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Title

Measuring Falls Events in Acute Hospitals – A Comparison of Three Reporting Methods to Identify Missing Data in the Hospital Reporting System

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ABSTRACT

Objectives: to compare three different methods of falls reporting and examine the characteristics of the missing data from the hospital incident reporting system.

Design: 14 month prospective observational study, nested within a randomized controlled trial.

Setting: Rehabilitation, stroke, medical, surgical and orthopaedic wards in Perth and Brisbane, Australia.

Participants: Fallers (n=153) who were part of a larger trial [n=1206 participants, mean age $75.1 \pm (11.0)$].

Measurements: Three falls events reporting measures - participants' self report of falls events, falls events reported in participants' case notes and falls events reported through the hospital reporting systems.

Results: There were 245 falls events identified in total by the three reporting systems. Participants' case notes captured 226 (92.2%) falls events, hospital incident reporting systems captured 185 (75.5%) falls events and participants' self report captured 147 (60.2%) falls events. Falls events were significantly less likely to be recorded in hospital reporting systems when a participant sustained a subsequent fall, (P=.01) or when the fall occurred in the morning shift (P=.01) or afternoon shift (P=.01).

Conclusion: Falls data that are missing from hospital incident report systems are not missing completely at random and therefore will introduce bias in some analyses where the factor investigated is related to whether the data is missing. Multimodal approaches to collecting falls data are preferable to relying on a single source alone.

Key words: incident reporting, accidental falls, hospitals, inpatients

INTRODUCTION

Falls are one of the most common adverse events that occur in hospital patients. Incident reports demonstrate that up to 41% of patient safety incidents in the United Kingdom¹ and 38% of incidents in Australia² are due to slips, trips and falls. Falls are associated with serious adverse outcomes^{3, 4} and since evidence for effective interventions to prevent falls is still limited,^{4, 5} further investigations are a high priority for health systems. But determining the effects of falls interventions outside tightly controlled research trials may be difficult because it has previously been noted that falls events are under-reported.^{6, 7} Presumably this occurs because of barriers to incident reporting that have been identified in other studies⁸⁻¹⁰ including evidence of large variations in the quality of falls reporting at the local level.¹¹ Reporting of falls events may also be reduced by additional specific barriers as falls have different spatio-temporal characteristics to other adverse events.¹² Approximately two thirds of falls are unwitnessed, ^{13, 14} staff may perceive that falls are due to patient factors rather than being a hospital-caused event, staff may disagree as to what actually constitutes a fall¹² and patients themselves may be reluctant to report a fall.⁶

Hospital incident reporting systems such the National Patient Safety Agency^{1, 15} and Adverse Incident Monitoring System¹⁶ have been developed to facilitate reporting and response to adverse events in hospital.¹⁷ However, it is known that despite use of incident reporting systems, the number of adverse events may be underestimated.^{18, 19} In particular, incident reports alone may significantly underestimate falls events in an acute care setting.²⁰ It has been recommended by some that barriers to reporting be addressed,⁸⁻¹⁰ that multiple sources be used to capture adverse events data^{18, 21} and that improvements are required in the quality

of falls reporting as frequency may be substantially underestimated if incident systems are the sole method of collecting data about falls events.^{18, 20, 22}

It could be questioned whether under-reporting constitutes a problem from the perspective of researchers and clinicians trying to monitor fall rates. If the under-reporting of falls is due to a persistent random process unrelated to other factors, then this data could be considered to be "missing completely at random (MCAR)."²³ For example if unreported falls events are not related to another variable (such as patient age, whether they have sustained any injury or which clinical setting they are in) then the analysis used to estimate risk factors or measures of intervention effect may be less powerful but will not be biased. However if apparently random unreporting of falls events is related to another measured variable, the missing data may be classified as "missing at random (MAR)", where the observation being measured is not related to the outcome of interest, after controlling for another variable.²³ For example falls events that are unreported may be related to another variable such as patient age, where staff may be less likely to report falls in younger patients due to a lower perceived risk of injury. Finally data may be "missing not at random (MNAR)" - where unreported falls are related to a factor not observed by the investigator.²³ If unreported falls data are either MAR or MNAR then analysis could lead to biased estimates in investigations of falls risk factors or falls prevention interventions if the reason for the missing data is related to the risk factor or the intervention respectively.²⁴ Given the criteria for MCAR, MAR, and MNAR described above, it is impossible to fully investigate the type of missing data that unreported falls might represent. However, it is still possible to ascertain whether unreported falls data are related to any of the observed variables recorded, and therefore to identify that the missing data are not MCAR.²⁴

The aims of this study were to compare three independent methods of falls reporting (incident system reports of falls events, participant reports of falls events and participant case notes reports of falls events) and to examine whether reporting of falls via the hospital reporting system is associated with either intrinsic factors related to the participant or spatio-temporal factors related to the fall.

METHODS

Design

The design was a prospective, observational study conducted over 16 months nested within a randomized controlled trial (RCT) that investigated the effect of patient education on falls in older hospitalized patients. The protocol for the RCT is described elsewhere.²⁵

Setting

The study was conducted on the geriatric assessment and rehabilitation and orthopaedic units and medical wards of the Princess Alexandra Hospital (PAH), Brisbane, Australia, and the restorative and stroke unit and medical and surgical wards of the Swan Districts Hospital (SDH), Perth, Australia during the period from February 2008 to April 2009.

Participants

The participants for this study were a cohort of fallers who were part of a larger RCT [(n = 1466) eligible patients approached, (n = 1206) subsequently enrolled, 6 participants still in hospital; data for these outliers censored at the time of analysis]. Participants in the RCT were admitted to recruiting wards for a variety of medical problems and were eligible for inclusion in the trial if they were over 60 years of age and they, or their family member or guardian gave written consent. Participants were older patients [mean age 75.1 ± (11.0)], 53.2% were female (n=642) and comprised a variety of admission medical diagnoses including 37.1% with orthopaedic conditions (n=447), 13.9% with pulmonary conditions (n= 168), 8.1% with stroke (n=98), 5.6% with cardiac conditions (n=67), and a range of other diagnoses such as falls, Parkinson's disease, amputations and surgical procedures. Participants' mean level of cognition was 8.3 ± 2.1 [measured using the Short Portable

Mental Status Questionnaire (SPMSQ), range 0 to 10, higher denotes better cognition]²⁶ and 89.9% of participants (n=1085) spoke English as their first language.

Outcome Measures

Three approaches to collection of in-hospital falls were undertaken. These were:

- i. Falls events reported by the participant to the research assistant.
- ii. Falls events recorded in the participants' case notes.
- iii. Falls events reported to the hospital incident reporting system.

There is no gold standard approach to which the three approaches being investigated could be compared. Therefore it was considered that when investigating the proportion of falls recorded through the hospital incident reporting systems, the sum of all three approaches would be considered the gold standard comparator.

The definition of a fall event was the World Health Organisation definition namely: "any event when the participant unexpectedly comes to rest on the ground, floor or another lower level."²⁷ Each fall was also recorded as resulting in injury if an injury was reported by any one of the three reporting methods. Injury was classified as none reported, mild (bruise, pain), moderate (loss of consciousness post fall, dental injury, dislocation, laceration, sutures,) or severe (fracture).

Data were collected on the following potential participant intrinsic risk factors that could influence reporting of falls events: age, gender, medical diagnosis on admission, cognitive status using the SPMSQ²⁶ as well as the number and sequence of falls for each faller, (i.e. if the fall was their first, second or third fall and so on). It was hypothesized that these factors may be related to under-reporting, for example previous qualitative research identified that

staff may be less likely to report a fall if the patient had was older or had a cognitive deficit as it was considered that the patient was "at fault" rather than staff,²⁸ or regarding gender, staff were more likely to report an injurious fall and male patients may be less likely to sustain an injury in a fall.¹³

Falls events data collected were spatio-temporal falls characteristics (ward, time, day of week, location on ward, staff supervision level at time of fall) and subsequent type of injury if any.

Procedure

Prior to the commencement of the trial staff on participating wards received additional training in what constituted a fall and how falls should be reported (that is, recorded via the hospital incident reporting system and recorded in the patient case notes). This consisted of a single session in which staff viewed a 10 minute DVD which visually and verbally gave the definition of a fall²⁷ and subsequently demonstrated the application of the definition using various case simulations.

Consecutive patient admissions to targeted wards were approached for consent to participate in the study. Agreement from a family member or carer was also sought where the patient was identified as having a cognitive impairment. Consenting patients were enrolled in the RCT and allocated into three groups including a control group and two intervention groups. Participants formed a subset of the ward population at any one time and staff were not informed about who was enrolled in the trial.

For direct participant report, each participant was visited by a research assistant (who was

blinded to group allocation) each weekday unless acute illness, investigation or other patient care meant that patient could not be approached by research staff. Participants were asked if they had fallen and details of any fall were recorded. Additionally, immediately prior to discharge, participants were also asked if they had fallen during their admission. All participants' reported falls details were checked for consistency with the participants' case notes. The participants' case notes were also used as a primary source of information about falls events and were reviewed daily or second daily for participants with a short length of stay or twice weekly for participants admitted for longer than two weeks. Additionally each participant's case notes were checked each Monday after the weekend and at discharge to capture any potential delayed entries. Falls recorded in the participants' case notes were also checked with the participant by asking whether they recalled details of the fall. Where a fall was recorded in the notes, at least two research staff would independently review the recorded circumstances and reach agreement on the nature of the data recorded. Any queries on falls data were referred to the site investigators (SM, AMH) and if necessary to the chief investigator THa.

The official hospital incident reporting system at each site forms part of a national confidential voluntary government reporting system.¹⁶ Access to identified data is strictly controlled and de-identified reports are produced for staff at the local level at regular intervals. The system was scanned at the conclusion of the study for any fall related incident reports involving study participants through an electronic search using their unique participant identification number. This resulted in an extensive list of falls incident reports for the cohort confirming the presence (or absence) of an incident report for falls previously identified, as well as potentially identifying any additional falls events that occurred during the study period but were not reported by the participant or recorded in the participants' case

notes.

Statistical Analysis

The characteristics of falls events reported through the incident reporting system alone and through the sum of all three approaches were presented using descriptive statistics (number and percentage where applicable). Participant intrinsic factors and fall-related spatio-temporal characteristics were then entered into univariate logistic regression analyses as independent variables with whether fall events were captured through the incident reporting system being the dependent variable. Each analysis included clustering by participant and use of robust variance estimates to account for multiple observations (falls) by individual participants.

Statistical tests were conducted using Stata SE version 10 software (StataCorp Texas, USA).

Ethics

This study was approved by local hospital ethics committees and The University of Queensland Medical Research Ethics Committee. The main RCT was registered with the Australian Clinical Trials registry- registration number (ACTRN12608000064303).

RESULTS

There were 153 participants in the RCT who fell, and 245 falls were recorded using all three collection methods.

The number of falls recorded through each reporting approach and commonality across approaches is presented through a Venn diagram (Figure 1). Falls reported in the incident reporting system (n=185) comprised 75.5% of all falls events recorded, falls events in participants' case notes (n=226) comprised 92.2% of falls events recorded and participant reports of falls (n=147) comprised 60.1% of falls events recorded.

Outcomes from univariate logistic regression analyses comparing falls events reported through the hospital incident system with falls events not reported by the incident reporting system (i.e. captured only by patient case note review or patient self-report) and the spatiotemporal characteristics and participant risk factors are presented (Table 1).

Falls reported in the hospital incident reporting were less likely to include falls subsequent to the first by individual participants (P=.01) and were significantly less likely to include falls that occurred during the morning (P=.01) or afternoon nursing shifts (P=.01). Within these shifts, falls events were significantly less likely to be reported between 6 and 10 am (P=.04) and 2 and 6 pm (P=.04). There were no other significant associations between participant intrinsic factors or fall-related spatio-temporal factors investigated and whether the fall was recorded on an incident report. When a fall resulted in moderate or severe physical injury it was significantly more likely to be recorded on an incident report (P=.03).

DISCUSSION

The lower incidence of falls reporting in the hospital system is in keeping with other studies and opinions that falls are considerably underreported.^{6,19,20} The Australian hospital incident reporting systems in this study only captured 75% of falls events including 78% of injurious falls, even though this study was preceded by a period of staff training to enhance consistency in reporting of falls. A previous study found that less than 50% of falls events in this study could through incident reporting systems.¹⁹ The increased capture of falls events in this study could be explained by staff training, increased falls reporting practice due to awareness of the trial or differences between the United Kingdom and Australia and may suggest that falls underreporting is still not fully explained. The usefulness of any reporting system is that information needs to be correctly classified as to what, where, and how medical management is incorrect to allow preventative and corrective strategies to be developed.^{16, 22} Routine auditing of patients' case notes (which in this study captured 92.2% of falls events) and other hospital data has been suggested as a method that allows a more timely response to this problem ^{4, 18, 19, 22} and this is confirmed by the findings of this study.

In this study the missing reported falls events data are missing at random. The missing reported falls data were not related to characteristics of the patients who fell, such as age and cognitive level. Therefore use of incident reporting system results to identify the characteristics of the population of fallers may not be problematic. However the missing data was related to the time of day. Falls were less likely to be reported when they occurred in the morning or afternoon shifts and particularly between 6 and 10 am and 2 and 6 pm. Staff perceptions of insufficient time and high workload have been found to be commonly reported barriers to falls incident reporting.²⁸ It is possible that the times of day associated with

reduced likelihood of a fall being recorded on an incident report coincide with the times that staff are at their busiest.

The importance of this finding is highlighted by the response of health administrators and practitioners to temporal variations in the rates of falls. A large national observational study in the United Kingdom recently suggested that daily peaks and troughs were not of a size that warranted additional prevention measures.¹¹ Previous studies that relied on hospital incident reporting systems have identified peaks in falls on geriatric units during the 7am to 3pm shift.^{29, 30} This peak was also witnessed in the present study, as was the increased propensity for falls to go unreported on incident reports. Hence it is conceivable that the magnitude of daily peaks and troughs previously observed through studies relying on data from incident reporting systems has provided an underestimate of the peaks. If the true magnitude of the peaks had been known, recommendation for specific strategies targeted at these times may have been made.

This study also found that moderate or severe injurious falls were significantly likely to be reported on incident reports, in contrast to a similar investigation that found that both non injurious and injurious falls were underreported through the incident reporting system.²⁰ This differs from other research that reported adverse events leading to patient harm were less likely to be reported through hospital incident systems.¹⁹ Qualitative research has previously identified that hospital staff feel they are more likely to record a fall on an incident report if a patient was injured,²⁸ but alternatively, identified barriers to falls reporting may suggest that staff may hesitate to report adverse events likely to lead to litigation.^{9, 10} There was also a near significant trend for falls to be reported on incident reports less frequently on Mondays

and Thursdays. Again theories relating to higher levels of staff busyness on these days could be postulated but would have to be examined in future research in order to be confirmed.

A further problem exists for researchers seeking to reduce the rate of falls in hospitals by targeting patients who have experienced a fall in hospital for intervention. The present study identified that falls subsequent to the first were at higher risk of going unrecorded on incident reports. Hence, if a study evaluating such an intervention approach used only incident reports to measure falls, then the intervention would have dramatically reduced power to detect a significant reduction in the rates of falls.

Falls events may have been missed even with three different reporting mechanisms, however the presence of research assistants on the ward on a daily basis makes this unlikely. One study site has electronic incident reporting and the other uses a paper system which is subsequently converted onto electronic storage, therefore there may have been limitations within either system that restricted staff from completing an incident report.

Researchers investigating falls in hospitals should be cautious about developing and evaluating falls prevention programmes based on falls event data obtained only through incident reporting systems and should collect data through additional reporting methods such as prospective case note review. Future investigations should continue to determine the gold standard approach to measuring falls events in hospitals.

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Author contributions

THa was principally responsible for the project conception and design of multimedia. AH was responsible for project organisation, intervention provision and data collection at the SDH site and SM at the PAH site. AH and THa were principally responsible for the data analysis and drafting of the manuscript. SM, KH, THo, SB, DO, CB contributed to project conception and design, interpretation of data analysis and critical revision of the manuscript.

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Table 1. Participant and Spatio-Temporal Characteristics of Falls Reported by Any of Three Reporting Methods Compared with Falls Reported by the Hospital Incident Reporting System

Variable	Total falls recorded using any	Falls recorded in incident	Falls not recorded in incident	Odds	Robust (95% CI),
	reporting methods (N=245)	reporting system (n=185)	reporting system (n=60)	Ratio	p value
		n (%)	n (%)		
Age					
≥60 to 70	47	37 (78.7)	10 (21.3)	1.37	(0.61, 3.28), 0.42
\geq 70 to 80	85	63 (74.1)	22 (25.9)	0.89	(0.45, 1.79), 0.76
≥80 to 90	92	70 (76.1)	22 (23.9)	1.06	(0.50, 2.20), 0.88
≥90 to 100	10	6 (60.0)	4 (40.0)	0.47	(0.10, 2.05), 0.32
Gender (male)	136	101 (74.3)	35 (25.7)	0.86	(0.44, 1.71), 0.69
Language (EFL)*	215	163 (75.8)	52 (24.2)	0.88	(0.34, 2.28), 0.80

SPMSQ (0-10) †

<u>>8</u>	149	117 (78.5)	32 (21.5)	1.51	(0.75, 3.01), 0.25
<u>></u> 6 < 8	65	47 (72.3)	18 (27.7)	0.79	(0.35, 1.77), 0.57
<6	31	21 (67.7)	10 (32.3)	0.64	(0.28, 1.48), 0.30
Diagnosis					
Stroke	38	29 (76.3)	9 (23.7)	1.06	(0.47, 2.37), 0.89
Orthopaedic	87	69 (79.3)	18 (20.7)	1.40	(0.67, 2.89), 0.36
Amputee	29	24 (82.8)	5 (17.2)	1.57	(0.59, 4.15), 0.36
Other geriatric	32	21 (65.6)	11 (34.4)	0.57	(0.20, 1.60), 0.30
Rehabilitation ward (vs	221	168 (76.0)	53 (24.0)	1.61	(0.64, 4.04), 0.31
acute ward)					
No supervision at time of	211	160 (75.8)	51 (24.2)	0.75	(0.30, 1.83), 0.53

fall

Injurious fall (mild)	35	23 (65.7)	12 (34.3)	0.57	(0.27,1.21). 0.14
Injurious fall (moderate or	62	53 (85.5)	9 (14.5)	2.28	(1.07, 4.81), 0.03
severe)					
First Fall (vs subsequent	153	107 (69.9)	46 (30.1)	1.39	(1.07, 1.82), 0.01
falls)					
Day of Week					
Monday	37	24 (64.9)	13 (35.1)	0.54	(0.26, 1.11), 0.09
Tuesday	42	35 (83.3)	7 (16.7)	1.77	(0.75, 4.19), 0.19
Wednesday	35	27 (77.1)	8 (22.9)	1.11	(0.50, 2.49), 0.78
Thursday	38	26 (68.4)	12 (31.6)	0.73	(0.33, 1.58), 0.43
Friday	29	23 (79.3)	6 (20.7)	1.28	(0.51, 3.21), 0.59

Saturday	31	25 (80.6)	6 (19.4)	1.41	(0.56, 3.56), 0.46
Sunday	32	24 (75.0)	8 (25.0)	0.97	(0.40, 2.33), 0.96
Time of fall					
6-10am	73	49 (67.1)	24 (32.9)	0.54	(0.29, 0.99), 0.04
10am-2pm	45	31 (68.9)	14 (31.1)	0.66	(0.32, 1.36), 0.27
2-6pm	43	38 (88.3)	5 (11.6)	2.86	(1.05, 7.76), 0.03
6-10pm	27	23 (85.2)	4 (14.8)	2.00	(0.61, 6.46), 0.25
10pm-2am	26	21 (80.8)	5 (19.2)	1.41	(0.51, 3.90), 0.50
2-6am	28	22 (78.6)	6 (21.4)	1.49	(0.52, 4.22), 0.45
Time of Fall by shift					
AM Shift 6am to 2pm	118	80 (67.8)	38 (32.2)	0.44	(0.23, 0.83), 0.01
PM Shift 2pm to 10pm	70	61 (87.1)	9 (12.9)	2.81	(1.26, 6.23), 0.01

O/N Shift 10pm to 6am	54	43 (79.6)	11 (20.4)	1.10	(0.52, 2.30), 0.80
Location of fall at bedside	139	102 (73.4)	37 (26.6)	0.82	(0.44,1.54), 0.55
(vs other location)					

* Language (EFL) denotes English is first language spoken by patient

† SPMSQ denotes Short Portable Mental State Questionnaire, range 0 to10, lower score indicates greater cognitive impairment

Figure 1. Falls Events Captured by the Three Reporting Methods.

