HC software in February and March, 2005. Clients were excluded if they were closed to Home Care within 30 days of opening (N=58), did not receive a complete MDS-HC assessment (N=141), or were classified as palliative (N=6). From the remaining clients, a sample of 400 opened to community Home Care was selected using SPSS. Approximately three quarters of the sample (74.7%) were referred through community intake, with the remaining clients opened to Home Care while in hospital. Data was included to describe the sample and compare to the general community-coordinated Home Care population. The description for the population is based on an internal WRHA report that included all community-coordinated clients opened as of December 31, 2004.⁹⁷ Table 5-1 presents several demographic, functional and medication usage indicators for both the sample and the population.

⁹⁷ Johnson, Keir. "Home Care Report on Community Areas: RAI-HC Data, 2004." Winnipeg, Manitoba: Winnipeg Regional Health Authority, June, 2005

Figure 5-1 Data Collection and Review Methods with Client Counts

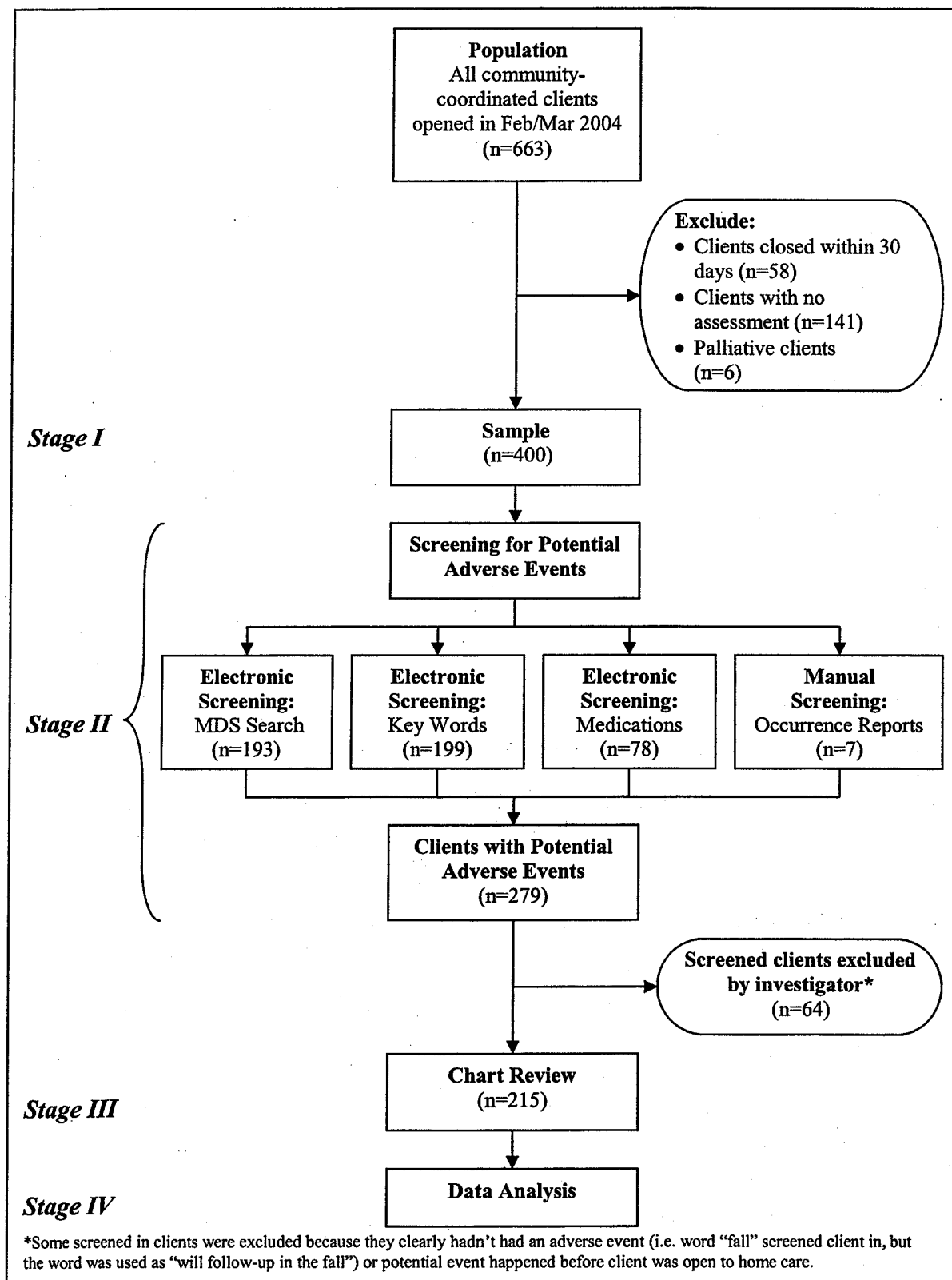


Table 5-1 Sample and Population Characteristics

	Study Sample (n=400)	Home Care Population* (n=10,991)
Age		
Mean (SD, range)	75.4 (12.8, 26-96)	77.5 (13.8, 15-104)
≥ 65 years	81.5%	87.8%
≥ 85 years	23.8%	33.5%
Gender		
Female	65.7%	70.9%
Geographic Distribution, by Community Area†		
St. James Assiniboia	10.0%	10.2%
Assiniboine South	4.8%	5.2%
Fort Garry	5.0%	5.5%
St. Vital	8.0%	7.6%
St. Boniface	5.5%	7.3%
Transcona	4.0%	2.7%
River East	16.0%	12.9%
Seven Oaks	12.0%	9.7%
Inkster	1.8%	2.2%
Point Douglas	3.0%	6.6%
Downtown	15.5%	15.0%
River Heights	10.3%	12.5%
Functional characteristics		(n=9026)
Cognitive Impairment (CPS ≥ 2)‡	26.5%	27.3%
Depression (DRS ≥ 2)‡	7.3%	8.6%
ADL Dependency (ADL Hierarchy ≥ 2)‡	17.0%	22.0%
IADL Dependency (IADL Involvement ≥ 2)‡	81.5%	87.7%
Medication usage		
Medications in prior 7 days§		
≥ 1 medication	91.8%	96.5%
≥ 6 medications	53.8%	61.0%
≥ 9 medications	26.0%	32.9%
Psychotropic drug use§	30.3%	34.6%

Notes: Sample and population characteristics are based on data collected using the MDS-HC assessment, unless otherwise noted.

*The description of the home care population is drawn from a report based on all community-coordinated clients opened as of December 31, 2004. For age, gender and geographic distribution, all clients were included (n=10,991). For functional and medication use characteristics, only clients with assessments less than one year old were included (n=9026).

†There are twelve Community Areas in Winnipeg which are identified using conventional Postal Codes. For the sample and the population, 4.6% and 2.6% of clients, respectively, had an invalid postal code so no community area could be assigned; these clients are included in all other measures. For maps of the twelve community areas, see Community Area Boundary Maps, available online at <http://www.wrha.mb.ca/howcare/decsup/files/population/CABoundaryMaps03.pdf>

‡Functional characteristics include: CPS (Cognitive Performance Scale), where a score of 2 or greater indicates some level of impairment; DRS (Depression Rating Scale), where a score of 3 or greater indicates potential depression; ADL Hierarchy, where a score of 2 or greater indicates assistance in any of eating, toilet use, locomotion, and eating; and IADL involvement, where a score of 2 or greater indicates that at least one of ordinary housework, meal preparation and/or phone use was performed by someone else. Various sources, see Keir Johnson, "Home Care Report on Community Areas: RAI-HC Data, 2004" Winnipeg, Manitoba: Winnipeg Regional Health Authority, June 2005.

§ Medications in last 7 days include both prescription and over-the-counter drugs; psychotropic drug use includes any of antipsychotics/neuroleptics, anxiolytics, antidepressants, hypnotics.

The age and gender distribution of the sample was similar to the Home Care population: the mean age was 75.4 years (range 26-96), compared to a mean age of 77.5 (range 15-104) for the population. Sixty-six percent of the sample was female, compared to 70.9% of the population. Similarly, the geographic distribution of the sample and the population among the twelve Winnipeg Community Areas was similar. With regards to health and functioning, the sample and population had similar levels of cognitive impairment, depression, ADL performance, and IADL performance. Both the sample and population reported similar patterns of medication usage.

It is important to note that while similar, the sample differed slightly from the population in all of these areas. The sample was slightly younger overall, exhibited slightly lower rates of impairment in all four functional domains, and used slightly fewer medications. These differences are most likely because the sample included clients just open to home care while the population profile is cross-sectional, including a very high proportion of clients who had been open to Home Care for several years; consequently, the population is slightly older and slightly more functionally declined than the younger sample. There is also a mild variation in the geographic distribution of clients, possibly due to demographic differences among the twelve Community Areas.⁹⁸

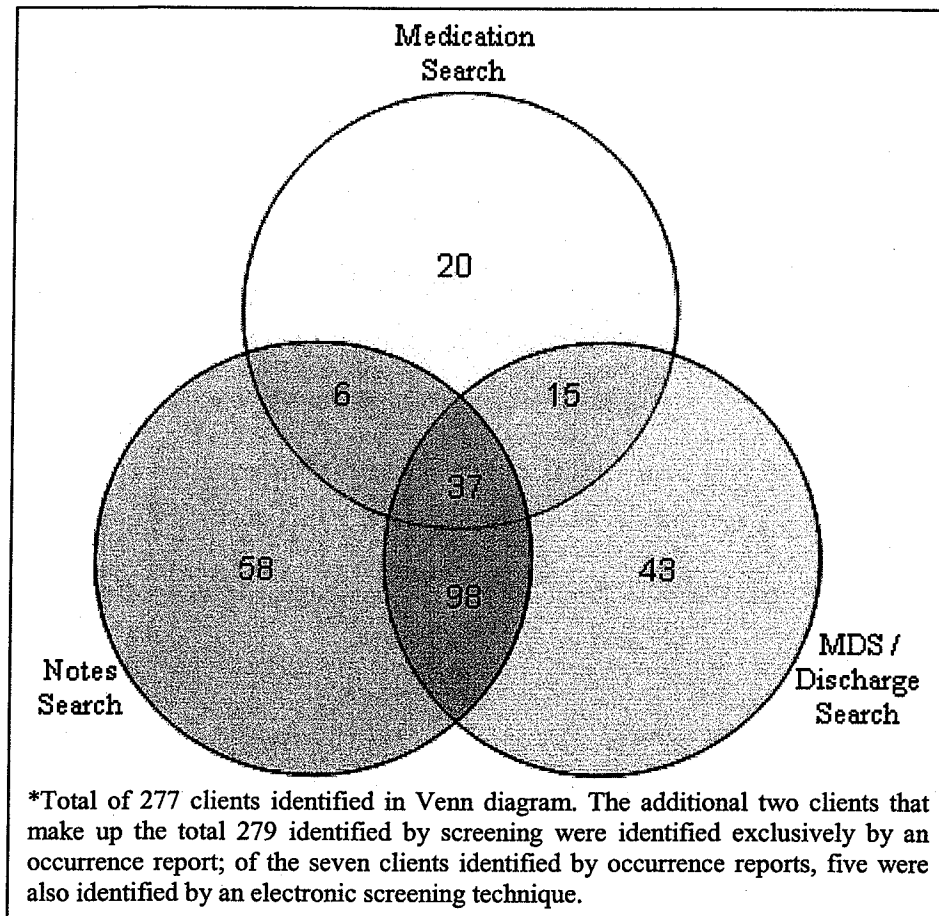
⁹⁸ As the age distributions and population sizes differ among Community Areas, it is likely that the incidence of new home care cases varies (i.e. younger Areas may have a lower than average incidence while Areas with an older mean age may have higher incidence). See Winnipeg Regional Health Authority, "Community Health Assessment Report, 2004," Winnipeg Regional Health Authority, Population Health and Health System Analysis, 2004. Retrieved 30-JAN-2005 from <http://www.wrha.mb.ca/howcare/cha/>

Screening

The entire sample was subject to a mixed screening process. There were four screening methods used to identify clients who may have had an AE: (1) searching clients' assessments, (2) searching for key words in notes, (3) searching for potentially inappropriate medications, and (4) cross-referencing WRHA occurrence reports. The first three methods were electronic and the last method was completed manually. These screening techniques are described in detail in chapter four.

In total, 279 clients (69.8% of sample) were identified by one or more of the four screening techniques. Several clients were identified by more than one technique. Figure 5-2 uses a Venn diagram to illustrate the three electronic screening techniques and the number of clients who were triggered using each—where circles overlap, the number of clients indicated screened positive using both approaches. For example, 15 clients were screened in by both the medication search and MDS-HC/discharge search criteria and 37 clients by all three electronic screening techniques. When clients were identified by multiple screening techniques, the various screens triggered could indicate the presence of one or more possible adverse events. For example, a client may be screened in because a note contained the word “fall” and an occurrence report was found that indicated the client had fallen; these two screen triggers likely point to the same possible event. Alternatively, two triggers may reveal two distinct possible events. In this situation, a client could have been identified because a note contained the word “ulcer” and the MDS-HC assessment indicated the client had a fall in the ninety days prior to assessment; these are two distinct possible events.

Figure 5-2 Matches for Electronic Screening Techniques



Of the 279 clients identified by the mixed screening process, 64 were excluded during a brief manual review of the screens. Generally, screens were excluded because the context of the key word was inappropriate or the potential event occurred prior to the file being opened to Home Care. An example of inappropriate context included searching for the key word “die” and finding the note mentioning “client’s husband died in hospital last night.” Several screens were excluded because they clearly occurred prior to Home Care involvement or beyond the one year timeframe (i.e. client had a fall before intake to Home Care). In some cases, a client was not excluded but one of the screening triggers was removed, most often for the reasons just mentioned. None of the occurrence report or

medication search matches were removed. Remaining were 215 screened in clients (53.8% of sample) who had possibly experienced an AE. Searching notes for key words identified the most clients, while only a handful of occurrence reports were found among the sample. Table 5-2 reports the number of clients who were screened in by each search technique, indicating the number of initial matches and the number excluded manually due to issues noted earlier.

Table 5-2 Search Types

Search Type	Number of Clients Screened In, before exclusion*	Number of clients excluded*
MDS-HC Assessment Search	193	38
Key Word Search	199	45
Medication Search	78	0
Occurrence Reports	7	0
Any Search Type	279	64
*A brief manual review of all screened in clients was conducted to exclude clients that were inappropriately selected. The search types will sum to more than the total as several clients were screened in by multiple search types.		

The comprehensive results for each screening technique, broken down by the various screening criteria, are included in the appendix. All clients who screened positive and were not excluded advanced to the chart review stage and were manually reviewed to determine if an AE did, in fact, occur.

Chart Review Findings

Of the 215 clients reviewed by chart reviewers, 22 clients were found to have suffered at least one AE. When compared to the original sample, this indicates a 5.5% annual incidence of adverse events. Twenty-six AEs were found among these 22 clients, with three clients having had two or three AEs. An AE was considered to have occurred when

the event was scored as four or greater on the AE rating scale; Table 5-3 includes the seven point scale and the number of clients scored for each rating.

Table 5-3 Distribution of AE Rating Scale for All Completed Reviews

AE Rating Scale Score	Frequency*	Percent*
0 No event occurred	79	36.1
1 Virtually no evidence event caused by care	101	46.1
2 Slight to modest evidence event caused by care	7	3.2
3 Not likely event caused by care (less than 50/50, but close call)	6	2.7
4 More likely event caused by care (more than 50/50, but close call)	14	6.4
5 Moderate to strong evidence event caused by care	7	3.2
6 Virtually certain evidence event caused by care	5	2.3
Total	219	100.0
*219 reviews were completed for 215 clients because three clients were found to have had multiple events; this accounts for the discrepancy.		

Most hospital studies, including the recent Canadian Adverse Events Study, use a score of four or greater as the cut off because it indicates the event was most likely caused by care (more than 50/50, moderate to strong evidence, or virtually certain evidence). The Quality in Australian Health Care Study, on the other hand, included all events rated as two or higher as this study focused more on quality improvement.⁹⁹ If the Australian scoring convention was used in this study, the number of clients who experienced an

⁹⁹ RM Wilson et al. "The Quality in Australian Health Care Study." *Medical Journal of Australia* 163, no. 9 (1995): 458-71.

adverse event would increase to 35 from 22, changing the incidence of adverse events over a one year period to 8.8% from 5.5%. However, the more commonly used cut off of four or greater was used for this study to more closely align with the major Canadian study.

The most common type of AE was, by far, injurious falls, accounting for nearly half (46.2%) of all events. ADEs was the next most common type (23.1%), followed by non-injurious falls (15.4%). Pressure ulcers, mental harm/injury and other make up the remaining 15.4%. Figure 5-3 illustrates the proportions of the various types of AEs. Most AEs (69.3%) resulted in temporary harm or injury to the client, with only one of the 26 events causing permanent harm. Otherwise unneeded hospitalization, premature PCH placement and other were identified as the level of harm for the remaining AEs. Figure 5-4 illustrates the levels of harm associated with the AEs.

Figure 5-3 Types of Adverse Events

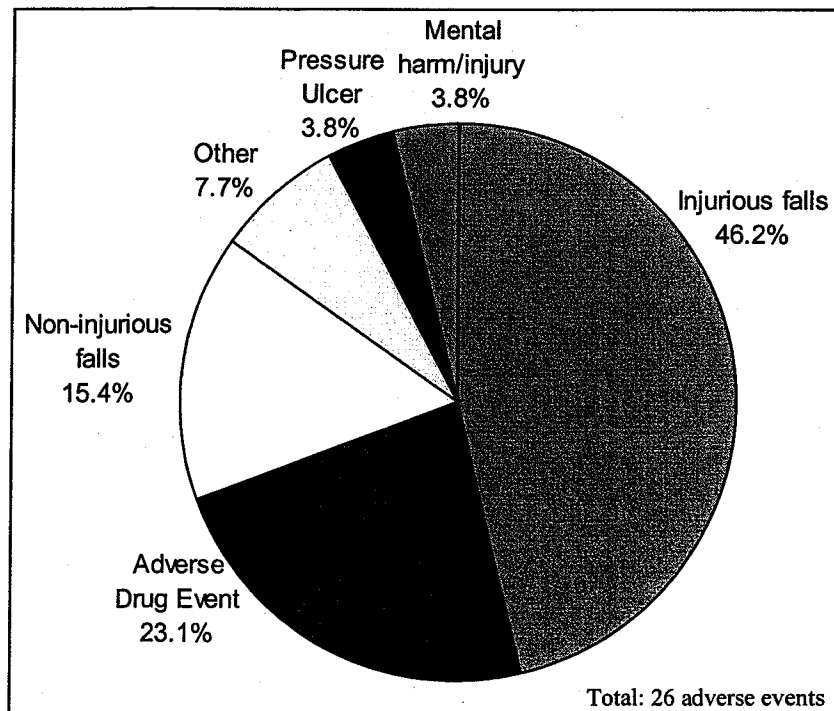
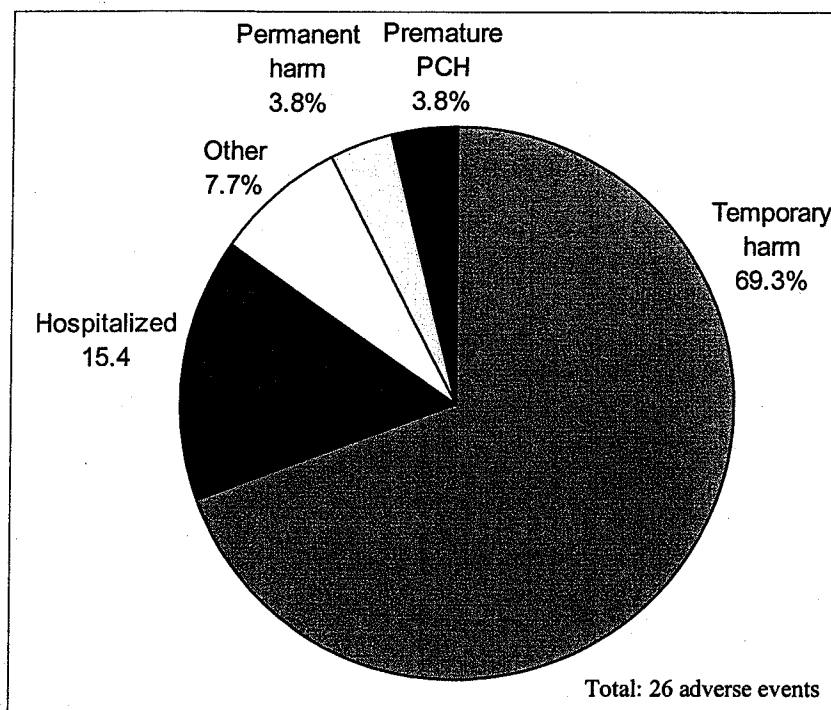


Figure 5-4 Levels of Harm of Adverse Events

Home Care was identified as the cause in half of all AEs; nearly all of the AEs caused by Home Care were due to coordination problems. Caregivers (family or friends) were identified by chart reviewers as the cause for 42.3% of the AEs, as were other health care providers. Other providers included both family physicians and hospitals. Finally, clients were identified as the cause for 30.8% of AEs. Reviewers could identify multiple causes; indeed, 46.2% of AEs were caused by multiple domains. The details of the cause of AEs are included in Table 5-4.

Table 5-4 Cause or Domain of Adverse Events

Cause/Domain of AE	Frequency	Percent
Home Care		
Direct Service Staff	1	3.8
Coordination Staff	12	46.2
Client	8	30.8
Caregiver	11	42.3
Other providers (non-home care)	11	42.3

Note: Sums to more than 100% as multiple cause could be indicated.

The final aspect of adverse events for which data was collected was preventability and ameliorability. Of the 26 AEs found, more than four in ten (42.6%) were rated as ameliorable, which means the harm or impact could have been reduced if a different approach had been taken. More than a quarter (26.9%) was rated as preventable. Among the 22 clients who experienced an AE, 45.5% had an AE that was ameliorable and 27.3% that was preventable. Table 5-5 lists the preventability and ameliorability of AEs. Similar to the rating scale used to identify AEs, the preventability and ameliorability rating scale used a score of four or greater to identify events that were preventable or ameliorable; the distribution of scores for this scale is reported in table 5-6.

Table 5-5 Preventability and Ameliorability of Adverse Events

Preventability/ Ameliorability of AE	For All AEs		For All Clients Who Experienced an AE	
	Frequency	Percent	Frequency	Percent
Preventable	7	26.9	6	27.3
Ameliorable	11	42.3	10	45.5
Neither	8	30.8	6	27.3
Total	26	100.0	22	100.0

Table 5-6 Distribution of Preventability/Ameliorability Rating Scale for All Adverse Events

Preventability/ Ameliorability Rating Scale	Preventability		Ameliorability	
	Frequency	Percent of All AEs	Frequency	Percent of All AEs
1 Virtually no evidence	0	0.0	1	3.8
2 Slight to modest evidence	1	3.8	1	3.8
3 Not likely (close call)	3	11.5	2	7.7
4 More likely (close call)	8	30.8	2	7.7
5 Strong evidence	2	7.7	4	15.4
6 Virtually certain evidence	1	3.8	1	3.8
Total	15	57.7	11	42.3

Note: Chart reviewers could rate either the preventability or the ameliorability of an AE, but not both.

Interestingly, chart reviewers judged in retrospect nearly all of the AEs caused by Home Care coordinators and direct service staff as amenable (71.4%) or preventable (23.1%); only one of the AEs caused by Home Care (7.1%) was judged as neither preventable nor amenable. This is quite different from ratings for other providers (physicians and hospitals); reviewers rated only 36.4% of events caused by other providers as amenable or preventable. Nearly all of AEs caused by Home Care were falls while ADEs accounted for just over half of the AEs caused by other providers. Table 5-7 provides a description of the types and preventability and amenability of AEs by cause.

Table 5-7 Description of AEs by Cause

	Home Care Providers		Non-Home Care Providers		
	DSS* (n=1)	Coordinators (n=13)	Other Providers (n=11)	Caregivers (n=11)	Clients (n=7)
Type of AE					
Fall – injurious	0.0	61.5	27.3	54.5	14.3
Fall – non-injurious	100.0	30.8	9.1	18.2	28.6
Pressure ulcer	0.0	0.0	9.1	0.0	0.0
ADE	0.0	0.0	54.6	9.1	28.6
Mental harm/injury	0.0	7.7	0.0	9.1	14.3
Other	0.0	0.0	0.0	9.1	14.3
Preventability and Ameliability					
Amenable	0.0	76.9	18.2	45.5	42.9
Preventable	100.0	15.4	18.2	36.4	0.0
Neither	0.0	7.7	63.6	18.2	57.1
Note: Some AEs were double counted as multiple providers were identified as the cause (i.e. a single AE caused by Home Care Coordinators and Caregivers was counted twice)					
* DSS = Direct Service Staff					

In cases where reviewers rated an AE as preventable or amenable, they were also required to explain how the AE could have been prevented or ameliorated. The full responses to this question, which have been edited for clarity, are included in the appendix. The explanations offered by reviewers are useful in understanding the unique

challenges home care faces compared to hospital care. While home care faces medical events, there are also social issues which can result in AEs; the explanations of how events could have been prevented or ameliorated reflect this element. Some of the comments relate to client choice and family care and the need for client and family education.

Most of the comments reflect “system” issues, such as practice and communication. The most common explanation for preventing or ameliorating an AE was by referring the client to Community Therapy Services for an occupational or physical therapy assessment due to a history of falls or high risk for falls; this should not be surprising given that falls, both injurious and non-injurious, accounted for the majority of AEs. Another comment reflected the reliance Home Care has on other providers, an issue identified in both the literature and consultation sessions. In this event, a client with a history of falls waited for a referral to psychogeriatrics from his or her family physician; while waiting, the AE in question occurred. Once the client was seen by psychogeriatrics, ambulation improved and there was no record of additional falls. By relying on a physician to complete the referral to an external psychogeriatrics centre, there was a delay and the AE in question occurred. These comments help to reinforce the findings from the consultation sessions and literature review about the home care environment.

Potentially Inappropriate Medications

Identifying ADEs was challenging for this study, as discussed in chapter four. To allow a more focused review of medications, client files of were searched for potentially

inappropriate medications;¹⁰⁰ only elderly clients were included in this screen (n=326 or 81.5% of sample). A total of 78 clients had taken potentially inappropriate medications—this is 23.9% of the seniors in the sample (95% CI 19.4% - 28.5%). The most common types of potentially inappropriate medications included short acting nifedipine, amitriptyline, long-term use of stimulant laxatives and selected muscle relaxants and antispasmodics. Table 5-8 lists all potentially inappropriate medication classifications used by Home Care clients that were identified during the screening stage.

While many of these medications were listed as high risk by the Beers expert panel, very few resulted in AEs when subject to a chart review. Only eight of the 78 clients who were taking potentially inappropriate medications had an AE; only two were identified by chart reviewers as an ADE. It is difficult to determine the effects these medications had on clients as assessments are completed infrequently and any adverse reactions were likely reported to physicians or hospitals rather than home care. It is likely that more than two clients taking potentially inappropriate medications experienced adverse reactions, though the extent is unknown and impossible to estimate with the information available.

Generalizing to the Home Care Population

Based on the sample size, it is possible to generalize the results to the WRHA Home Care population. The results are generalized to an annual population size of 14,624 clients, which includes all clients opened at the beginning of the 2004 calendar year to community Home Care, and the number of intake in the following twelve months.¹⁰¹

¹⁰⁰ This study used the same list of potentially inappropriate medications as Fialová et al.

¹⁰¹ This information was obtained from the monthly statistics collected by the Home Care program.

Table 5-8 Potentially Inappropriate Medication Use

Potentially Inappropriate Medication	Frequency[†]	Percentage of clients taking inappropriate medications (n=78)[†]
Short acting nifedipine (Adalat or Nifedipine)	18	23.1
Amitriptyline	12	15.4
Long-term use of stimulant laxatives*	10	12.8
Muscle relaxants & antispasmodics	8	10.3
Ferrous sulfate	6	7.7
Long acting benzodiazepines	5	6.4
Digoxin	3	3.8
Amiodarone	3	3.8
Doxepin	2	2.6
Anticholinergics and antihistamines	2	2.6
Ticlopidine	2	2.6
Niacin	2	2.6
Short acting benzodiazepines	1	1.3
Dipyridamole (extended-release)	1	1.3
Methyldopa	1	1.3
Meperidine	1	1.3
Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs	1	1.3
Orphenadrine	1	1.3
Nitrofurantoin	1	1.3
Doxazosin	1	1.3
Clonidine	1	1.3
Mineral Oil	1	1.3
Cimetidine	1	1.3
Any Potentially Inappropriate Medication	78	
*Long term use could not be established in screening		
†These columns will sum to more than total clients (n=78) and 100% because some clients had taken more than one potentially inappropriate medication.		

Unlike the sample, this number does not exclude clients opened for less than 30 days, or those who were identified as palliative, as this information was not available for the population.

As mentioned earlier, an annual AE incidence of 5.5% was found among the sample of

400 clients (95% CI 3.3% - 7.7%). Based on the 2004 population size noted above and using these upper and lower limits to generalize to this population, it is likely that between 478 and 1131 WRHA community-coordinated Home Care clients experience an AE annually. Four percent of the sample experienced an AE that was either preventable or ameliorable (95% CI 2.1% - 5.9%), which means between 304 and 866 clients experience a preventable or ameliorable AE annually.

Methods Evaluation

The data collection and analysis methods were evaluated using several analytical approaches. The first approach examined inter-rater reliability, which is a common criticism of the chart review approach. Several steps were taken to ensure a high level of consistency among reviewers' approaches; these were discussed in the methods chapter (chapter four). As mentioned earlier, originally all clients who screened positive were to receive two independent reviews, with a third review conducted if there were irreconcilable differences between the first two reviewers. Unfortunately, due to constraints on chart review resources, the methods were amended and only a small sub-sample of clients received two independent reviews. A sub-sample of 39 clients received two independent reviews; this accounts for 18.1% of the total number of clients screened and identified as requiring a review.

To determine inter-rater reliability, the relevant variables—rating if an AE occurred and rating preventability/ameliorability—were dichotomized, with scores of four or greater indicating the presence of an AE and the same cut off applying for preventability and

ameliorability. The percentage of agreement and Kappa statistic were used to determine inter-rater reliability. For rating if an AE had occurred, reviewers agreed 87.2% of the time; the Kappa statistic for judging this variable was 0.65, which is described as substantial.¹⁰² To describe inter-rater agreement on rating an event as preventable or ameliorable, only those units in the sub-sample identified as having had an AE were included. For this small number of clients (n=7), reviewers agreed on all cases, which translates to a Kappa score of 1.00, or perfect agreement.

Another concern about the chart review technique, especially in the home care environment, was the adequacy of the client records. For all cases reviewed, the adequacy of the file for the purpose of chart reviewing was rated from (1) record adequate to (4) severe deficiencies. Nearly all records (96.8%) were deemed adequate or having only slight deficiencies. For records not seen as adequate, reviewers were instructed to describe the deficiencies in the record. Some related to missing information—“[w]ere referrals made to CTS (Community Therapy Services)? No notes of such in file”—while most were rated as inadequate due to poor documentation. Comments such as “very difficult to make sense of notes” and “difficult to ascertain what happened when - notes difficult to read” appeared several times. The distribution of adequacy rating scores is listed in table 5-9.

¹⁰² Kappa scores are described as 0.21-0.40, “fair”; 0.41-0.60, “moderate”; 0.61-0.80, “substantial”; and 0.81-1.00, “almost perfect.” See JR Landis and GG Koch. “The measurement of observer agreement for categorical data. *Biometrics* 33, no. 1 (1977): 159-174.

Table 5-9 Distribution of Record Adequacy Rating

	Frequency	Percent
1 - Client record adequate	181	84.2
2 - Some deficiencies	27	12.6
3 - Major deficiencies	6	2.8
4 - Severe deficiencies	1	0.5
Total	215	100.0

The cost of the actual chart reviews was also of interest. All four chart reviewers kindly volunteered their time to this study. While much of the work related to data collection was completed by the investigator, the reviewers used their expertise to investigate and determine if an AE had occurred. Reviewers noted the start and end time for each client reviewed. In total, reviewers completed 254 reviews. The mean time spent on a chart review was 7.6 minutes (range 1-34, std. dev 5.7). Clients rated as having experienced an AE took more than twice the time to review than those who did not have an AE ($p < 0.0001$). To determine the cost, the total time spent on chart reviews was summed (32.6 hours). An additional minute was added to each review to account for set-up time (4.3 hours). There was also three and a half hours of training for four trainers (14 hours). In total, reviewers volunteered 50.9 hours. At a rate of \$37.71 per hour,¹⁰³ the total cost for chart reviewing was \$1919.44. This cost does not include any equipment or supplies (reviewers used WRHA equipment, such as computers; supplies, such as copies of the chart review form, were provided by the investigator).

¹⁰³ This figure was provided by the chart reviewers as an acceptable representation of their hourly pay.

6. DISCUSSION AND CONCLUSION

While there have been several major adverse event studies around the world, they focus almost exclusively on hospital care, which is only one part of the health care system.

With aging populations in most Western nations, it is likely that the number of individuals using home care services will swell; Winnipeg is certainly no exception. This study examined the incidence of adverse events among Winnipeg Home Care clients.

This study had three broad goals. In the absence of any substantial studies focusing on home care, this study first sought to develop an appropriate definition for the term “adverse event” and describe its underlying concepts of cause and harm. Second, a data collection methodology was developed to facilitate measuring the incidence of AEs. Third, the methodology was tested with a sample of clients to describe the incidence, type, harm, cause and preventability or ameliorability of AEs among Home Care clients. A discussion of the study follows, organized around these three goals. A discussion of the methods, which encompasses both of the first two goals, is presented first, followed by a discussion of the results. The advantages, limitations and recommendations for future research end the chapter.

DISCUSSION: METHODS

The methodology for this study relied on two critical components: the development of an appropriate definition for “adverse event” and designing effective and efficient data collection methods with limited resources. While working towards an appropriate definition for the term “adverse event,” relevant literature was examined and qualitative research conducted to better understand the home care context and the types and causes of events that could occur in home care. In addition to developing a useful definition, this exercise helped to understand two important and unique aspects of home care. First, care delivery is fragmented as it is shared among several providers, including home care direct service staff, other health care providers, informal caregivers and clients themselves. The success of home care services relies on other health care providers and the care provided by informal caregivers and clients. Second, home care faces unique challenges as it handles not only medical problems, but also social issues—it is impacted by client and family choices and lifestyles which can, at times, create difficult social situations that can leave clients at risk and cause an AE. The definition for “adverse event” and its underlying concepts, found in chapter three, was rooted in these important considerations. This definition was tremendously helpful in understanding the home care context and, therefore, in designing a data collection methodology.

After considering a variety of methods and reviewing the resources available to this study, the chart review method was selected to measure the incidence of AEs among Home Care clients. This method has been used in several prominent studies, but has also been criticized for many reasons, namely inadequate documentation and a loss of context,

inefficient screening, poor inter-rater reliability and review bias. This study sought to address all of these potential weaknesses.

In a retrospective study, any review is limited by the information that is available; any missing data can result in a loss of context. This issue was compounded in Home Care by concerns about inadequate documentation. For each review, chart reviewers rated the adequacy of client files for making their judgements about whether an AE had occurred and determining its type, harm, cause and preventability or ameliorability. Nearly all (96.8%) records that received a review were rated as adequate or as having only slight deficiencies—there were very few cases that reviewers felt they had major or severe deficiencies. However, it is possible, indeed most likely, that additional AEs occurred and were not documented in clients' files, especially AEs caused by non-home care providers, informal caregivers and clients.

For all of the major chart review studies that were found, there were two key stages: screening and chart reviewing. The screening stage, which is intended to identify clients in the sample requiring a more thorough expert review, has been criticized for being inefficient (i.e. a high number of false positives are advanced forward for a chart review). The major hospital studies relied on a manual screening process; electronic screening, however, has emerged as a potentially more efficient approach. This study sought to use electronic screening to identify clients requiring a full chart review to make the screening process as efficient as possible. However, after an extensive literature search and consultation sessions with Home Care staff, a great deal was still unknown about AEs in

home care. As this study was the first to conduct a comprehensive investigation of AEs in home care, it was exploratory and descriptive in design. Accordingly, while the study attempted to make the screening process as efficient as possible by using a mixed screening technique, it also sought to be as cautious and sensitive as possible to avoid excluding clients who had an AE. Consequently, the use of reviewers time may not be viewed as efficient as the number of clients who required a chart review ($n=215$) accounted for more than half of the sample ($n=400$). Only 22 of the 215 clients reviewed had an AE; 193 clients, or 89.8% of the clients distributed among reviewers, did not have an AE. The screening process itself was moderately efficient; the electronic screening took little time while the manual search for occurrence reports and manual review of screens to exclude any that clearly did not have an AE was time consuming.

The last two concerns—inter-rater reliability and reviewer bias—relate specifically to chart reviewing. Reviewer bias is a concern in any observational or review study. The reviewers used in this study were recruited because they are known to consistently consider the client's perspective, an important characteristic in determining if an AE had occurred.

As the chart review approach relies on reviewers' ratings, a major concern is how two reviewers would independently rate an event. As this study was not able to conduct two independent reviews for all clients, a sub-sample of 39 clients received two reviews to enable reporting of inter-rater reliability. Reviewers agreed 87.2% of the time; the Kappa statistic, used to rate inter-rater agreement, was 0.65, which is described as substantial.

The Kappa score for this study was comparable to, and in many cases higher than, several major chart review studies.

DISCUSSION: RESULTS

This study found the annual incidence of AEs among Winnipeg Home Care clients to be 5.5% (95% CI 3.3% - 7.7%). Of these clients, 45.5% had an AE that was amenable and 27.3% that was preventable. This AE rate is lower than the incidence found in Canadian hospitals (7.5%) but higher than American hospital studies (2.9% to 3.7%).¹⁰⁴ It is considerably lower, however, than rates found among hospital patients following discharge (19% - 23.2%).¹⁰⁵ The preventability and amenability ratings for this study, 26.9% and 42.3% respectively, are higher, but comparable to non-home care studies. Moreover, they are acceptable at face value. The Canadian and American hospital studies, which only rated preventability, found that between 42% and 58% of AEs were preventable. The two post discharge studies found that 30.5% and 27.6% of AEs were preventable, and 31.6% and 22.4% amenable.

It is suspected that the incidence of AEs reported in this study may underestimate the real frequency due to a comparably lower incidence of adverse drug events (ADEs) and possible unreported information about AEs caused by other providers. For the two post discharge studies, ADEs were the most common type of AE. In this study, falls were by

¹⁰⁴ Baker et al., "Canadian Adverse Events Study"; Thomas et al. "Incidence and types of adverse events"; Brennan et al.

¹⁰⁵ Forster et al., "Adverse events among medical patients"; Forster et al., "Incidence and Severity of Adverse Events."

far the most common type of event; falls, both injurious and non-injurious, account for nearly two thirds of the AEs while adverse drug events for 23.1% of AEs. Overall, only 1.0% of clients in the sample experienced an ADE. This is significantly lower than the 20.1% incidence of ADEs found among home care clients post hospital discharge.¹⁰⁶

While the populations examined probably differ significantly—it is likely that more patients receive medication changes while in hospital which could result in ADEs post-discharge—the ADE rates are vastly different which raises the concern that this study was not able to capture many of the ADEs that may have occurred. This limitation was anticipated in the design stage because it was thought that ADEs were likely reported to physicians or hospitals rather than Home Care and, therefore, may not be noted in the Home Care file. Furthermore, as MDS-HC assessments are completed infrequently, it was anticipated that signs and symptoms of ADEs may be missed.

While this study found that other providers, more specifically physicians and hospitals, were involved in 42.3% of AEs among Home Care clients, it is suspected that these providers caused additional events that were not noted in the Home Care file. For example, consider a client who experienced an AE while in hospital. It is possible this AE was not recognized as such by the hospital; this perception would likely not be questioned by Home Care and the AE would, therefore, not be detectable by reviewing the client's Home Care file. Even if the hospital recognized this event as an AE, it is still possible that this information would not be shared with and/or documented by Home Care. As it is likely that Home Care clients may experience ADEs or AEs caused by

¹⁰⁶ Gray, Mahoney, and Blough.

other providers which are not documented in the home care file, it is believed that this study has underreported the annual incidence of AEs among Home Care clients.

An interesting finding in this study related to the cause of AEs. While Home Care was noted to be the cause in half of the 26 AEs uncovered, other providers, informal caregivers, and clients were identified as the cause in 42.3%, 42.3% and 30.8% of AEs, respectively. This confirms findings from the literature review and consultation sessions, which noted that care provision in Home Care is somewhat fragmented, relying not only on Home Care employees, but other health care providers, informal caregivers and clients. One of the studies reviewed in chapter two examined operational failures, or errors, in home care.¹⁰⁷ It found that patients (or clients) and family were responsible for 52% of errors, home care for 39%, and the broader health care system for 9%. While this study examined errors rather than AEs, the results nevertheless demonstrate that errors can be caused by non-home care contributors.

Improving “Client Safety”

The results of this study are important at both the care delivery and coordination level and the program planning and policy-making level; understanding these findings could help to improve “client safety” by reducing the incidence of AEs. Generally, preventable and ameliorable AEs are likely the easiest to tackle as existing care processes probably exist that could prevent or ameliorate these AEs. The following discussion includes four broad issues that could lead to improved client safety—the word “issues” is used here

¹⁰⁷ Bruno and Ahrens.

rather than “recommendations” as further research and discussion are encouraged before taking action.

The first issue relates to the fragmentation of care provision and the reliance on other providers. Several AEs were caused by physicians and hospitals, informal caregivers, and clients themselves. Physicians and hospitals were noted to be the cause in 42.3% of AEs, although most (63.6%) were rated as neither preventable nor ameliorable. For those that were rated as preventable or ameliorable, stronger communication and collaboration between Home Care and other providers may have helped.¹⁰⁸ Informal caregivers and clients were also identified as the cause in many preventable and ameliorable AEs. In nearly all of these situations, the reviewers noted that additional client and family education could have prevented or ameliorated the AEs. Strengthening communication and collaboration between Home Care and other providers and improving client and family education could help to reduce the incidence of AEs.

The second issue relates to those AEs caused by Home Care. All but one of the AEs caused by Home Care were caused by coordination problems, not by direct service staff. Nearly all of the AEs caused by coordinators were falls and were judged as preventable or ameliorable. It would seem that a falls prevention program, including education for coordinators, could result in a reduction of AEs.

¹⁰⁸ One event was rated as ameliorable because the client had a fall while waiting for psychogeriatrics; the delay was caused by waiting for the client's physician to complete the referral form. More communication and follow-up could have prevented the delay. Another event was rated as preventable because the reviewer felt the client was discharged too early from hospital. If the hospital had delayed discharge until the client was better able to manage, the client would have been safer at home the AE could have been prevented.

The use of occupational or physical therapy (OT and PT) services is another issue. The most common method suggested by reviewers for preventing or ameliorating falls was an OT or PT assessment through Community Therapy Services (CTS).¹⁰⁹ The use of OT and PT services, or more appropriately the under use of these services, may be a broader problem in WRHA Home Care. A 2002 report on WRHA Home Care MDS-HC data raised a similar concern about usage of these services.¹¹⁰ One of the Home Care Quality Indicators (HCQIs), which is calculated using MDS-HC assessment data, identifies the prevalence of clients with ADL/rehabilitation potential but no therapies.¹¹¹ The rate for this HCQI identifies clients who may have ADL/rehabilitation potential but did not receive OT, PT or exercise therapy in the seven days prior to assessment. The 2002 report found a prevalence of 86.3% for this HCQI among WRHA Home Care clients, compared to 72.5% in Ontario.¹¹² Among clients who may have ADL/rehabilitation potential, the report found that significantly more clients in Ontario receive OT (11.8% vs. 3.7% in WRHA) and about double the clients receive PT (16.4% vs. 8.1% in WRHA).¹¹³ A recent internal WRHA report updated this information and found the 2004 prevalence for this HCQI to be 84.4%.¹¹⁴ OT and PT services may be underutilized in the WRHA, as

¹⁰⁹ CTS is contracted by WRHA Home Care to provide occupational and physical therapy services.

¹¹⁰ Hirdes, Poss and Dalby.

¹¹¹ This HCQI includes all clients who trigger the ADL/rehabilitation potential Client Assessment Protocol (CAP)—similar to a clinical practice guideline, CAPs are intended to help assessors make decisions about care planning—which identifies clients who may have the potential for either improving ADL functioning or lessening an anticipated decline in ADL functioning. See Hirdes et al., “interRAI Home Care Quality Indicators (HCQIs) for MDS-HC, Version 2.0.” interRAI, 2001. Retrieved 13-FEB-2005 from http://interrai.org/applications/hcqi_table_final.pdf

¹¹² Hirdes, Poss and Dalby, 46-47.

¹¹³ Ibid.

¹¹⁴ Johnson.

evidenced by both the MDS-HC analysis and the comments from chart reviewers in this study; more effective use of these services may have the biggest impact on client safety.

The final issue concerns the practice of occurrence reporting in Home Care. Only seven occurrence reports were found for the sample examined in this study; this represents less than two percent of the sample. There were only three AEs found for clients who had an occurrence report and all three were falls. This study, however, found 16 falls that were judged as AEs, which means less than one in five falls judged to be an AE had an occurrence report. One participant in the consultation sessions thought occurrences were underreported; these findings seem to support that assertion. The problem of underreporting in Home Care is most likely related to the way care is provided. Care provision is fragmented, shared between home care, other health care providers, informal caregivers and clients. Occurrences are probably not collected for AEs where informal caregivers and clients are the cause. For occurrences that are caused by other health care providers, they are likely reported to their home departments or programs and not connected to Home Care. As occurrence reporting is an important measure of quality, it may be useful to review current occurrence reporting practices to determine if modifications are needed to capture missing events. Also, continuous prompting for occurrence reporting may improve the possible underreporting problem.¹¹⁵

¹¹⁵ For a discussion on continuous prompting techniques, see Murff, Harvey J., et al. "Detecting adverse events for patient safety research."

ADVANTAGES, LIMITATIONS AND RECOMMENDATIONS FOR FURTHER RESEARCH

As this was the first study to examine all types of AEs in home care, it provides a starting point for understanding the client safety situation. Overall, the methods used in this study were successful. The study was able to sample, screen, review and analyze a sample of 400 Home Care clients to determine the incidence, type, harm, cause and preventability and ameliorability of AEs, and did so with no funding and limited resources. It was also able to address several potential weaknesses, namely inter-rater reliability. The methods used for this study, both to develop the definition of adverse event and for measuring AEs among clients, could prove useful not only for other Home Care programs, but also for other parts of the health care system, such as mental health, public health, and long-term care, that have not been the focus of patient safety research

The results of this study offer important information about one critical aspect of home care quality—client safety. As such, this study has direct implications for Home Care quality improvement. The findings could help to improve client safety if the incidence of AEs among Home Care clients can be reduced.

However, the study has several limitations. The screening process, while effective, was not highly efficient and required extensive use of chart reviewers' volunteered time. The chart reviewers were limited by the information available to them; loss of information and context can result in an inability to judge an AE. While nearly all records were rated as adequate or having only slight deficiencies, it is certainly possible that additional AEs occurred but were not documented in the Home Care file. Moreover, the fragmented

nature of care delivery in home care leaves a gap in information about AEs caused by other providers. The results of the study reflect the incidence of AEs among Winnipeg Home Care clients; the transferability of the findings to other jurisdictions, both inside and outside of Manitoba, are unknown as populations, services and practice differ significantly.

Perhaps the biggest limitation of this study is the probable underestimation of ADEs. Due to limited client information and resources, it was anticipated that identifying ADEs based on Home Care data would be extremely challenging. Therefore, the study searched for potentially inappropriate medications among only the seniors in the sample; this excludes 18.5% of the sample under 65 years. This approach found a very low frequency of ADEs, and it is suspected that the incidence, in fact, is much higher.

Additional research can help to address some of these limitations. Developing a more efficient screening technique to minimize the number of false positives that advance to the chart review stage could allow for a less resource-intensive study. Additional research should develop a more comprehensive approach to identify ADEs—perhaps linking Home Care data with other health care databases, such as hospital abstracts and physician billing information, could address this issue.¹¹⁶ The findings are limited to Winnipeg Home Care clients; research should be pursued in jurisdictions outside of Winnipeg. This

¹¹⁶ The Manitoba Centre for Health Policy has developed a world class population health research system by linking administrative health care databases across the continuum of care. This could be an appropriate organization to conduct further research. See <http://www.umanitoba.ca/centres/mchp/> For example, one could compare hospital use and death between those taking potentially inappropriate medications and those who are not.

will allow for a broader understanding of client safety in home care, and allow for comparison among regions. Finally, the WRHA should, internally, further investigate the findings of this study to better understand the causes and methods of preventing or ameliorating AEs and work to improve client safety by reducing the incidence of adverse events among Winnipeg Home Care clients.

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APPENDICES

Appendix A – Methods and Research Instruments

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Consultation Session Participant Consent Form

Informed Consent Form

Research Project Title: Adverse Events Among Winnipeg Home Care Clients

Researcher: Keir Johnson, MPA Student

This consent form, a copy of which will be left with you for your records and reference, is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, you should feel free to ask. Please take the time to read this carefully and to understand any accompanying information.

Project Description

The topic of patient safety has recently received considerable attention, with prominent studies in Canada, the United States and other countries examining this critical health care issue. Most studies, however, focus exclusively on hospitals, with few investigating the safety of other health care services, such as home care. The integrating theme for this study is that no part of the health care system, including home care, is free of adverse events (AEs). This thesis seeks to tailor hospital-centric patient safety terms to the home care context, develop a home care AE measurement methodology, and test this methodology with a sample of home care clients from the Winnipeg Health Region.

Description of your participation

You will participate in one of two consultation sessions with Home Care employees. The first session includes Case Coordinators and the second includes program Specialists, Manager(s), Director(s) and Quality Improvement Manager. The one time consultation session will last approximately two hours. Participants will discuss adverse events in the home care context and ultimately attempt to establish home care-specific patient safety definitions. No recording devices will be used, however notes will be taken. Your comments may be edited for clarity. All participants will have a chance to review the results from the consultation session to ensure that the information is accurate.

Anonymity and Confidentiality

The names of participants will not be included in the final study, however the titles of participants will be included. For Case Coordinators, your participation can be kept anonymous as there are one hundred individuals who share the same title. For participants in the second group, anonymity may not be maintained as there are few, or sometimes only one, individual with a specific title (i.e. Home Care Director). **Please beware that you could potentially be identified as your job title will be included in the final study.** You will be contacted via email inviting you to review the information to be included in the final study prior to its release. Only the researcher (KJ) and potentially an assistant will have access to the session notes that may include names; all information relating to the consultation sessions will be stored in a locked filing cabinet in a WRHA site office and will be destroyed after the final results are written.

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the researcher from his legal and professional responsibilities. You are free to withdraw from the study at any time, and/or refrain from answering any questions you prefer to omit, without prejudice or consequence. Your continued participation should be as informed as your initial consent, so you should feel free to ask for clarification or new information throughout your participation.

Researcher:
Keir Johnson, MPA Student

Academic Supervisor:
Dr. Paul Thomas, Professor
(204) 474-8116

This research has been approved by the Joint Faculty Research Ethics Board. If you have any concerns or complaints about this project you may contact any of the above-named persons or the Human Ethics Secretariat at 474-7122, or e-mail margaret_bowman@umanitoba.ca. A copy of this consent form has been given to you to keep for your records and reference.

Participant's Signature

Date

Researcher's Signature

Date

Consultation Session Leader's Guide

Page 1

Consultation Session – Leader's Guide

Greetings/Introductions/Rules

20 Minutes

- Greetings
- "Housekeeping" details
- Information about the study and today's session
- How today's session will work
 - You are all here to share your perspectives regarding home care client safety.
 - Be sure to share your thoughts with the group; you do not need to address me.
 - At times, I may interrupt you when you are speaking – this is not because you are right or wrong. I may ask you to clarify what you are saying or may bring the discussion back on track if it drifts off topic.
 - Please feel free to ask me to restate or clarify a question.
- Ground rules
 - I ask that everything that is said in this room, stays in this room.
 - Everyone's thoughts and opinions are valuable; there are no right or wrong answers.
 - Speak clearly
 - Only one person speak at one time
 - Everyone should have equal time to share openly their ideas, no one person should dominate the discussion
 - Information from today's session will be included in my final thesis. The job titles of everyone participating today will also be included, however your names will not.
 - Are these rules acceptable to everyone? Does anyone have any other rules they would like to add?
- Informed Consent Form Collection (consent forms were shared in advance)
- Introductions.

Existing Definitions of Adverse Event**10 Minutes**

- There are many definitions for the term “adverse event.” A major goal of today’s session is to translate the term “adverse event” to the home care context – please keep this in mind, we will revisit this at the end of the session.
- I’ll take a few minutes to review some of the concepts shared by existing definitions:
 - An incident in which harm resulted to a person receiving health care
 - Incidents are sometimes described as undesirable and unintended
 - Harm is often described as injury, temporary or permanent disability, and death. It has also been described as:
 - Any complication
 - Prolonging hospitalization or additional care efforts
 - Physical, emotional, or financial liability for the patient
 - Any adverse outcome
 - Caused by health care management, not by underlying condition or disease
 - Health care management could include actions of individual staff as well as broader systems, policies, processes, or procedures.
- As we discuss the concept of safety in home care, keep these concepts in mind as we will revisit definitions near the end of the session.

Safety in Home Care**15 Minutes**

- An adverse event, regardless of definition, involves a disagreeable event caused by the care received. What kinds of events can happen in home care?
 - Probes
 - Fall, Pressure Ulcer, Adverse Drug Event, etc
 - Remember difference between errors and adverse events (a client’s medication administration call could be missed but not result in harm – that would be an error but not an adverse event).

Causes of Home Care Adverse Events**15 Minutes**

- What can cause adverse events in home care?
 - Probes
 - Coordination problems
 - Wrong care plan
 - Substandard care delivered

- Human error
- Other system problems
- Family/client inaction or wrong action
- Other providers (i.e. programs, hospitals, physicians, etc.)

Lunch delivered**5 Minutes****Revisiting Definitions****25 Minutes**

- Given our discussion of the safety situation in home care, let's revisit the concepts I introduced to you earlier.
- I have two concepts related to defining "adverse event" up on the wall. We will decide which elements of each concept should be included; this will help me to create a definition for adverse event and proceed with my study. The 2 concepts are:
 - Harm or impact
 - Cause or domain
- Each concept is represented by a different colour. Each of you should now have dot stickers for each colour. I'd like everyone to take a few minutes to get up and stick your dot stickers on the elements of each concept you think should be included. Please only stick one dot on a concept. If two elements are side-by-side, you must choose either of these concepts but not both. *[demonstration]*

Does anyone have any questions before we begin?

<<Dot Voting>>
- Discuss voting if there are any questions that arise (i.e. if voting for a side-by-side element is split, discuss why people voted for each).

Methodology Review**15 Minutes**

- Where do you think I would find information that could indicate an adverse event occurred?
 - Probes
 - Occurrence reports
 - Notepads (i.e. if fall is included in a note)
 - MDS Assessment (i.e. if item K5=>1 indicating that client has fallen in last 90 days)
 - Others?

Closing**5 Minutes**

WRHA Occurrence Report

Page 1

4185152578 Report ID (Office Use Only)													
<div style="display: flex; align-items: center;"> <div> OCURRENCE REPORT (version 2.0) <input type="checkbox"/> Staff Injury Report Submitted </div> </div>													
Date Of Occurrence / / / / / / <div style="display: flex; justify-content: space-around; font-size: 8px;"> D D M M Y Y Y Y </div>													
Time Of Occurrence : : <div style="display: flex; justify-content: space-around; font-size: 8px;"> (24 Hour Clock) <input type="checkbox"/> Occurred Once <input type="checkbox"/> More than once </div>													
ADDRESSOGRAPH or DEPARTMENT or NAME & ADDRESS OF PRIMARY PERSON INVOLVED													
1. LOCATION OF OCCURRENCE <div style="border: 1px solid black; height: 20px; width: 100%; margin-bottom: 5px;"></div> If OUTSIDE Building: <input type="checkbox"/> On Property <input type="checkbox"/> Off Property	OFFICE USE ONLY Facility Patient / Client / Res ID Number <div style="border: 1px solid black; height: 20px; width: 100%; margin-bottom: 5px;"></div> Facility/Org # Primary Dept Code <div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; width: 40%; height: 20px;"></div> <div style="border: 1px solid black; width: 40%; height: 20px;"></div> </div>												
2a. PRIMARY PERSON AFFECTED (Choose One) <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 50%; vertical-align: top;"> Patient-type or Client/Resident of: <input type="checkbox"/> In-patient <input type="checkbox"/> Supportive Housing <input type="checkbox"/> Out-patient <input type="checkbox"/> Home Care <input type="checkbox"/> Emergency <input type="checkbox"/> Public Health <input type="checkbox"/> Day-patient <input type="checkbox"/> Community Mental Health <input type="checkbox"/> PCH Resident <input type="checkbox"/> Primary Care - Community <input type="checkbox"/> Services to Seniors <input type="checkbox"/> Access Centre <input type="checkbox"/> Other (specify) <input type="checkbox"/> Adult Day Program </td> <td style="width: 50%; vertical-align: top;"> Staff / Other: <input type="checkbox"/> Staff <input type="checkbox"/> None <input type="checkbox"/> Physician <input type="checkbox"/> Student <input type="checkbox"/> Volunteer <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Agency/Contractor <input type="checkbox"/> Other (specify) </td> </tr> </table>	Patient-type or Client/Resident of: <input type="checkbox"/> In-patient <input type="checkbox"/> Supportive Housing <input type="checkbox"/> Out-patient <input type="checkbox"/> Home Care <input type="checkbox"/> Emergency <input type="checkbox"/> Public Health <input type="checkbox"/> Day-patient <input type="checkbox"/> Community Mental Health <input type="checkbox"/> PCH Resident <input type="checkbox"/> Primary Care - Community <input type="checkbox"/> Services to Seniors <input type="checkbox"/> Access Centre <input type="checkbox"/> Other (specify) <input type="checkbox"/> Adult Day Program	Staff / Other: <input type="checkbox"/> Staff <input type="checkbox"/> None <input type="checkbox"/> Physician <input type="checkbox"/> Student <input type="checkbox"/> Volunteer <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Agency/Contractor <input type="checkbox"/> Other (specify)	2b. NOTIFICATION / WITNESS <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 60%; vertical-align: top;"> Persons Notified: <input type="checkbox"/> Physician <input type="checkbox"/> Supervisor / Manager <input type="checkbox"/> Family <input type="checkbox"/> Other Name of Person(s) Notified: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div> </td> <td style="width: 40%; vertical-align: top;"> Witnessed? <input type="checkbox"/> Yes <input type="checkbox"/> No Name of Witness: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div> </td> </tr> </table>	Persons Notified: <input type="checkbox"/> Physician <input type="checkbox"/> Supervisor / Manager <input type="checkbox"/> Family <input type="checkbox"/> Other Name of Person(s) Notified: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	Witnessed? <input type="checkbox"/> Yes <input type="checkbox"/> No Name of Witness: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>								
Patient-type or Client/Resident of: <input type="checkbox"/> In-patient <input type="checkbox"/> Supportive Housing <input type="checkbox"/> Out-patient <input type="checkbox"/> Home Care <input type="checkbox"/> Emergency <input type="checkbox"/> Public Health <input type="checkbox"/> Day-patient <input type="checkbox"/> Community Mental Health <input type="checkbox"/> PCH Resident <input type="checkbox"/> Primary Care - Community <input type="checkbox"/> Services to Seniors <input type="checkbox"/> Access Centre <input type="checkbox"/> Other (specify) <input type="checkbox"/> Adult Day Program	Staff / Other: <input type="checkbox"/> Staff <input type="checkbox"/> None <input type="checkbox"/> Physician <input type="checkbox"/> Student <input type="checkbox"/> Volunteer <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Agency/Contractor <input type="checkbox"/> Other (specify)												
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Report Initiated by: (Please PRINT) Date Reported (DD / MM / YYYY) <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> Name & Title: Dept Signature </div> <div style="width: 35%;"> <div style="border: 1px solid black; height: 20px; width: 100%;"></div> </div> </div>													
3. DEGREE OF INJURY / PROPERTY DAMAGE (Must be Completed) <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 33%; vertical-align: top;"> Degree of Injury At Time of Occurrence: <input type="checkbox"/> Non apparent <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> Death </td> <td style="width: 33%; vertical-align: top;"> Property Loss or Damage (if applicable): <input type="checkbox"/> Minor <input type="checkbox"/> None <input type="checkbox"/> Major </td> <td style="width: 33%; vertical-align: top;"> Classification of Occurrence: <input type="checkbox"/> Occurrence <input type="checkbox"/> Critical Clinical Occurrence <input type="checkbox"/> Critical Occurrence <input type="checkbox"/> Near Miss </td> </tr> </table>		Degree of Injury At Time of Occurrence: <input type="checkbox"/> Non apparent <input type="checkbox"/> Major <input type="checkbox"/> Minor <input type="checkbox"/> Death	Property Loss or Damage (if applicable): <input type="checkbox"/> Minor <input type="checkbox"/> None <input type="checkbox"/> Major	Classification of Occurrence: <input type="checkbox"/> Occurrence <input type="checkbox"/> Critical Clinical Occurrence <input type="checkbox"/> Critical Occurrence <input type="checkbox"/> Near Miss									
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4. CATEGORY OF OCCURRENCE. (Select only ONE category, then complete the related subsection below) <table style="width: 100%; font-size: 8px;"> <tr> <td><input type="checkbox"/> 4.1 Medications / Substances</td> <td><input type="checkbox"/> 4.2 Falls</td> <td><input type="checkbox"/> 4.3 Clinical Care</td> <td><input type="checkbox"/> 4.4 Missing Patient/ Client/ Res</td> </tr> <tr> <td><input type="checkbox"/> 4.5 Abuse/ Aggression/ Harassment</td> <td><input type="checkbox"/> 4.6 Pt/CI/Res Documentation</td> <td><input type="checkbox"/> 4.7 Confidentiality</td> <td><input type="checkbox"/> 4.8 Equipment/ Supplies/ Property</td> </tr> <tr> <td><input type="checkbox"/> 4.9 Environment</td> <td><input type="checkbox"/> 4.10 Collision</td> <td><input type="checkbox"/> 4.11 Ambul Redirect Extension</td> <td><input type="checkbox"/> 4.12 Other</td> </tr> </table>		<input type="checkbox"/> 4.1 Medications / Substances	<input type="checkbox"/> 4.2 Falls	<input type="checkbox"/> 4.3 Clinical Care	<input type="checkbox"/> 4.4 Missing Patient/ Client/ Res	<input type="checkbox"/> 4.5 Abuse/ Aggression/ Harassment	<input type="checkbox"/> 4.6 Pt/CI/Res Documentation	<input type="checkbox"/> 4.7 Confidentiality	<input type="checkbox"/> 4.8 Equipment/ Supplies/ Property	<input type="checkbox"/> 4.9 Environment	<input type="checkbox"/> 4.10 Collision	<input type="checkbox"/> 4.11 Ambul Redirect Extension	<input type="checkbox"/> 4.12 Other
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→ 4.1 MEDICATIONS / THERAPEUTIC & DIAGNOSTIC SUBSTANCES <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 33%; vertical-align: top;"> 4.1.1 Type of Agent Involved: <input type="checkbox"/> IV Fluids / TPN <input type="checkbox"/> Medication <input type="checkbox"/> Contrast Media <input type="checkbox"/> Vaccine <input type="checkbox"/> Narcotic / Controlled Drug <input type="checkbox"/> Non-prescribed Drug / Alcohol <input type="checkbox"/> Blood / Blood Products <input type="checkbox"/> Radiopharmaceutical Substance <input type="checkbox"/> Other (specify) </td> <td style="width: 33%; vertical-align: top;"> 4.1.2 Type of Error: <input type="checkbox"/> Wrong Medication <input type="checkbox"/> Wrong Time of Admin/Removal <input type="checkbox"/> Wrong Route/Site <input type="checkbox"/> Wrong Rate of Administration <input type="checkbox"/> Wrong Pt/CI/Res <input type="checkbox"/> Wrong Form of Drug <input type="checkbox"/> Wrong Dose <input type="checkbox"/> Outdated Product <input type="checkbox"/> Extra Dose <input type="checkbox"/> Unresolved Count <input type="checkbox"/> Omitted Dose <input type="checkbox"/> Tissue Infiltration <input type="checkbox"/> Unordered Drug <input type="checkbox"/> Other (specify) </td> <td style="width: 33%; vertical-align: top;"> 4.1.3 Route of Administration: <input type="checkbox"/> PO <input type="checkbox"/> SC <input type="checkbox"/> Epidural <input type="checkbox"/> Transdermal <input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> Other (specify) </td> </tr> </table>		4.1.1 Type of Agent Involved: <input type="checkbox"/> IV Fluids / TPN <input type="checkbox"/> Medication <input type="checkbox"/> Contrast Media <input type="checkbox"/> Vaccine <input type="checkbox"/> Narcotic / Controlled Drug <input type="checkbox"/> Non-prescribed Drug / Alcohol <input type="checkbox"/> Blood / Blood Products <input type="checkbox"/> Radiopharmaceutical Substance <input type="checkbox"/> Other (specify)	4.1.2 Type of Error: <input type="checkbox"/> Wrong Medication <input type="checkbox"/> Wrong Time of Admin/Removal <input type="checkbox"/> Wrong Route/Site <input type="checkbox"/> Wrong Rate of Administration <input type="checkbox"/> Wrong Pt/CI/Res <input type="checkbox"/> Wrong Form of Drug <input type="checkbox"/> Wrong Dose <input type="checkbox"/> Outdated Product <input type="checkbox"/> Extra Dose <input type="checkbox"/> Unresolved Count <input type="checkbox"/> Omitted Dose <input type="checkbox"/> Tissue Infiltration <input type="checkbox"/> Unordered Drug <input type="checkbox"/> Other (specify)	4.1.3 Route of Administration: <input type="checkbox"/> PO <input type="checkbox"/> SC <input type="checkbox"/> Epidural <input type="checkbox"/> Transdermal <input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> Other (specify)									
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4.1.5 List Actual Medication / Agent Order: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>	OFFICE USE ONLY Therapeutic Class of Drug Ordered: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>												
4.1.6 List Medication / Agent Involved: <div style="border: 1px solid black; height: 20px; width: 100%; margin-top: 5px;"></div>													
→ 4.2 FALLS <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 33%; vertical-align: top;"> 4.2.1 Patient / Client / Resident Found: <input type="checkbox"/> Patient/CI/Res Rm <input type="checkbox"/> Dining Rm <input type="checkbox"/> Shower <input type="checkbox"/> Lounge/ Rec. Area <input type="checkbox"/> Bathroom <input type="checkbox"/> Hallway <input type="checkbox"/> Other (specify) </td> <td style="width: 33%; vertical-align: top;"> 4.2.2 Fell From: <input type="checkbox"/> Bed/ Crib <input type="checkbox"/> Walker <input type="checkbox"/> Toilet/ Commode <input type="checkbox"/> Standing Posn <input type="checkbox"/> Stretcher <input type="checkbox"/> Chair <input type="checkbox"/> Broda/ Wheelchair <input type="checkbox"/> Exam Table <input type="checkbox"/> Tub <input type="checkbox"/> Stairs <input type="checkbox"/> Other: </td> <td style="width: 33%; vertical-align: top;"> 4.2.3 Fell While: <input type="checkbox"/> Ambulating <input type="checkbox"/> Transferring <input type="checkbox"/> Other: <input type="checkbox"/> Standing </td> </tr> </table>		4.2.1 Patient / Client / Resident Found: <input type="checkbox"/> Patient/CI/Res Rm <input type="checkbox"/> Dining Rm <input type="checkbox"/> Shower <input type="checkbox"/> Lounge/ Rec. Area <input type="checkbox"/> Bathroom <input type="checkbox"/> Hallway <input type="checkbox"/> Other (specify)	4.2.2 Fell From: <input type="checkbox"/> Bed/ Crib <input type="checkbox"/> Walker <input type="checkbox"/> Toilet/ Commode <input type="checkbox"/> Standing Posn <input type="checkbox"/> Stretcher <input type="checkbox"/> Chair <input type="checkbox"/> Broda/ Wheelchair <input type="checkbox"/> Exam Table <input type="checkbox"/> Tub <input type="checkbox"/> Stairs <input type="checkbox"/> Other:	4.2.3 Fell While: <input type="checkbox"/> Ambulating <input type="checkbox"/> Transferring <input type="checkbox"/> Other: <input type="checkbox"/> Standing									
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<table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 50%; vertical-align: top;"> 4.2.4 Details: <table style="width: 100%;"> <tr> <td style="width: 33%;"> Bed Position <input type="checkbox"/> Bed Up <input type="checkbox"/> Bed Down </td> <td style="width: 33%;"> Side Rails <input type="checkbox"/> Split <input type="checkbox"/> Full Length </td> <td style="width: 33%;"> Rail Position: <input type="checkbox"/> Up <input type="checkbox"/> Down <input type="checkbox"/> Partial </td> </tr> </table> </td> <td style="width: 50%; vertical-align: top;"> Other: <input type="checkbox"/> Restrained <input type="checkbox"/> Light On <input type="checkbox"/> Brakes On <input type="checkbox"/> Call System in Reach <input type="checkbox"/> On Falls Protocol </td> </tr> </table>		4.2.4 Details: <table style="width: 100%;"> <tr> <td style="width: 33%;"> Bed Position <input type="checkbox"/> Bed Up <input type="checkbox"/> Bed Down </td> <td style="width: 33%;"> Side Rails <input type="checkbox"/> Split <input type="checkbox"/> Full Length </td> <td style="width: 33%;"> Rail Position: <input type="checkbox"/> Up <input type="checkbox"/> Down <input type="checkbox"/> Partial </td> </tr> </table>	Bed Position <input type="checkbox"/> Bed Up <input type="checkbox"/> Bed Down	Side Rails <input type="checkbox"/> Split <input type="checkbox"/> Full Length	Rail Position: <input type="checkbox"/> Up <input type="checkbox"/> Down <input type="checkbox"/> Partial	Other: <input type="checkbox"/> Restrained <input type="checkbox"/> Light On <input type="checkbox"/> Brakes On <input type="checkbox"/> Call System in Reach <input type="checkbox"/> On Falls Protocol							
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Bed Position <input type="checkbox"/> Bed Up <input type="checkbox"/> Bed Down	Side Rails <input type="checkbox"/> Split <input type="checkbox"/> Full Length	Rail Position: <input type="checkbox"/> Up <input type="checkbox"/> Down <input type="checkbox"/> Partial											
4.2.5 Related Factors: <table style="width: 100%; font-size: 8px;"> <tr> <td style="width: 50%;"> <input type="checkbox"/> Footwear <input type="checkbox"/> Equipment Failure <input type="checkbox"/> Obstacles Present <input type="checkbox"/> Other (specify) </td> <td style="width: 50%;"> <input type="checkbox"/> Decreased LOC / Orientation <input type="checkbox"/> Bowel / Bladder Problem <input type="checkbox"/> Environmental Conditions </td> </tr> </table>		<input type="checkbox"/> Footwear <input type="checkbox"/> Equipment Failure <input type="checkbox"/> Obstacles Present <input type="checkbox"/> Other (specify)	<input type="checkbox"/> Decreased LOC / Orientation <input type="checkbox"/> Bowel / Bladder Problem <input type="checkbox"/> Environmental Conditions										
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8073152578	<div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto;"></div>	Report ID (Office Use Only)	OCCURRENCE REPORT (version 2.0)
4.3 CLINICAL CARE			
4.3.1 Category: <input type="checkbox"/> Care Delivery <input type="checkbox"/> Surgery <input type="checkbox"/> Assessment <input type="checkbox"/> Discharge <input type="checkbox"/> Procedure <input type="checkbox"/> Diagnostic Test <input type="checkbox"/> Treatment <input type="checkbox"/> Diagnosis <input type="checkbox"/> Transfer/Transport of Patient/CI/Res <input type="checkbox"/> Other (specify) <input type="checkbox"/> Referral/Consultation		4.3.2 Type: <input type="checkbox"/> Cancelled <input type="checkbox"/> Delayed <input type="checkbox"/> Incorrect <input type="checkbox"/> Missed <input type="checkbox"/> Incomplete <input type="checkbox"/> Break in Continuity <input type="checkbox"/> Policy/Care Map/Protocol/ Procedure variance <input type="checkbox"/> Injury (Not Fall Related) <input type="checkbox"/> Other (specify)	
4.3.3 Details / Related Factors: (choose all that apply) <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <input type="checkbox"/> Sterile Technique <input type="checkbox"/> Surgical Count <input type="checkbox"/> Isolation Technique <input type="checkbox"/> Foreign Body <input type="checkbox"/> Specimen Handling <input type="checkbox"/> Cross Match <input type="checkbox"/> Specimen Labelling <input type="checkbox"/> Communication <input type="checkbox"/> Clinical Documentation <input type="checkbox"/> Coordination <input type="checkbox"/> Organ Removal / Repair <input type="checkbox"/> Misidentity <input type="checkbox"/> Skin Breakdown/Burn/Tear <input type="checkbox"/> Other (specify) </div> <div style="width: 35%;"> Unavailable: <input type="checkbox"/> Physician <input type="checkbox"/> Bed <input type="checkbox"/> Time Slot <input type="checkbox"/> Staff <input type="checkbox"/> Consent <input type="checkbox"/> Blood <input type="checkbox"/> Equipment <input type="checkbox"/> Order <input type="checkbox"/> Health Record <input type="checkbox"/> Test/Lab Result <input type="checkbox"/> Referral </div> </div>			
4.4 MISSING PATIENT / CLIENT / RESIDENT		4.5 ABUSE / AGGRESSION / HARASSMENT	
4.4.1 Date Last Seen & Date Returned: Last Seen: / / Time: : D D M M Y Y Y Y Returned: / / Time: : D D M M Y Y Y Y		4.5.1 Category: <input type="checkbox"/> Abuse <input type="checkbox"/> Aggression <input type="checkbox"/> Harassment	
4.4.2 Additional Facts: <input type="checkbox"/> Designated Mentally Incompetent (MHA) <input type="checkbox"/> Predetermined Risk to Self or Others <input type="checkbox"/> On Wandering Protocol/ Registry <input type="checkbox"/> On Pass		4.5.2 Types: <input type="checkbox"/> Verbal <input type="checkbox"/> Sexual <input type="checkbox"/> Written <input type="checkbox"/> Mental <input type="checkbox"/> Physical <input type="checkbox"/> Financial	
On Special Observation: <input type="checkbox"/> Constant <input type="checkbox"/> Suicidal <input type="checkbox"/> Close		4.5.3 Specifics: From: <input type="checkbox"/> Patient/CI/Res <input type="checkbox"/> Self <input type="checkbox"/> Staff <input type="checkbox"/> Patient/CI/Res <input type="checkbox"/> Physician <input type="checkbox"/> Staff <input type="checkbox"/> Student <input type="checkbox"/> Physician <input type="checkbox"/> Volunteer <input type="checkbox"/> Student <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Volunteer <input type="checkbox"/> Contract Person <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Animals <input type="checkbox"/> Contract Person <input type="checkbox"/> Unknown <input type="checkbox"/> Property	
4.6 PATIENT / CLIENT / RESIDENT DOCUMENTATION			
4.6.1 Category of Documentation <input type="checkbox"/> Registration <input type="checkbox"/> Waiver of Liability <input type="checkbox"/> Clinical Documentation <input type="checkbox"/> Lab Results <input type="checkbox"/> Consent <input type="checkbox"/> Computer Application		4.6.2 Types: <input type="checkbox"/> Removed <input type="checkbox"/> Duplication <input type="checkbox"/> Inaccurate <input type="checkbox"/> Incomplete <input type="checkbox"/> Missing / Unavailable <input type="checkbox"/> Other (specify)	
4.7 CONFIDENTIALITY			
4.7.1 Category of Information: <input type="checkbox"/> Patient / Client / Resident <input type="checkbox"/> Staff <input type="checkbox"/> Business / Financial		4.7.2 Mode of Communication: <input type="checkbox"/> Written <input type="checkbox"/> Visual Media <input type="checkbox"/> Verbal <input type="checkbox"/> Facsimile <input type="checkbox"/> Computerized	
4.7.3 Type of Confidentiality Issue: <input type="checkbox"/> Use <input type="checkbox"/> Access <input type="checkbox"/> Disclosure <input type="checkbox"/> Location			
4.8 EQUIPMENT / SUPPLIES / PROPERTY			
4.8.1 Category: <input type="checkbox"/> Equipment <input type="checkbox"/> Property <input type="checkbox"/> Supplies		4.8.2 Owned by: <input type="checkbox"/> Facility <input type="checkbox"/> Other Facility <input type="checkbox"/> Patient/CI/Res <input type="checkbox"/> Volunteer <input type="checkbox"/> Staff <input type="checkbox"/> Visitor / Family <input type="checkbox"/> Physician <input type="checkbox"/> Contract Person <input type="checkbox"/> Student <input type="checkbox"/> Vendor	
4.8.3 Problem: <input type="checkbox"/> Damaged <input type="checkbox"/> Defective Upon Opening / First Use <input type="checkbox"/> Not Working Property <input type="checkbox"/> Disposal Issue <input type="checkbox"/> Recall / Alert <input type="checkbox"/> Missing <input type="checkbox"/> Unavailable		4.8.4 Equipment / Supplies / Property Information: Generic Name / Description _____ Manufacturer and/or Vendor _____ Model _____ BME # _____ Serial / Catalog / Lot # _____ Manufacture / Sterilize Date _____ Expiry Date _____ Additional Information _____	
4.9 ENVIRONMENT			
4.9.1 Type: <input type="checkbox"/> Leak <input type="checkbox"/> Penetration from Sharp <input type="checkbox"/> Spill <input type="checkbox"/> Transport (Materials) <input type="checkbox"/> Fire <input type="checkbox"/> Fume / Vapor / Odor <input type="checkbox"/> Smoke <input type="checkbox"/> Temperature <input type="checkbox"/> Dust / Dirt <input type="checkbox"/> Pest Infestation <input type="checkbox"/> Disposal <input type="checkbox"/> Staff Personal Safety <input type="checkbox"/> Noise <input type="checkbox"/> Other		4.9.2 Substance Involved: <input type="checkbox"/> Regulated / Controlled Products <input type="checkbox"/> Water <input type="checkbox"/> Blood / Body Fluids / Feces <input type="checkbox"/> Tobacco <input type="checkbox"/> Biological or Chemical Agent <input type="checkbox"/> Natural Gas <input type="checkbox"/> Communicable / Infectious Disease <input type="checkbox"/> Medical Gas <input type="checkbox"/> Ozone Depleting Substance <input type="checkbox"/> PCB <input type="checkbox"/> Radiation (specify agent if known) <input type="checkbox"/> Other (specify)	
4.9.3 Related Factors: <input type="checkbox"/> Exits / Hallways Obstructed <input type="checkbox"/> Combustible Materials <input type="checkbox"/> Wedged Fire Doors <input type="checkbox"/> Fire Extinguisher Accessibility <input type="checkbox"/> Burned Out Exit Light <input type="checkbox"/> Heating / Air Conditioning Issue <input type="checkbox"/> Construction <input type="checkbox"/> Other (specify)			
4.10 COLLISION		4.11 AMBULANCE REDIRECT	
<input type="checkbox"/> With Moving Object <input type="checkbox"/> With Stationary Object Specify _____		<input type="checkbox"/> Extension Granted <input type="checkbox"/> Extension Denied	
<input type="checkbox"/> Specify			
5.0 REVIEWED BY IMMEDIATE SUPERVISOR/DESIGNATE OF STAFF MEMBER REPORTING THIS OCCURRENCE (Please Print)			
<input type="checkbox"/> No Follow-up Documentation will be Submitted		Name _____ Phone _____ Signature _____ Dept _____	
Date Reviewed (dd / mm / yyyy) / / 			

MDS-HC Assessment Form

**To review the MDS-HC assessment, please contact interRAI
through their web site at <http://www.interrai.org/>**

Client Service Address Information

Address:

Community:

Province:

Postal Code:

Country:

Phone Number:

SECTION A. ASSESSMENT INFORMATION

SECTION 1: NAME AND IDENTIFICATION INFORMATION	
1	<div>NAME OF CLIENT</div> <div> <div>a. (Last/Family Name)</div> <div>b. (First Name)</div> <div>c. (Middle Name/Initial)</div> </div>
2	<div>PHN NUMBER</div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>
3	<div>HEALTH INSURANCE NUMBER</div> <div> <div>b. MHS# number</div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>
4	<div>POSTAL CODE OF RESIDENCE</div> <div> <div>See RA/HC manual for homeless/missing codes.</div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>

SECTION A - ASSESSMENT INFORMATION		
3	DISCHARGE STATUS	Discharge Status 1. Recovered – service not required 2. Refused further services 3. Service provided by another program 4. Service provided by other 5. Placed in personal care home 6. Deceased 7. Chronic Care Placement 8. Hospitalized 9. Inter-regional transfer 10. Temporary discharge 11. Moved out of province 12. Not eligible for Home Care 13. Other
4	DISCHARGE DATE	Date of discharge <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> <div style="margin: 0 10px;">/</div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> <div style="margin: 0 10px;">/</div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> <div style="border: 1px solid black; width: 40px; height: 40px; margin: 5px;"></div> </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> Year Month Day </div>
5	NON-ADMISSION	Discharge Notification is due to Home Care Program Non-Admission 0. No 1. Yes

SECTION R. ASSESSMENT INFORMATION

1	SEX	M. Male	F. Female
2a	BIRTH DATE	<div> <div> <div></div><div></div><div></div><div></div> </div> <div> <div></div><div></div> </div> <div> <div></div><div></div> </div> </div> <div> <div>Year</div> <div>Month</div> <div>Day</div> </div>	
2b	ESTIMATED BIRTH DATE	Birth date is estimated? 0. No 1. Yes	
3	ABORIGINAL ORIGIN	Client's origin is Inuit, Métis or North American Indian 0. No 1. Yes	
4	MARITAL STATUS	<div> <div>1. Never married</div> <div>4. Separated</div> </div> <div> <div>2. Married</div> <div>5. Divorced</div> </div> <div> <div>3. Widowed</div> <div>6. Other</div> </div>	
5	LANGUAGE	<div>a. Primary language (See RALHC manual for additional codes.)</div> <div> <div>eng English</div> <div>fra French</div> <div></div><div></div><div></div> </div> <div> <div>b. Interpreter needed</div> <div>0. No 1. Yes</div> </div>	
6	EDUCATION (Highest Level Completed)	<div>1. No schooling</div> <div>6. Some college/university</div> <div> <div>2. 8th grade/less</div> <div>7. Diploma/Bachelor's degree</div> </div> <div> <div>3. 9-11 grades</div> <div>8. Graduate degree</div> </div> <div> <div>4. High school</div> <div>9. Unknown</div> </div> <div> <div>5. Technical or trade school</div> </div>	
7	RESPONSIBILITY/ADVANCED DIRECTIVES	<div>(Code for responsibility/advanced directives)</div> <div>0. No 1. Yes</div> <div>a. Client has a legal guardian/substitute decision-maker.</div> <div>b. Client has advanced medical directives in place (for example, a do not hospitalize order).</div>	
8	RESPONSIBILITY FOR PAYMENT	<div>(Check all that apply)</div> <div>a. Provincial/territorial government plan</div> <div>b. Other province/territory</div> <div>c. Federal government—Veteran Affairs Canada</div> <div>d. Federal government—First Nations and Inuit Health Branch (FNHB)</div> <div>e. Federal government—other (RCMP, Canadian Armed Forces, federal penitentiary inmate, refugee)</div> <div>f. Worker's Compensation Board (WCB/WSIB)</div> <div>g. Canadian resident—private insurance pay</div> <div>h. Canadian resident—public trustee pay</div> <div>i. Canadian resident—self pay</div> <div>j. Other country resident—self pay</div> <div>k. Responsibility for payment unknown/unavailable</div>	

3. SIGNATURES OF PERSONS COMPLETING THE ASSESSMENT:				
a. Signature of Assessment Coordinator				
b. Title of Assessment Coordinator				
c. Date Assessment Coordinator signed as complete	<div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div> <div style="border: 1px solid black; width: 40px; height: 30px; display: inline-block;"></div>	<div style="border: 1px solid black; width: 60px; height: 30px; display: inline-block;"></div>	<div style="border: 1px solid black; width: 60px; height: 30px; display: inline-block;"></div>	
	Year	Month	Day	
d. Other Signatures	Title	Sections	Date	
e.			Date	
f.			Date	
g.			Date	
h.			Date	
i.			Date	

SAMPLE Screen Sheet with Description

StudyCode: 999	
SearchType: MDS	
<i>SearchCriteria:</i> MDS-HC: Falls (K5) 09/09/2004 K5 = 1	All three screen items probably indicate same possible AE: a fall
<i>SearchCriteria:</i> Discharged: Hospitalized 30/11/2004 A3=8 (Hospitalized)	
SearchType: Notes	
<i>SearchCriteria:</i> Fall or fell 23/07/2004 Message received from worker that client had a fall in bathroom today. Client was dizzy, but did not want to call an ambulance.	Both screen items probably indicate the same adverse outcome: hospitalization
<i>SearchCriteria:</i> hospital terms in Hospital Track Notepad 15/12/2005 Admitted HSC October 2/04 – December 14, 2004	
SearchType: OccurrenceReport	
<i>SearchCriteria:</i> Occurrence 4.2 (Fall) 23/07/2004 Fall (4.2) in bathroom while ambulating. Degree of injury = non-apparent	

Page 1 of 1

Understanding and Using this Screen Sheet

In this sample screen, several screen items combine to indicate two issues with which the chart reviewer would follow-up. First, a fall seems to have occurred on July 23, 2004, as indicated by a WRHA occurrence report, a note, and a subsequent MDS-HC assessment. The chart reviewer would search for evidence that the fall was caused by care (actions or inactions) rather than just the underlying condition. The second concern is a hospitalization, which is indicated by a note and a discharge record (clients are discharged from Home Care if they are hospitalized for a prolonged period). The chart reviewer would examine the file to determine the reason for hospitalization; it may have been caused by an AE. For any events that cause harm to a client and are determined to have been caused by care, the chart reviewer would complete a chart review form.

Chart Review Form

Page 1

Home Care Adverse Event Review		
*Reviewer: _____	*Study Code: _____ Count: _____	
*Review Date: _____	Date of AE: _____	
*Review Start Time: _____	<div style="display: flex; justify-content: space-around; font-size: small;"> Day Month Year </div>	
* = Required for all screens		
AE Date Estimated: Yes / No <small>(Circle One)</small>		
AE review flagged by (check <u>all</u> that apply): <input type="checkbox"/> Occurrence Report <input type="checkbox"/> Notes <input type="checkbox"/> MDS-HC Assessment		
*1. Confidence event was an Adverse Event To be considered an Adverse Event, the event must meet two criteria: 1. it must result in harm to the client that negatively affects their overall health and/or functioning, and 2. it must be caused by the care provided and not the client's underlying condition *Confidence that harm was caused by care actions/inactions and not underlying condition (check <u>only one</u>): <input type="checkbox"/> 0 No event occurred (If coded 0, skip to question 6 and review end time) <input type="checkbox"/> 1 Virtually no evidence event caused by care (most likely due to underlying condition) <input type="checkbox"/> 2 Slight to modest evidence event caused by care <input type="checkbox"/> 3 Not likely event caused by care (less than 50/50, but close call) <input type="checkbox"/> 4 More likely event caused by care (more than 50/50, but close call) <input type="checkbox"/> 5 Moderate to strong evidence event caused by care <input type="checkbox"/> 6 Virtually certain evidence event caused by care		
2. Type of AE (check <u>only one</u>): <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Fall – injurious <input type="checkbox"/> Fall – non-injurious <input type="checkbox"/> Pressure ulcer <input type="checkbox"/> Other type of harm, specify: _____ </div> <div> <input type="checkbox"/> Adverse Drug Event <input type="checkbox"/> Emotional distress <input type="checkbox"/> Mental harm/injury </div> </div>		
3. Resulting Impact of AE (check <u>all</u> that apply): <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Death <input type="checkbox"/> Permanent harm <input type="checkbox"/> Temporary harm </div> <div> <input type="checkbox"/> Hospitalization <input type="checkbox"/> Premature PCH Placement <input type="checkbox"/> Other, specify: _____ </div> </div> Specify (type/duration): _____		
4. AE Domain (responsible party) (check <u>all</u> that apply): <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> WRHA Home Care DSS <input type="checkbox"/> WRHA Home Care Coordinators <input type="checkbox"/> WRHA Home Care Other: _____ Specify: _____ </div> <div> <input type="checkbox"/> Client (self care) <input type="checkbox"/> Informal caregiver <input type="checkbox"/> Other provider (GP, hospital, program, agency): _____ Specify: _____ </div> </div>		
5. Preventable/Ameliorable? Respond to 5a <u>or</u> 5b <u>or</u> 5c		
5a. Event was preventable: <input type="checkbox"/> 1 Virtually no evidence <input type="checkbox"/> 2 Slight to modest evidence <input type="checkbox"/> 3 Not likely (close call) <input type="checkbox"/> 4 More likely (close call) <input type="checkbox"/> 5 Strong evidence <input type="checkbox"/> 6 Virtually certain evidence	-OR-	5b. Event was ameliorable: <input type="checkbox"/> 1 Virtually no evidence <input type="checkbox"/> 2 Slight to modest evidence <input type="checkbox"/> 3 Not likely (close call) <input type="checkbox"/> 4 More likely (close call) <input type="checkbox"/> 5 Strong evidence <input type="checkbox"/> 6 Virtually certain evidence
-OR- 5c. <input type="checkbox"/> Evidence suggests AE was not preventable / ameliorable		
NOTE: If event is judged to be preventable/ameliorable, complete question 5d on reverse. ...See Reverse...		

5d. How could have event been prevented / ameliorated?

*6. Adequacy of Records

How adequate were the records in providing information to enable judgment of AE (check only one):

- ☐ 1 Client record adequate
- ☐ 2 Some deficiencies, specify: _____
- ☐ 3 Major deficiencies, specify: _____
- ☐ 4 Severe deficiencies, impossible to make judgment, specify: _____

7. Any other comments/concerns about this event/review?

***Review End Time:**

**Comprehensive Results of Search Types and Search Criteria:
Total Matches, Excluded and Associated Adverse Events**

Search Type	Search Criteria	Number of Clients Identified	Number Excluded	Number associated with an AE
MDS-HC Assessments and Discharge Records				
	Falls - K5 > 0	65	8	6
	Hospital use - P4a-c > 0	98	26	4
	Indwelling catheter (I2b) AND UTI (J1w)	1		
	Other injuries and fractures	35	12	2
	skin problems and ulcers	50	6	4
	Discharge: Deceased	27	1	1
	Discharge: Hospitalized	25		5
	Discharge: PCH Placement	23	1	3
Any MDS-HC Assessment or Discharge Record Match		193	38	13
Potentially Inappropriate Medication Search				
	Amiodarone	3		1
	Amitriptyline	12		2
	Anticholinergics and antihistamines	2		
	Cimetidine	1		
	Clonidine	1		
	Digoxin	3		
	Dipyridamole (extended-release)	1		
	Doxazosin	1		
	Doxepin	2		
	Ferrous sulfate	6		
	Long acting benzodiazepines	5		1
	Long-term use of full-dosage, longer half-life, non-COX-selective NSAIDs	1		
	Long-term use of stimulant laxatives	10		
	Meperidine	1		
	Methyldopa	1		
	Mineral Oil	1		
	Muscle relaxants & antispasmodics	8	1	1
	Niacin	2		
	Nitrofurantoin	1		
	Orphenadrine	1		
	Short acting benzodiazepines	1		
	Short acting nifedipine	18	1	4
	Ticlopidine	2		1
Any Potentially Inappropriate Medications		78	0	8

Comprehensive Results of Search Types and Search Criteria

Continued

Search Type	Search Criteria	Number of Clients Identified	Number Excluded	Number associated with an AE
Notes Search				
	Abuse	9	1	1
	Death and died	22	5	
	Fall or fell	131	28	16
	Fracture	21	1	3
	Hospital terms in Hospital Notepad*	43	4	4
	Infection	21	2	1
	Injur	23	4	3
	Overdose	3		1
	Reaction	5	1	1
	Rhabdo	1		
	Slipped	8	2	1
	Sore	31	5	1
	Ulcer	12	1	1
Any Key Word Match in Notepads		199	45	19
WRHA Occurrence Reports (Manual Search)				
	Occurrence 4.1 (Medications)	2		
	Occurrence 4.2 (Fall)	4		3
	Occurrence 4.3 (Clinical Care)	1		
Any Occurrence Report		7	0	3

* Searched hospital tracking notepad for following: Victoria, VGH, Health Science, HSC, Seven Oaks, SOGH, Grace, GGH, St. Boniface, SBGH, Concordia, CGH, ER, Hospital

Detailed Description of Adverse Events

The following comments were provided by chart reviewers for AEs they rated as preventable or ameliorable. The comments have been edited for clarity.

AE No.	Screening Criteria	Type of AE	Harm	Cause(s)	Preventable/Ameliorable	Prevention Comments
1	Notes: "Fall" Notes: "Reaction"	ADE	Temporary	Other: GP	Neither	
2	MDS: Falls (K5 > 0) MDS: Skin problems (N1=1) Notes: "Fall" Notes: "Sore"	Fall Injurious	Temporary	Home Care: Coordinators	Ameliorable	Referral to CTS as client has fallen in past and now fallen again. CC remarks 'client unsteady on feet'
3	MDS Discharge: Hospitalized MDS Discharge: PCH Placement Notes: "Fall" (x2)	Fall Injurious	Temporary	Home Care: Coordinators	Ameliorable	History of falls, CTS not used. Possible hallucinations and delusions not followed up on in care plan
4	MedSearch: Amiodarone	ADE	Temporary	Other: GP	Neither	
5	MDS: Hospital Use (P4a-c>0) MDS Discharge: Hospitalized MedSearch: Short acting nifedipine Notes: "Abuse" Notes: "Fall" (x4) Notes: "injur" (x2)	Other	Other	Caregiver	Ameliorable	No comments provided
6	MDS: Hospital Use (P4a-c>0) (x2) MDS: Skin problems (N2a=1) (x2) MDS Discharge: Deceased Notes: "ulcer" (x2) Hospital terms in Hospital Notepad	Pressure Ulcer	Temporary	Other: Hospital	Preventable	No comments provided
7	MDS Discharge: PCH Placement MedSearch: Amitriptyline Notes: "Fall" (x4)	Fall non-injurious	Hospitalized	Home Care: Coordinators Other: GP	Ameliorable	Falls may have been prevented by using a wheelchair in the home
8a	MedSearch: Short acting nifedipine Notes: "injur" (x2) Occurrence Report: 4.2 (Fall)	Fall non-injurious	Temporary	Home Care: Coordinators Caregiver Client	Ameliorable	Med Review, CTS, Client & Family Education, DSS Education
8b	MedSearch: Short acting nifedipine Notes: "injur" (x2) Occurrence Report: 4.2 (Fall)	Fall non-injurious	Temporary	Home Care: Coordinators Caregiver Client	Ameliorable	Med Review, CTS, Client & Family Education, DSS Education
9a	Notes: "Fall" Notes: "Overdose" (x3) Hospital terms in Hospital Notepad (x2)	ADE	Hospitalized	Client Other: Hospital	Neither	
9b	Notes: "Fall" Notes: "Overdose" (x3) Hospital terms in Hospital Notepad (x2)	ADE	Hospitalized	Client Other: Hospital	Neither	
9c	Notes: "Fall" Notes: "Overdose" (x3) Hospital terms in Hospital Notepad (x2)	ADE	Hospitalized	Caregiver Other: Hospital	Neither	

Detailed Description of Adverse Events

Continued

AE No.	Screening Criteria	Type of AE	Harm	Cause(s)	Preventable/Ameliorable	Prevention Comments
10	MDS Discharge: Hospitalized Notes: "Fall" Hospital terms in Hospital Notepad (x2) Occurrence Report: 4.2 (Fall)	Fall non-injurious	Temporary	Home Care: Direct Service Staff Client	Preventable	DSS should not have left client in bath tub alone to go answer phone (at client's request). Client should not have attempted getting out of tub unassisted.
11a	Notes: "fracture" Notes: "injur"	Fall Injurious	Temporary	Caregiver	Preventable	Client in abusive relationship, if had no contact with partner. Client chooses to maintain relationship as dependent on abusive partner for support
11b	Notes: "fracture" Notes: "injur"	Fall Injurious	Temporary	Caregiver	Preventable	Client in abusive relationship, if had no contact with partner. Client chooses to maintain relationship as dependent on abusive partner for support
12	Notes: "Fall"	Fall Injurious	Temporary	Home Care: Coordinators Caregiver	Preventable	Education for caregivers
13	MDS: Falls (K5 > 0) MDS: Hospital Use (P4a-c>0) (x2) MDS: Injuries/other fractures (J1o=1/2) (x2) MDS: Skin problems (N1=1) MDS Discharge: Hospitalized Med Search: muscle relaxants & antispasmodics Notes: "Fall" x3 Notes: "fracture" Occurrence Report: 4.2 (Fall)	Fall Injurious	Temporary	Caregiver	Preventable	Could have bought special shoes to make both legs even
14	MDS: Falls (K5 > 0) Notes: "Fall" (x9) Notes: "Slipped"	Fall Injurious	Temporary	Home Care: Coordinators Other: GP	Ameliorable	Psychogeriatric referral in Jan or Feb. Waited for Dr. referral. Should have intervened sooner. AE occurred while waiting. Once seen at psychogeriatrics, ambulation improved and no further falls reported.
15	MDS: Falls (K5 > 0) MDS Discharge: PCH Placement MedSearch: Ticlopidine MedSearch: Short acting nifedipine MedSearch: amitriptyline Notes: "Fall" Notes: "Infection"	Mental Harm/Injury	Premature PCH Placement	Home Care: Coordinators Caregiver Client	Ameliorable	Did not have to be placed this early. Wanted to be with wife who was placed client but could still manage in community
16	Notes: "Fall" (x4)	Fall Injurious	Temporary	Home Care: Coordinators	Ameliorable	Could have had CTS referral prior to client falling to reduce incidence of potential falls; client was clearly at risk.

Detailed Description of Adverse Events

Continued

AE No.	Screening Criteria	Type of AE	Harm	Cause(s)	Preventable/Ameliorable	Prevention Comments
17	Notes: "Fall" (x4)	Fall Injurious	Temporary	Home Care: Coordinators Caregiver	Ameliorable	CTS Referral
18	MDS: Skin problems (N1=1)	Other	Temporary	Client	Neither	
19	Notes: "Fall"	Fall Injurious	Temporary	Home Care: Coordinators	Ameliorable	Should've referred to CTS earlier given history of falls. Only referred after latest of many falls
20	MDS: Falls (K5 > 0) Notes: "Fall" (x2)	Fall Injurious	Permanent	Home Care: Coordinators Caregiver Client Other: GP	Neither	
21	MDS Discharge: Hospitalized MedSearch: long acting benzodiazepines	ADE	Other	Other: GP	Neither	
22	MDS: Falls (K5 > 0) MDS: Hospital Use (P4a-c>0) MDS: Injuries/other fractures (J10=1/2) MedSearch: Short acting nifedipine Notes: "Fall" Notes: "fracture" (x2) Hospital terms in Hospital Notepad (x3)	Fall Injurious	Temporary	Other: Hospital	Preventable	Could have kept client in hospital until she was able to manage and was safe at home - discharged too early

a, b, c: AE No. followed by "a" or "b" or "c" indicates the same client with multiple events (i.e. 8a and 8b indicates that this client had two AEs)

CTS: Community Therapy Services, which provides occupational and physical therapy (OT/PT) services for WRHA Home Care. When CTS referral/assessment is mentioned, the reviewer was indicating an OT/PT referral/assessment.