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Assessing adverse events among home care clients in three Canadian provinces using chart review

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ABSTRACT

Objectives The objectives of this study were to document the incidence rate and types of adverse events (AEs) among home care (HC) clients in Canada; identify factors contributing to these AEs; and determine to what extent evidence of completion of incident reports were documented in charts where AEs were found.

Methods This was a retrospective cohort study based on expert chart review of a random sample of 1200 charts of clients discharged in fiscal year 2009–2010 from publicly funded HC programmes in Manitoba, Quebec and Nova Scotia, Canada.

Results The results show that 4.2% (95% CI 3.0% to 5.4%) of HC patients discharged in a 12-month period experienced an AE. Adjusting to account for clients with lengths of stay in HC of less than 1 year, the AE incidence rate per client-year was 10.1% (95% CI 8.4% to 11.8%); 56% of AEs were judged preventable. The most frequent AEs were injuries from falls, wound infections, psychosocial, behavioural or mental health problems and adverse outcomes from medication errors. More comorbid conditions (OR 1.15; 95% CI 1.05 to 1.26) and a lower instrumental activities of daily living score (OR 1.54; 95% CI 1.16 to 2.04) were associated with a higher risk of experiencing an AE. Clients' decisions or actions contributed to 48.4% of AEs, informal caregivers 20.4% of AEs, and healthcare personnel 46.2% of AEs. Only 17.3% of charts with an AE contained documentation that indicated an incident report was completed, while 4.8% of charts without an AE had such documentation.

Conclusions Client safety is an important issue in HC, as it is in institutionalised care. HC includes the planned delivery of self-care by clients and care provision by family, friends and other individuals often described as 'informal' caregivers. As clients and these caregivers can contribute to the occurrence of AEs, their involvement in the delivery of healthcare

interventions at home must be considered when planning strategies to improve HC safety.

INTRODUCTION

Problems of client safety have been well investigated in acute care hospital settings, and, to a lesser extent, in long-term care, emergency room and primary care.^{1–5} However, only a few studies have used a similar approach to safety issues among home care (HC) clients. The studies of HC clients are limited with regard to small sample size^{6 7} population studied (eg, long-stay clients)^{7 8} and types of harm (eg, when only physical harm is examined).⁶

Client safety is usually assessed by measuring the incidence of adverse events (AEs). An AE has been defined as 'an event that results in unintended harm to the client by an act of commission or omission rather than by the underlying disease or condition of the client'.⁹

HC includes the provision of health-care interventions to clients of all ages (birth to extreme old age), for the purposes of providing curative, supportive, palliative and rehabilitation care for acute and longer term illnesses and conditions. HC differs from the hospital setting in terms of the nature of formal service provision, the inclusion of clients and family members in the direct provision of healthcare interventions, and the characteristics of the client receiving care.¹⁰ The aging of the population with concomitant increases in the prevalence of chronic conditions, combined with the need for healthcare authorities to find models of care that are more sustainable than institutionalised care, makes it likely that use of HC services will increase considerably in the coming years. For example, in Canada there was a 51%

increase in the number of HC clients from 1997 to 2007, with over 900 000 individuals receiving HC services in 2007.¹¹ Improving the safety of HC becomes more crucial given this rising utilisation and intensity of services provided in the home.

One of the first Canadian HC client safety studies reported a 5.5% annual incidence rate of AEs in a sample of 400 Winnipeg HC clients, of which injurious falls accounted for nearly half (46%).⁷ Two recent studies, one conducted in the USA¹² and one in Canada,⁶ found that 13% of HC clients experienced an AE. The two Canadian studies were limited in sample size, and each involved only one jurisdiction. The US study was based on clinical-administrative data not specifically designed to assess client safety.¹² Clinical-administrative databases constitute rich and cost-efficient sources of information on clients and services provided, but they have limitations in terms of the detail they can provide regarding the nature of AEs and contributing causes.⁸ Incident reports filed by healthcare staff are another means of documenting problems of quality but they have been found to under-report safety events, at least in institutional settings.^{13–15}

One more characteristic that distinguishes HC from hospital care, and has an impact on the calculation of the rate of AEs is the duration of care. The common way to calculate an AE rate in acute care hospitals is to assess the proportion of patients who experienced an AE, without necessarily taking into consideration the length of stay, which does not vary considerably across patients.^{1–5} However, since HC can be as short as a few days or lasts several years, it is more important to consider the length of ‘exposure’: the risk of experiencing an AE is likely to be higher in clients receiving HC for a full year than in those who were cared for only a few days. However, past HC studies did not fully take that reality into account while calculating AE rates.^{6 12}

This study attempted to fill these gaps by using data from client health records (or charts) to assess AEs and calculate an AE incidence rate per client-year.

The objectives of this study were to document the incidence rate and types of AEs among HC clients in three Canadian provinces in different regions of the country: Western Canada (Manitoba), Central Canada (Quebec) and Eastern Canada (Nova Scotia); identify the factors contributing to AEs among HC clients; and determine to what extent evidence of completion of incident reports was documented in charts where AEs were found.

METHODS

Definitions

The following definition of an AE for HC clients was adapted from that used in international studies of hospital AEs and a recent Canadian study of HC AEs: *an unintended physical, mental or social injury, harm or*

complication that results in disability, death or increased use of healthcare resources, and that is caused by health care rather than by the client’s underlying disease process.^{1–6} In the context of HC, ‘healthcare’ includes three sources of care: (paid) healthcare providers, (unpaid) informal caregivers and self-care (care provided by the clients themselves). An AE can be caused by an act of commission (eg, inadequate treatment plan or poorly executed treatments) or of omission (eg, missed diagnosis, failure to treat).

Study design and setting

This was a retrospective cohort study based on a review of charts of clients receiving publicly funded HC services in Manitoba, Quebec and Nova Scotia. In Manitoba, data were examined for clients receiving services under the responsibility of the Winnipeg Regional Health Authority, the largest city and major population centre for the province. In Quebec, publicly funded HC is provided by Health and Social Services Centers (CSSS). Due to budgetary limitations, only CSSSs in regions located within 260 km from Montreal (the provincial research coordination centre) were included in the sampling frame; this includes 10 of the 18 health regions in the province comprising about 90% of the Quebec population. Because Montreal is the most populous health region, five CSSSs were randomly selected out of its 12 CSSSs. In addition, five regions were randomly selected from the nine remaining regions and one CSSS was randomly selected from each of those five regions, for a total of 10 CSSSs in Quebec. In Nova Scotia, clients who received services provided by the Victorian Order of Nurses (VON) in the Halifax and Cape Breton Island (Sydney) regions were eligible for inclusion; these regions include the majority (57%) of the population of the province. All selected sites agreed to participate in the study and to provide access to client charts. Ethics approvals were obtained from the University of Manitoba, the Winnipeg Regional Health Authority, the University of Montreal, Dalhousie University, VON and each Quebec participating CSSS that required it.

Case selection and sample

Using a 95% confidence level and an estimated AE incidence of 13% (the highest rate reported in recent studies), a sample of 1200 charts provides a margin of error of 1.84% (Roasoft Inc sample size calculator) and allows for the identification of a sufficient number of AEs and the analysis of risk factors. Consistent with this parameter, the target study sample was 1200 cases, including 300 from the Winnipeg region, 600 from Quebec (60 from each of the 10 CSSSs) and 300 from Nova Scotia (150 from each of the two regions). In each of the study sites a random sample of clients who were discharged from the publicly funded HC programme in fiscal year

2009–2010 (1 April 2009–31 March 2010) was selected. If a client was discharged more than once in the period, the first discharge (considered the index admission) was selected. Exclusion criteria were discharged outside of the study range, cases in which no HC services were initiated, and/or where the HC services provided were not directed towards the client (eg, services were a direct support to a family caregiver). Charts were randomly selected in each province until the required numbers were obtained. In total, 1200 valid charts were reviewed. The sampling cascade is shown in figure 1.

Data collection

The format and approach to charting across the sample sites varied, but generally all charts included administrative data consistent with client identification; social data describing living situations; clinical data including healthcare history, diagnoses and medication use; and clients' physical, cognitive and interpersonal functional statuses (table 1 and see online supplementary appendix table 1). The charts were specific to the clients' HC and were compiled and

maintained by HC case managers or nurses; charts were not physician records or cross-sector healthcare electronic records. Entries were made on a daily, weekly, monthly or other schedule depending on the protocols required by the HC programme.

Selected charts were reviewed using an adaptation for HC of the standard method developed for hospital chart review,^{1–5} a method used in the recent study in Ontario Canada.⁶ Chart review forms, adapted from Sears *et al*⁶ were computerised and installed on portable computers. Chart review was carried out on the premises of each HC agency. The review process was performed in two stages. In the first stage, each selected HC chart was assessed by one member of a team of trained nurses for the presence of one or more of 24 screening criteria potentially sensitive to the occurrence of an AE (table 2) and used in the Ontario study.⁶ As reported by Sears *et al*⁶ these criteria were adapted from those applied in hospital AE studies, modified and validated through an expert Delphi process, and then tested for validity. Nurse reviewers also recorded information on the clients' demographics, functional status (activities of daily

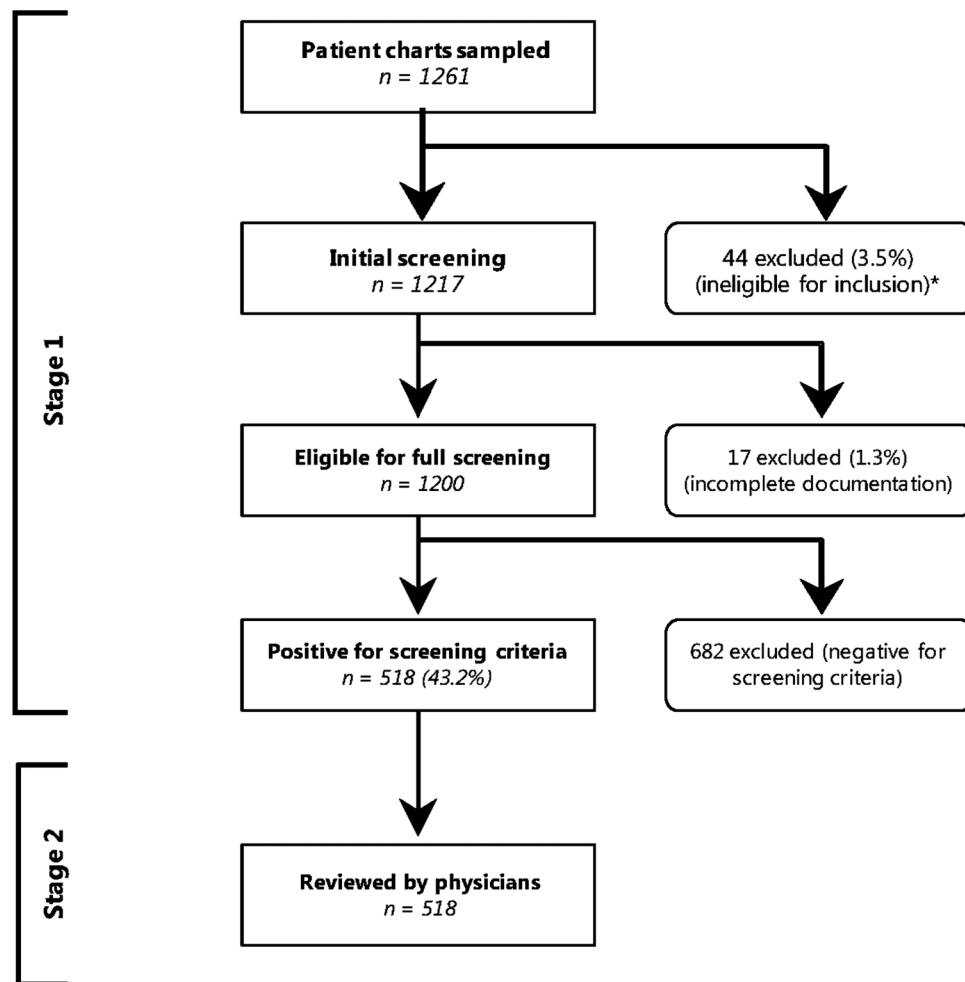


Figure 1 Sampling cascade. *Reasons for ineligibility were dates outside of study range; no home care episode; or home care service request was for informal caregiver.

Table 1 Characteristics of clients with or without AE (selected variables)†

Characteristic	Adverse events			p Value*
	No	Yes	Total	
Age (years)	71.20	75.93	71.52	0.016
Difficulty with communication later on during index admission (%)‡	14.46	23.75	15.10	0.025
Difficulty with communication at intake or later on during index admission (%)	15.35	24.05	15.94	0.041
Cognitive patterns problems (out of 3)§	0.65	1.12	0.68	0.004
Communication problems (out of 4)	0.71	0.96	0.72	0.017
Mood and behaviour problems (out of 2)	0.31	0.49	0.32	0.022
IADL (1 independent, 4 dependent)	2.35	2.82	2.39	0.000
IADL (% independent)	43.9	27.4	42.6	0.000
ADL (1 independent, 4 dependent)	1.63	1.86	1.65	0.015
ADL (% independent)	68.5	59.3	67.8	0.011
Client functional status has deteriorated during admission (%)	24.88	56.79	27.11	0.000
Pain (%)	55.57	75.38	57.01	0.002
History of falls (%)	30.00	43.84	31.09	0.014
Medications: number of prescriptions and over-the-counter meds:				
None	33	2	35	
1–3	154	9	163	
4–9	532	36	568	
>9	267	34	301	
Total	986	81	1067	0.015
Number of comorbid conditions (out of 32)	3.94	5.56	4.05	0.000
Cardiac and vascular disease (out of 7)	1.37	2.01	1.41	0.000
Transient ischaemic attack	0.08	0.15	0.08	0.032
Coronary artery disease	0.21	0.40	0.22	0.000
Hypertension	0.50	0.67	0.51	0.004
Neurological				
Other dementia	0.07	0.17	0.08	0.002
Infections (out of 5)	0.25	0.53	0.27	0.001
Pneumonia	0.07	0.14	0.07	0.018
Urinary tract infection	0.06	0.20	0.07	0.000
Other infection	0.11	0.20	0.12	0.026
Diabetes	0.26	0.38	0.26	0.012
Respiratory (out of 2)	0.18	0.33	0.19	0.020
Emphysema/chronic obstructive lung disease	0.12	0.25	0.13	0.001
Other comorbid conditions not noted above	0.59	0.70	0.60	0.045

*p Value indicates significant difference between cases with and without adverse event, based on χ^2 test for categorical variables and t test for continuous variables. None of the p values correct for multiple comparisons.

†This table presents only the statistically significant variables. See online supplementary appendix table 1 for all tested variables.

‡Indicates the percentage of clients with this characteristic.

§Indicates the average number of problems or conditions in this category.

living (ADL); instrumental ADL (IADL)) and comorbid conditions (presence/absence). Ordinal ADL scores (1–4) were calculated as the sums of the scores on each item (1=independent; 2=with difficulty; 3=assistance; 4=dependent) divided by the number of items.¹² IADL scores (1–4) were calculated the same way. A higher score thus meant a higher level of functional impairment.

In the second stage, charts that were positive for at least one screening criterion were reviewed by one member of a team of trained physicians experienced in HC. An AE was identified when a physician

reviewer determined that all three AE criteria were met: there was an injury and the client experienced disability, death or increased use of services, and it was likely caused by healthcare (ie, the causation rating was at least four: more than a 50% likelihood of being caused by healthcare). To make this determination, physician reviewers first assessed whether the client suffered any unintended injury, harm or complication. If there was no injury, the review process stopped. If there was an injury reviewers determined if the injury resulted in disability, death or increased use of healthcare services (eg, intensified or prolonged

Table 2 Screening criteria in the stage 1 review

Criterion	Charts with criterion		Adverse event charts with criterion		χ^2 †	
	N	%‡	N	%§		
1	Unplanned admission (including readmission) to home care within the 6 months after discharge from index admission	57	4.8	13	16.0	**
2	Request for admission (denied or wait-listed) to home care within the 6 months after discharge from index admission	3	0.3	0	0.0	
3	Recognised actual or potential environmental risks	108	9.0	12	14.8	
4	Recognised actual or potential risks related to client behaviour	115	9.6	19	23.5	**
5	Inappropriate/inaccurate home care or service provider assessment of client	11	0.9	0	0.0	
6	New problem/diagnosis noted during index admission	243	20.3	38	46.9	**
7	Client injury, harm, trauma or complication during home care admission	182	15.2	34	42.0	**
8	Unplanned assessment/treatment by primary care provider during index admission	67	5.6	17	21.0	**
9	Unplanned visit to hospital emergency department during index admission	279	23.3	49	60.5	**
10	Unplanned admission to acute care hospital during index admission	242	20.2	31	38.3	**
11	Unplanned admission/request for admission to long-term care facility	45	3.8	3	3.7	
12	Adverse drug reaction during index admission	7	0.6	4	4.9	**
13	Acquired infection/sepsis	115	9.6	32	39.5	**
14	Development of neurological deficit not present on admission but present at the time of discharge from the index home care stay	8	0.7	2	2.5	*
15	Emotional or psycho-social problem in patient or informal caregiver	44	3.7	9	11.1	**
16	Unexpected death:	37	3.1	2	2.5	
17	Other client complications, for example, AMI, CVA, PE, DVT, etc	101	8.4	12	14.8	*
18	Expected family/informal caregiver availability for client assistance not realised	17	1.4	4	4.9	**
19	Dissatisfaction with care documented in the client record and/or evidence of complaint lodged	17	1.4	1	1.2	
20	Adverse event reported by a caregiver	50	4.2	8	9.9	**
21	Documentation or correspondence indicating litigation, either contemplated or actual	1	0.1	0	0.0	
22	Inappropriate discharge/inadequate discharge plan for index admission	2	0.2	0	0.0	
23	Unplanned admission to any hospital within the 6 months after discharge from index admission	21	1.8	4	4.9	**
24	Any other undesirable outcomes not covered above	7	0.6	0	0.0	
Mean number of criteria per chart		3.40		3.63		

* $p < 0.05$; ** $p < 0.01$.

† χ^2 indicates the association between the presence of a criterion and the risk of an adverse event.

‡Out of 1200 fully audited charts.

§Out of 81 charts with adverse events.

AMI, acute myocardial infarction; CVA, cerebrovascular accident (stroke); DVT, deep vein thrombosis; PE, pulmonary embolus.

HC, additional treatment, medical consultations, emergency room visit, hospital admission). Finally, the physician reviewers used the six-point scale (1 = virtually no evidence of healthcare causation; 2 = slight to modest evidence of healthcare causation; 3 = healthcare causation not likely (less than 50/50, but ‘close call’); 4 = healthcare causation more likely (more than 50/50, but ‘close call’); 5 = moderate to strong evidence of healthcare causation; 6 = virtually certain evidence of healthcare causation), employed in previous studies,^{1–6} to determine the extent to which healthcare (whether by paid healthcare providers, informal caregivers or the client), rather than the clients’ disease processes, was responsible for the

injury. Physician reviewers also judged the preventability of each AE using the 6-point scale (1 = virtually unpreventable; 2 = slight to modest preventability; 3 = preventability not quite likely (less than 50/50, but ‘close call’); 4 = preventability more than likely (more than 50/50, but ‘close call’); 5 = strongly preventable; 6 = virtually certain for preventability) also used in previous studies.^{1–6}

After each day of chart review, nurses and physician reviewers transferred data to a secure web depot at the coordinating research centre at the University of Montreal. At both stages of the review process, interrater reliability was also assessed on a random sample of 10% of the charts using the κ statistic.¹⁶

Agreement between nurses for the first stage of the review process (presence of a screening criterion) was moderate ($\kappa=0.58$). Agreement between physicians for the second stage of the review ranged from fair for the determination of whether an injury had occurred ($\kappa=0.35$) to excellent for the determination of whether the injury had a consequence ($\kappa=1.0$).¹⁶

Reviewers looked for AEs that occurred during the HC index admission and that were detected during either the index or during subsequent HC admissions over the 6-month period after discharge from the index admission. Since HC length of stay can be very long, they also limited identification of AEs to the 12 months preceding discharge from the index admission. Only information present in the HC charts could be used; information in hospital charts or elsewhere was not available unless mentioned in the HC charts.

Data analysis

Descriptive analysis was used to document client characteristics and AEs. The AE rate was calculated as the proportion of charts in which at least one AE was found (as done in other studies) and as the incidence rate per client-year (number of AEs over the total length of stay of all clients divided by 365); both rates were weighted for the sampling strategy. The sampling weights were based on inverse probability of being included in the sample for each province (Manitoba, Quebec and Nova Scotia). For Quebec and Nova Scotia, the weights were based on a stratified sampling by region. For Manitoba, the weights were based on a simple random sample.¹

Bivariate analysis and forward stepwise multivariate logistic regression were used to identify factors associated with the risk of having an AE. In addition to age and sex, the following variables that were significant in bivariate analysis were tested in the multivariate regression: number of comorbid conditions; number of medications; length of stay; ADL score (1–4); IADL score (1–4); communication; mood; and cognitive problems.

RESULTS

Of the 1200 charts that were reviewed by nurses, 518 (43.2%) were positive for at least one screening criterion. Two-thirds of criteria were found to be associated ($p<0.05$) with finding an AE in the chart (table 2). The five most prevalent screening criteria identified in charts with an AE were: unplanned visit to hospital emergency department during index admission ($n=49$, 60.5%); new problem/diagnosis noted during index admission ($n=38$, 46.9%); client injury, harm, trauma or complication during HC admission ($n=34$, 42%); acquired infection/sepsis ($n=32$, 39.5%); and unplanned admission to acute care hospital during index admission ($n=31$, 38.3%).

The results show that 417 of the 518 clients were found to have experienced 715 injuries (first criterion of the AE definition); 409 of the 417 clients injured had resulting disability, death or increased use of healthcare resources (second criterion of the definition). The third AE criterion (caused by healthcare rather than by the client's underlying disease process) was identified 93 times (ie, there were 93 AEs) across 81 clients. Most (71 of 81) clients had only one AE; nine clients experienced two AEs and one client experienced four AEs. After weighting for the sampling strategy, the overall AE rate (proportion of clients with AEs=81/1200) was 4.2% (95% CI 3.0% to 5.4%); 56% ($n=52$) of the 93 AEs were judged preventable by the physician reviewers. Adjusting the analysis to account for clients with lengths of stay on HC of less than 1 year, the AE incidence rate per client-year was 10.1% (95% CI 8.4% to 11.8%).

Table 3 presents the types of AEs suffered by clients. The most frequent AE was an injurious fall ($n=16$, 17.2%), but medication was involved in 21.5% ($n=20$) of AEs, whether it was related to an injurious fall ($n=4$) or another type of AE. Wound infections ($n=13$, 14%) and psychosocial, behavioural or mental health problems ($n=11$, 11.8%) were also frequent.

In terms of potential impact, 91.4% ($n=85$) of AEs were associated with an increased use of healthcare resources, 68.8% ($n=64$) with client disability and 7.5% ($n=7$) with death. More than one impact for each AE was possible. Healthcare personnel were

Table 3 Types of adverse events (injuries)

Adverse event	N	%
Fall injury	16	17.2
Wound infection	13	14.0
Psychosocial, behavioural, mental problem	11	11.8
Medication problem (adverse drug reaction)*	6	6.5
Pressure ulcer	6	6.5
Other wound problem	4	4.3
Non-wound infection	4	4.3
Syncope or seizure	4	4.3
Delayed wound healing	3	3.2
Shortness of breath	3	3.2
Skin tear or laceration	3	3.2
Hypo/hyperglycaemia	3	3.2
Gastrointestinal problem	3	3.2
Intravenous site problem	3	3.2
Fracture	2	2.2
Bleeding—minor	2	2.2
Other	7	7.5
Total	93	100

*In addition to the six cases of medication problems that correspond to direct adverse drug reactions, there were 14 cases among the other listed injuries in which medication was involved, including four injurious falls, for a total of 20 (21.5%) adverse event positive cases.

judged by physician reviewers to have contributed to the occurrence of the AE (a rate of 4 or higher on the six-point causation scale) in 46.2% (n=43) of AEs, informal caregivers in 20.4% (n=19) of AEs and clients in 48.4% (n=45) of AEs. Two or three of those types of people were involved in 14% (n=13) of AEs.

Some characteristics of clients who experienced an AE differed significantly compared with non-AE clients. The characteristics significantly ($p \leq 0.05$) related to AEs are age, difficulty with communication, cognitive problems, mood and behaviour problems, IADL and ADL scores, functional status, pain, history of falls, number of medications and number of comorbid conditions (Table 1 presents the statistically significant variables; online supplementary appendix table 1 presents all variables tested). When these significant characteristics were tested together in a logistic regression analysis, only two remained statistically significant: the number of comorbid conditions which increased the risk of experiencing an AE by 15% for each additional comorbid condition a client had (OR 1.15; 95% CI 1.05 to 1.26); and the IADL score when the risk of having an AE increased by 54% with each increase in level of the four-point IADL score (ie, as the client becomes more dependent) (OR 1.54; 95% CI 1.16 to 2.04). The final model is shown in Table 4; its strength is reflected by the C statistic (0.672; 95% CI 0.613 to 0.732) and the goodness of fit ($p=0.659$).¹⁷

Finally, in the first stage of review, nurse reviewers checked if there was indication in the chart that an incident report was filled out by healthcare professionals. Only 17.3% (n=14) of the 81 charts in which an AE was found contained documentation of an incident report, while 4.8% (n=54) of charts without an AE did. More specifically, for the most common types of AEs, documentation regarding incident report generation was present in 6.2% (n=1) of charts with a fall injury, 7.7% (n=1) of charts with a wound infection, 27.3% (n=3) of charts with a psychosocial, behavioural or mental health problem and 33.3% (n=2) of charts in which a medication problem was found.

DISCUSSION

This is the first study to assess AEs among HC clients across different regions of Canada using chart review. In contrast with some previous studies^{7 18 19} we considered all age groups, all medical conditions and all types of AEs, including psychosocial and mental-health-related AEs. We found that the proportion of clients who experienced an AE was 4.2% (95% CI 3.0% to 5.4%). This rate is much lower than the 13% found in Ontario⁶ and in the USA.¹² However, we went beyond the calculation of a simple proportion of clients experiencing an AE: we took into consideration the 'exposure' time of clients, that is, the length of HC stay, and calculated an AE incidence rate per client-year. We think this measure is an improvement on previous calculations and should be applied in future studies. Our AE incidence rate per client-year was 10.1% (95% CI 8.4% to 11.8%). This is higher than the annual incidence rate of 5.5% observed in Winnipeg.⁷ These different rates may be due to differences in HC services, client characteristics and/or the methods used to assess the charts.⁶

Injurious falls were among the most common AEs found in this study and in other studies whether the methodology was based on chart review^{6 7} or secondary data analysis.⁸ We noted a particular issue with medication problems. Medication errors can cause direct and immediate adverse drug reactions (eg, rash) and we found six such cases among the 93 AEs. However, we were able to identify 14 additional cases in which a medication error contributed to another type of AE (eg, a medication caused dizziness that provoked a fall; a client refused to take prescribed medication and developed a psychotic episode). The role of medication in such AEs cannot be established by analysing secondary data alone; this underlines the need for expert review of client charts to identify the causal chain, provided sufficient information is available in the charts.

Our study shows that clients with more comorbid conditions (ie, more complex cases) and those who had a higher score for IADL, (ie, those who were more functionally vulnerable), were at greater risk of experiencing an AE. This finding is consistent with

Table 4 Multiple logistic regression of variables associated with the risk of experiencing an adverse event

Variable*	Wald	p Value	Exp (B)	95% CI	
				Low	High
Number of comorbid conditions	8.879	0.003	1.15	1.05	1.26
IADL score†	8.694	0.003	1.54	1.16	2.04
Intercept	101.805	0.000			
C statistic=0.672 (95% CI 0.613 to 0.732)					
Goodness of fit: p=0.659					

*Variables tested were age, sex, number of comorbid conditions, number of medications, length of stay, ADL score, IADL score, communication, mood and cognitive problems.

†IADL, instrumental activities of daily living. Score ranged from 1 (independent) to 4 (dependent).

the results of other studies of HC safety^{6 12} and hospital safety.¹ However, beyond clients' conditions, being cared for at home poses particular challenges for client safety since a significant portion of care is provided by the clients themselves and their caregivers, and not by healthcare professionals. This is reflected in the physician reviewers' determination that clients contributed to the occurrence of 48.4% of AEs, informal caregivers to 20.4% of AEs, while healthcare personnel contributed to the causation of 46.2% of AEs. This tri-partite contribution to AE causation is consistent with the findings of the Ontario study⁶ of contributing sources and suggests that safety in HC is dependent upon clients and informal caregivers being aware of risks and possessing the skills to mitigate those risks, as well as HC staff. The complex dynamic of care that occurs when providing service in the home may not be as easily amenable to risk reduction as care in more controlled care environments, such as hospitals. This study provides HC programmes with the evidence of where the incidence of AEs is greatest and what the consequences can be. The results can help effectively target education for staff, clients and informal caregivers to improve safety procedures and quality of care.

Our study showed that a small minority of charts (17.3%) in which an AE was found contained documentation that an incident report was filled out by healthcare professionals. This low proportion may be due to the fact that including an incident report (or a copy of it) in a client chart might not be compulsory in all HC programmes or that the incident reporting system does not allow for the linkage of incident reports with client charts. However, in at least one of the provinces studied here there is a requirement to place a copy of the incident report in the chart but the documentation of incident reports in charts with an AE was still low (14.8%). Beyond organisational policies, many reasons have been proposed to explain low incident reporting in institutionalised settings, including unclear or inadequate forms, lack of feedback on reporting, fear of personal consequences and lack of time to fill out forms.^{20–22} These same factors might apply in HC. In addition, the fact that 4.8% of cases without an AE contained evidence that an incident report was completed suggests that what is reported does not necessarily correspond to the definition of an AE that was used in this study and that HC programmes may have different criteria for generating incident reports. This finding also suggests that it would be beneficial for HC agencies to develop a national standard for what the processes for reporting AEs should be.

This study has a number of limitations. First, as with most other studies that used the same two-stage review method, charts that were not screened positive by nurses were not reviewed by physicians. It is thus possible that some of these cases may have

experienced an AE, yet the list of screening criteria used was quite extensive; thus the likelihood that a chart without any of these criteria contained information indicating that there was an AE may be quite low, however human factors such as reviewer fatigue and temporal trending may affect the sensitivity with which the screening criteria were identified. Second, it is possible that information relevant to client safety may not be present in client charts either because healthcare providers are not always present with the client and hence do not observe an AE, or they are not mandated to record it in the chart. Third, although inter-rater reliability was comparable to that of other HC⁶ or hospital studies^{1 3 5} using the same methodology, it was far from perfect on some dimensions. This suggests that professional judgment was not clear cut based on documentation available and given the complexity of care environment/dynamics of providing care in the home. Fourth, the fact that the number of cases with each type of AE was rather low limits the possibility of finding specific risk factors. For example, the risk factors associated with injurious falls is probably different from those associated with wound infections. Our analysis combined all AEs. A much larger sample would be needed to assess the risk factors associated with each type of AE and the specific actions that might reduce the likelihood of AEs occurring. Fifth, not all information regarding other types of healthcare received by HC clients (eg, physician and pharmacist care) was available in the charts, so it was not possible to detect all AEs that led to emergency room visits or hospital admissions. An inter-sectoral electronic client chart that records a more complete history of healthcare use (including physician visits, emergency room visits, acute care and long-term care facility admissions) would allow for a better assessment of client care safety.

This study has expanded the breadth of safety in healthcare research by providing evidence of AEs that are relevant to HC. However, HC programmes vary across Canadian provinces in many ways (eg, governance and organisation, services, including roles of professional and non professional staff, quality and accountability, conceptions of safety, etc.).¹¹ Future research should document the programmes' specific elements and attempt to link them with indicators of AEs to identify which components of care in which contexts are safer for clients. This would help programmes select actions to take to improve HC safety.

CONCLUSION

Client safety is an important issue in HC just as it is in institutionalised care. Sicker and more dependent clients are at a higher risk of experiencing an AE and special attention should be devoted to these subgroups. Moreover, unlike institutional settings, homes are not designed for healthcare and are not regulated environments; and healthcare personnel are not

present on a continuing basis.²³ These environmental factors may contribute to risks that HC clients encounter. The important role in HC of clients themselves and of their unpaid caregivers must be taken into consideration when planning strategies to improve HC safety.

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Appendix Table 1. Characteristics of clients with or without AE (all variables tested)

Characteristic	Adverse events			
	No	Yes	Total	p-value ¹
Sex: Proportion of Female (%) ²	59.87	54.32	59.50	0.325
Age (years)	71.20	75.93	71.52	0.016
Client was at private home/apt before home care admission (%)	54.78	55.56	54.83	0.892
At the time of index admission, living alone (%)	37.44	33.33	37.17	0.460
Number of key informal helpers:				
None	83	3	86	
1-2	868	76	944	
3 or more	41	2	43	
Total	992	81	1073	0.318
Length of stay (days)	347.31	465.60	355.30	0.089
Difficulty with communication at intake of index admission (%)	12.34	21.25	12.95	0.220
Difficulty with communication later on during index admission (%)	14.46	23.75	15.10	0.025
Difficulty with communication at intake or later on during index admission (%)	15.35	24.05	15.94	0.041
Discharge alive from index admission (%)	88.74	82.72	88.33	0.103
Significant procedure performed before admission (%)	29.94	23.46	29.50	0.217
Cognitive patterns problems (out of 3) ⁴	.65	1.12	.68	0.004
Communication problems (out of 4)	.71	.96	.72	0.017
Mood & Behaviour problems (out of 2)	.31	.49	.32	0.022
IADL score = (1 independent, 4 dependent)	2.35	2.82	2.39	0.000
IADL (% independent)	43.9	27.4	42.6	0.000
ADL (1 independent, 4 dependent)	1.63	1.86	1.65	0.015
ADL (% independent)	68.5	59.3	67.8	0.011
Client functional status has deteriorated during admission (%)	24.88	56.79	27.11	0.000
Pain (%)	55.57	75.38	57.01	0.002
History of falls (%)	30.00	43.84	31.09	0.014
Notation of environmental home hazard (%)	16.25	24.64	16.86	0.073
Psychotropic medications (%)	26.39	32.05	26.82	0.278
Medications: Number of prescriptions & over-the-counter meds:				
None	33	2	35	
1-3	154	9	163	
4-9	532	36	568	
>9	267	34	301	
Total	986	81	1067	0.015

Appendix Table 1. Characteristics of clients with or without AE (all variables tested) (cont.)

Characteristic	Adverse events			
	No	Yes	Total	p-value ²
Number of comorbid conditions (out of 32)	3.94	5.56	4.05	0.000
Cardiac and vascular disease (out of 7)	1.37	2.01	1.41	0.000
Cerebrovascular accident (stroke)	.11	.17	.12	0.097
Transient ischemic attack	.08	.15	.08	0.032
Congestive heart failure	.09	.15	.09	0.079
Coronary artery disease	.21	.40	.22	0.000
Hypertension	.50	.67	.51	0.004
Peripheral vascular disease	.08	.10	.09	0.645
Other cardiac/vascular disorder	.29	.38	.30	0.093
Neurological (out of 6)	.19	.31	.20	0.068
Alzheimer	.05	.07	.05	0.345
Other dementia	.07	.17	.08	0.002
Acute brain injury	.01	.01	.01	0.953
Hemiplegia/hemiparesis	.04	.05	.04	0.782
Quadraplegia/quadraparesis	.01	0.00	.01	0.475
Multiple sclerosis	.01	0.00	.01	0.370
Senses (out of 2)	.17	.16	.17	0.856
Cataract	.13	.12	.13	0.965
Glaucoma	.04	.04	.04	0.773
Psychiatric	.12	.22	.13	0.100
Infections (out of 5)	.25	.53	.27	0.001
HIV	.00	0.00	.00	0.703
Pneumonia	.07	.14	.07	0.018
Tuberculosis	.00	0.00	.00	0.590
Urinary tract infection	.06	.20	.07	0.000
Other Infection	.11	.20	.12	0.026
Hematologic (out of 2)	.12	.11	.12	0.878
Chronic Anemia	.10	.10	.10	0.926
Other hematological disease/condition	.02	.01	.02	0.580
Cancer	.27	.25	.27	0.690
Diabetes	.26	.38	.26	0.012
Parkinson	.02	.04	.02	0.224
Musculoskeletal (out of 3)	.41	.51	.42	0.166
Arthritis	.25	.31	.26	0.259
Hip fracture	.05	.06	.05	0.728
Other fracture	.10	.14	.11	0.364
Respiratory (out of 2)	.18	.33	.19	0.020
Emphysema/Chronic obstructive lung disease	.12	.25	.13	0.001
Asthma	.06	.09	.06	0.338
Other comorbid conditions not noted above	.59	.70	.60	0.045

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1. p-value indicates significant difference between cases with and without adverse event, based on Chi-square test for categorical variables and t-test for continuous variables.
None of the p-values correct for multiple comparisons.
 2. Indicates the percentage of clients with this characteristic.
 3. Indicates the average number of problems or conditions in this category.