

Falls prevention in hospitals and mental health units: an extended evaluation of the FallSafe quality improvement project

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Abstract

Background: inpatient falls are a major patient safety issue causing distress, injury and death. Systematic review suggests multifactorial assessment and intervention can reduce falls by 20–30%, but large-scale studies of implementation are few. This paper describes an extended evaluation of the FallSafe quality improvement project, which presented key components of multifactorial assessment and intervention as a care bundle.

Methods: data on delivery of falls prevention processes were collected at baseline and for 18 months from nine FallSafe units and nine control units. Data on falls were collected from local risk management systems for 24 months, and data on under-reporting through staff surveys.

Results: in FallSafe units, delivery of seven care bundle components significantly improved; most improvements were sustained after active project support was withdrawn. Twelve-month moving average of reported fall rates showed a consistent downward trend in FallSafe units but not controls. Significant reductions in reported fall rate were found in FallSafe units (adjusted rate ratio (ARR) 0.75, 95% confidence interval (CI) 0.68–0.84 $P < 0.001$) in the 12 months following full implementation but not in control units (ARR 0.91, 95% CI 0.81–1.03 $P = 0.13$). No significant changes in injurious fall rate were found in FallSafe units (ARR 0.86, 95% CI 0.71–1.03 $P = 0.11$), or controls (ARR 0.88, 95% CI 0.72–1.08 $P = 0.13$). In FallSafe units, staff certain falls had been reported increased from 60 to 77%.

Conclusion: introducing evidence-based care bundles of multifactorial assessment and intervention using a quality improvement approach resulted in improved delivery of multifactorial assessment and intervention and significant reductions in fall rates, but not in injurious fall rates.

Keywords: older people, fall prevention, quality improvement, injury

Background

Falls are a major patient safety issue for hospitals, reflecting the existing vulnerability of older patients with multiple health problems to falling, compounded by risks from their acute illness, their treatment and an unfamiliar environment [1]. Typical whole-hospital studies report rates of between 3 and 5 falls per 1,000 occupied bed days (OBDs),

representing over 250,000 falls annually in English hospitals [2] and over 1 million falls in US hospitals [3].

Falls can have serious consequences; 30–50% of falls in hospitals result in some injury, with fractures occurring in 1–3% [4], often leading to very poor outcomes [5] and greatly increased lengths of stay [6]. Even falls without injury cause distress to patients and careers, creating a downward spiral where fear of falling leads to reduced mobility. Healthcare

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staff's concern may be compounded by fear of complaints and litigation [7].

Evidence on falls prevention in hospital is limited; few RCTs exist and most before-and-after studies are of low quality [8]. However, systematic reviews consistently indicate that multifactorial assessments and intervention may reduce falls in hospital by ~20–30% [9–11]. The components of multifactorial assessment and intervention differ between studies, with an evidence overview [4] noting the importance of assessing mobility, confusion, continence and need for toileting assistance, medication, and postural hypotension or syncope. A multidisciplinary approach facilitated by unit-based staff [12, 13] appeared more likely to succeed than interventions from visiting specialists [14].

Translating evidence for complex interventions into routine clinical practice is challenging; audits of current practice in the UK [15, 16] suggest only a minority of inpatients received appropriate multifactorial assessment and intervention to reduce their risk of falling, and most staff received very limited falls prevention education. The FallSafe project [18] aimed to improve this situation through presenting the key components of multifactorial assessment and intervention as care bundles, and supporting their implementation across 16 inpatient care settings in the South of England through educating and empowering local leaders. The quality improvement methodology and the initial project findings have been previously published [18, 19] and are summarised in Supplementary data available in *Age and Ageing* online, Appendix 1. This extended evaluation aims to describe the impact of the FallSafe project after 12 months of implementation of the full care bundles, including assessing sustainability for 6 months after active project support was withdrawn [20].

Methods

Ethics

As secondary analysis of data collected for quality improvement purposes, ethics committee approval was not required. No patient identifiable data were collected.

Inclusion criteria

All units who participated in the original FallSafe project were included unless:

- They had formally withdrawn from the project.
- There was no control unit available.
- The FallSafe unit or control unit had been closed or changed patient specialty.

Control units were selected from the specialty most similar to each FallSafe unit within the same hospital.

Project phases

For evaluation purposes, data were analysed in four consecutive 6-month periods commencing February 2010:

- (1) Baseline period.
- (2) Introduction period (initial training and partial care bundle implementation).
- (3) Implementation period (full care bundle implementation with active project support).
- (4) Sustain period (full care bundle implementation without active project support).

Process measures

FallSafe leads collected process measures for nine care bundle components (Supplementary data are available in *Age and Ageing* online, Appendix 1) from up to 20 patients per unit per month as an integral part of their quality improvement efforts, using formats that defined collection methods and evidence of compliance [18].

The collated data, including justifications for each occasion a component was considered 'not applicable', were entered on an Excel database. 'Not applicable' entries were reviewed by a specialist nurse, and altered to 'not compliant' if the justification appeared inadequate.

Outcome measures

Reported falls were obtained from local incident reporting systems for FallSafe and control units and standardised to the National Patient Safety Agency's classifications of no harm and harmful falls [2]. These data were converted into fall rates and injurious fall rates per 1,000 OBDs, graphically presented as moving 12-month average rates to compensate for seasonal variation. Statistical analysis was pre-planned as rate ratio using whole-year before-and-after data for the pooled intervention and pooled control units. Analysis used random effects Poisson regression modelling with adjustment for hospital clusters to calculate 95% confidence intervals (CIs) and *P*-values. Direct comparison of intervention and control units was not pre-planned, as non-equivalent patient populations and baseline fall rates were anticipated, but in response to peer review, analysis of group-by-time interaction effects was added.

An adaptation [18] of Question 17 from the NHS staff survey [21] was used to assess under-reporting of falls. Data were collected from an opportunity sample of 10 nurses per unit at the end of Period 1 and towards the end of Period 2/beginning of Period 3 of the project, and replies were collated into the percentage of respondents who were 100% certain that the last fall they had witnessed had been reported as an incident.

Results

Inclusion

Of the original 16 FallSafe units, seven units were excluded. Of these, three units were unable to provide any control unit; three units had been closed, merged or changed specialty;

Table 1. Percentage of patients receiving relevant care bundle components

Care bundle component	Baseline	End of Period 3	End of Period 4	Baseline versus Period 3	Baseline versus Period 4	Period 3 versus Period 4
1 Call bell in sight and reach	95% (104/110)	100% (104/104)	99% (110/111)	0.03	0.07	0.99
2 Cognitive screen	60% (64/107)	82% (89/109)	70% (85/121)	<0.001	0.12	0.05
3 Asked about fear of falling	31% (24/78)	76% (102/134)	78% (115/148)	<0.001	<0.001	0.78
4 History of falls	85% (69/81)	99% (134/136)	97% (145/150)	<0.001	0.003	0.45
5 Lying and standing BP	30% (22/74)	70% (48/69)	52% (40/77)	<0.001	0.008	0.04
6 Medication review requested	49% (41/83)	75% (66/88)	82% (79/96)	<0.001	<0.001	0.28
7 Dose of night sedation NOT given last night	66% (50/76)	87% (129/148)	90% (137/153)	<0.001	<0.001	0.59
8 Safe footwear on feet	93% (111/119)	98% (104/106)	99% (115/116)	0.11	0.04	0.61
9 Evidence of urine dip-test taken and recorded ^a	55% (50/91)	84% (118/141)	83% (126/151)	<0.001	<0.001	0.99

All 'not applicable' data were discarded and compliance calculated as patients receiving the care bundle component divided by the number of patients the care bundle component was applicable to Bold text denotes changes that were statistically significant at $P \leq 0.05$.

^aEducation of the FallSafe leads included the context that positive signs of bacteria are frequently found in the urine of older patients and that further testing or treatment would not be appropriate where patients had no other signs or symptoms of urinary tract infection.

and one unit withdrew from the project when it was unable to recruit a replacement FallSafe lead.

Nine of the original FallSafe units located in eight different hospitals met criteria for participation in the extended evaluation. These were three mental health units for older people with dementia, three orthopaedic trauma units, one general orthopaedic unit, one acute medicine for older people unit and one respiratory medicine unit.

Only one of these nine FallSafe units could provide a control of equivalent speciality (general orthopaedics). Remaining controls were two elective orthopaedic units, one general surgery unit, two general or mixed medicine units and three mixed or functional mental health units.

Process measures

Process data were available from FallSafe units for 19 monthly data points for the care bundle components introduced first, and 12 monthly data points for those introduced last. Delivery of seven care bundle components significantly improved between baseline and Period 3. Delivery of components already close to high reliability (i.e. delivered for at least 95% of patients) at baseline also increased but was not statistically significant. Improvements were sustained during Period 4 for all components except for cognitive screening and lying and standing BP, which showed signs of slippage, although remaining above baseline levels (Table 1 and Supplementary data are available in *Age and Ageing* online, Appendix 2).

Outcome measures

Twelve-month moving average of reported fall rates showed a consistent downward trend in FallSafe units but not in controls (Figure 1).

FallSafe units saw a significant reduction in reported fall rate (adjusted rate ratio (ARR) 0.75, 95% CI 0.68–0.84), $P < 0.001$ in the 12 months following full implementation of the care bundle. No significant changes were found in reported fall rate from controls (ARR 0.91, 95% CI 0.81–

1.03 $P = 0.13$), in injurious fall rate from FallSafe units (ARR 0.86, 95% CI 0.71–1.03 $P = 0.11$) or in injurious fall rate from controls (ARR 0.88, 95% CI 0.72–1.08 $P = 0.13$) (Table 2). Poisson mixed regression was used to look at the group (FallSafe, control), by time period (phase 12, phase 34) interaction effect and for fall rates was significant ($P = 0.01$). The interaction effect for injurious fall rate was not significant.

Comparison of average reported fall rates in seasonally equivalent periods in FallSafe units indicated a rate decrease of 10% between Periods 1 and 3, and a rate decrease of 41% between Periods 2 and 4. Comparison of average reported fall rates in controls indicated a rate increase of 8% between Periods 1 and 3, and a rate decrease of 22% between Periods 2 and 4 (Table 2).

As only six acute and three mental health units were included in the sample, detailed stratification by hospital type was inappropriate, but reported fall rate changed more in the mental health units (rate ratio 0.54 Periods 3+4:1+2) than in acute units (rate ratio 0.91 Periods 3+4:1+2). Modelling using negative binomial regression rather than Poisson regression indicated a wider CI (0.64–1.04) for the reduction in total fall rate for the FallSafe units.

Towards the end of the baseline Period 1, 60% (45/75) of nurses on FallSafe units reported that they were 100% certain that the last fall they had witnessed had been reported. Towards the end of Period 2/beginning of Period 3, 77% (49/64) of nurses on FallSafe units reported that they were 100% certain that the last fall they had witnessed had been reported.

Discussion

Prior to this paper, little evidence existed on whether efforts to improve in-hospital falls prevention have resulted in changes in the delivery of multifactorial assessment and intervention; earlier studies have not provided data on process changes [8], leaving it unclear whether studies reporting no significant change in fall rates should attribute this to

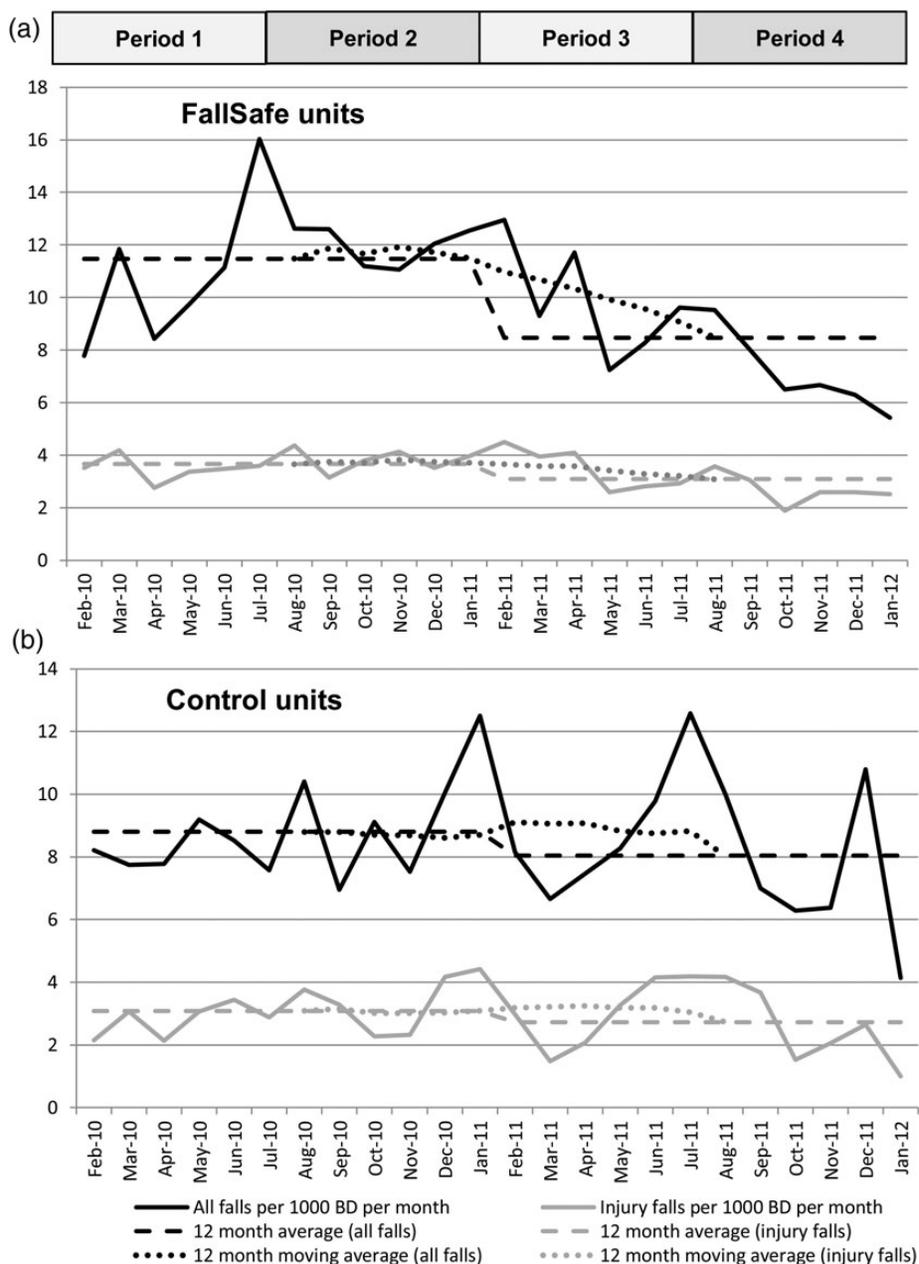


Figure 1. Fall and injurious fall rates per 1,000 OBDs in (a) FallSafe units and (b) control units.

ineffective interventions or ineffective implementation [10]. The significant improvement in provision of multifactorial assessment and intervention delivered and sustained in the FallSafe project compares favourably with routine practice (e.g. 70% of patients with lying and standing BP assessed on FallSafe units during Period 3 compared with 7% in a regional audit [22]). These process data also suggest that the influence of the FallSafe leads extended to the wider multi-disciplinary team (e.g. the reductions in night sedation from 34% of patients at baseline to 10%). There were limitations to these data. All FallSafe process measures were self-reported, with no independent verification except scrutiny of any ‘not applicable’ responses. Additionally, no data were collected on the quality of delivery of individual care bundle

components (e.g. whether requests for medication review actually resulted in appropriate changes to medication other than night sedation).

Most existing evidence for successful in-hospital falls prevention comes from units specialising in the medical treatment or rehabilitation of older people [4], but this evaluation suggests that the FallSafe care bundles can be implemented in a wider range of acute inpatient specialities. Importantly, given the dearth of evidence for falls prevention in mental health units for older people [9], the project showed that multifactorial assessment and intervention could be successfully delivered in this setting.

The collection of outcome data is a major challenge for any in-hospital falls improvement project. Formal reporting

Table 2. Reported falls and OBDs data^a

	(Period) Dates	FallSafe unit 9 units	Nominated control unit 9 units
Total OBDs	(1) Feb 10–Jul 10	33,583	32,426
	(2) Aug 10–Jan 11	35,822	33,041
	(3) Feb 11–Jul 11	33,495	30,274
	(4) Aug 11–Jan 12	32,942	31,657
Total falls	(1) Feb 10–Jul 10	366	265
	(2) Aug 10–Jan 11	430	311
	(3) Feb 11–Jul 11	329	266
	(4) Aug 11–Jan 12	234	232
Total injury falls	(1) Feb 10–Jul 10	117	91
	(2) Aug 10–Jan 11	137	111
	(3) Feb 11–Jul 11	116	91
	(4) Aug 11–Jan 12	89	78
Total falls Per 1,000 OBD	(1) Feb 10–Jul 10	10.90	8.17
	(2) Aug 10–Jan 11	12.00	9.41
	(3) Feb 11–Jul 11	9.82	8.79
	(4) Aug 11–Jan 12	7.10	7.33
	(12) Feb 10–Jan 11 (34) Feb 11–Jan 12	11.47 8.47	8.80 8.04
Total injury falls Per 1,000 OBD	(1) Feb 10–Jul 10	3.48	2.81
	(2) Aug 10–Jan 11	3.82	3.36
	(3) Feb 11–Jul 11	3.46	3.01
	(4) Aug 11–Jan 12	2.70	2.46
	(1 + 2) Feb 10–Jan 11 (3 + 4) Feb 11–Jan 12	3.66 3.09	3.09 2.73
Relative risk of a fall occurring on any OBD	Period 3:Period 1	0.90	1.08
	Period 4:Period 2	0.59	0.78
	Periods 3+4:Periods 1+2	0.74	0.91
	Regression modelling with 95% CI ^a	0.75 (0.68–0.84), <i>P</i> < 0.001	0.91 (0.81–1.03), <i>P</i> = 0.13
	Relative risk of an injury fall occurring on any OBD	Period 3:Period 1	0.99
Period 4:Period 2	0.71	0.73	
Periods 3+4:Periods 1+2	0.84	0.88	
Regression modelling with 95% CI ^a	0.86 (0.71–1.03), <i>P</i> = 0.11	0.88 (0.72–1.08), <i>P</i> = 0.22	

^aThe data were modelled using random effects Poisson regression with adjustment for hospital clustering. Stata V11 statistical software was used for the modelling. 95% CI, 95% confidence interval.

of falls as incidents is known to be incomplete [23], with only around 75% of falls captured [24]. However, for in-hospital falls (unlike other adverse events [23]) case note review and staff and patient recall may be even less reliable sources [24–26] and the completeness of data collection methods such as ‘safety crosses’ and ‘safety thermometers’ is untested, although increasingly popular [27]. The approach used by higher quality research studies (dedicated staff triangulating case notes, incident reports and verbal reports of falls each day) is resource intensive.

Although without the resources to match the data collection methods of a high-quality research study, this evaluation supplemented reported fall rates with survey data on the completeness of reporting, unlike all previously published in-hospital quality improvement projects [8] and most RCTs [10], which relied on reported falls alone. The increase from 60 to 77% observed in the proportion of nurses certain the last fall they had witnessed had been reported appears to support prior speculation that increased awareness of falls prevention can lead to increases in the completeness of reporting [4]. These contextual data indicate that the 25% decrease in reported fall rate seen in FallSafe units in the 12

months after full care bundle implementation can be confidently attributed to fewer falls rather than decreased reporting.

Although falls are known to result in significantly greater healthcare and social care costs [28], calculating the cost–benefit of in-hospital falls prevention is complex, as vulnerability to falling is closely related to patient age and levels of long-term and acute illness, and the influence of these factors on length of stay and discharge destination are difficult to separate from the impact of the fall itself. Additionally, identifying and treating underlying causes of falls, particularly delirium, may have general health benefits that extend beyond falls prevention [4]. A recent economic model incorporating these complexities considered that in-hospital multifactorial assessment and intervention is cost-effective if costs are <£100 per patient admitted [29] and there is at least a 15% reduction in overall fall rate. FallSafe, with multiple patients being admitted to each unit and direct and opportunity costs of <£700 per unit per month [19] would fall comfortably inside this threshold.

Contemporaneous influences (e.g. changes to whole-hospital falls policy or staffing levels) could also affect fall

rates. However, finding appropriate control units was difficult. Unit-level fall rates can differ 10-fold, with the highest rates seen in older adult specialities, and the lowest in elective specialities [4]. Most of the control units could not be matched for specialty; the FallSafe units were mainly drawn from specialities with patient populations more vulnerable to falling than controls, and had a baseline fall rate that was 33% higher than controls. Direct comparison of control and intervention units was therefore inappropriate, but our finding of no significant change in reported fall rates in control units using parallel before-and-after analysis suggests that any contemporaneous influences were not major, and our analysis of interaction effects indicates that the changes over time in fall rate in the FallSafe wards were significantly greater than the changes over time in the control units.

Analysis of in-hospital falls data is also problematic. This evaluation avoided common errors seen in previous studies [30] by analysing fall rates rather than fall numbers, comparing seasonally equivalent periods, and adjusting for clustering, but other analytical challenges remain. Falls are not truly independent events, as each fall increases the risk of further falls, and their distribution is highly skewed, with a very small proportion of patients experiencing multiple falls, creating difficulties for the assumptions of independence made by various statistical models. We are confident that our finding of a statistically significant reduction in reported fall rate in FallSafe units was based on pre-planned analytical techniques that are more appropriate than those used in previous reports of in-hospital quality improvement projects [8] and some RCTs [10]. However, it is debatable if the use of random effects negative binomial regression or random effects Poisson regression would be more appropriate, and the former would widen CIs.

As the evaluation of a quality improvement project, sample size was dictated by project funding. Given the power calculations made in prior cluster RCTs [13, 14], it is unlikely that this evaluation was powered to detect significant changes in injurious fall rates, and only a non-significant reduction in injurious fall rate in FallSafe units was found.

Although seven units were excluded from this evaluation, in six cases, this arose from wider local service reconfiguration or refurbishment programmes that confounded process and outcome data; similar changes in service provision represent an increasing challenge to longer-term evaluations of Quality Improvement projects and research design. These wider service changes were unrelated to the performance of individual units and are therefore unlikely to have biased the remaining sample. However, one FallSafe unit with high levels of staff turnover and temporary staff withdrew from the FallSafe project after their third successive FallSafe lead had left the unit. This underlines the challenges of translating evidence into clinical practice and highlights the need for any unit to be 'improvement ready'.

Whilst no quality improvement project can be expected to be sustainable without at least internal management support, this evaluation suggests that most improvements were maintained after external project support was withdrawn. The

decreases seen in the proportion of patients receiving cognitive assessment and lying and standing BP checks during the sustain phase indicate the importance of a hospital-wide approach to staff training; as these were not previously part of standard nursing competencies in most FallSafe units, the additional training would need repetition as new staff were recruited. Importantly, as the education and empowerment of local FallSafe leads was the key mechanism of change, the approach would not be sustainable in the longer term without active succession planning.

Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.z

Key points

- Educating and empowering a unit-based nurse appears to be an effective method of delivering a falls prevention care bundle.
- Improved delivery of care bundles of multifactorial assessment and intervention resulted in reduced fall rates.
- The costs of implementing change were more than offset by established economic benefits.

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Conflicts of interest

The authors were all members of the steering group for the FallSafe project; neither they as individuals nor the CEEU as

host organisation had any financial interest in the outcome of the FallSafe project; the resource pack the CEEU developed to support hospitals to replicate the approach is available for download without charge.

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