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Prioritising Responses Of Nurses To deteriorating patient Observations (PRONTO): a pragmatic cluster randomised controlled trial evaluating the effectiveness of a facilitation intervention on recognition and response to clinical deterioration

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ABSTRACT

Background Most hospitals use physiological signs to trigger an urgent clinical review. We investigated whether facilitation could improve nurses' vital sign measurement, interpretation, treatment and escalation of care for deteriorating patients.

Methods In a pragmatic cluster randomised controlled trial, we randomised 36 inpatient wards at four acute hospitals to receive standard clinical practice guideline (CPG) dissemination to ward staff (n=18) or facilitated implementation for 6 months following standard dissemination (n=18). Expert, hospital and ward facilitators tailored facilitation techniques to promote nurses' CPG adherence. Patient records were audited pre-intervention, 6 and 12 months post-intervention on randomly selected days. Escalation of care as per hospital policy was the primary outcome at 6 and 12 months after implementation. Patients, nurses and assessors were blinded to group assignment. Analysis was by intention-to-treat.

Results From 10 383 audits, improved escalation as per hospital policy was evident in the intervention group at 6 months (OR 1.47, 95% CI (1.06 to 2.04)) with a complete set of vital sign measurements sustained at 12 months (OR 1.22, 95% CI (1.02 to 1.47)). There were no significant differences in escalation of care as per hospital policy between study groups at 6 or 12 months post-intervention. After adjusting for patient and hospital characteristics, a significant change from T0 in mean length of stay between groups at 12 months favoured the intervention group (−2.18 days, 95% CI (−3.53 to −0.82)).

Conclusion Multi-level facilitation significantly improved escalation as per hospital policy at 6 months in the intervention group that was not sustained at 12 months. The intervention group had increased vital sign measurement by nurses, as well as shorter lengths of stay for patients at 12 months. Further research is required

Key messages

What is already known on this topic

- Failure to rescue patients remains a global problem, despite decades of research on recognition of and response to clinical deterioration in hospitalised patients. Testing of interventions to promote behavioural changes in clinicians to address patient deterioration has been lacking.

What this study adds

- Our multi-level facilitation intervention showed variable effect, an initial improvement in escalation in the intervention wards was not sustained, although increased vital sign measurement and reduced hospital stays were sustained. Between-group differences were not significant except for a reduction in length of stay.

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Key messages

How this study might affect research, practice or policy

- Further understanding of facilitation approaches and thresholds necessary to effect sustainable change is warranted. The study highlights the potential for targeted behavioural change interventions, supported by electronic decision support systems, to decrease cognitive burden and improve patient safety.

to understand the dose of facilitation required to impact clinical practice behaviours and patient outcomes.

Trial registration number ACTRN12616000544471p

INTRODUCTION

Early detection of clinical deterioration is a primary goal of health professionals internationally, to reduce complications associated with failure to rescue.[1] However, there is clear evidence that recognition and response to clinical deterioration in hospital are frequently suboptimal and a serious patient safety risk.[2–6] Cardiac arrest, unplanned intensive care admissions and unexpected death are often preceded by acute clinical deterioration which may be missed, misinterpreted or mismanaged.[4 7]

Rapid response systems (RRSs) were developed to mitigate patient safety risks through early identification of clinical deterioration, timely notification to the relevant team to respond to the deterioration and treatment of the patient to reverse or stabilise the deterioration at the point of care.[8–10] Vital signs (VS) are the physiological tracking system universally used for determining urgent treatment needs. Nurses measure, document, interpret and monitor VS; yet, VS measurement alone does not mitigate adverse outcomes; VS deviations must be recognised, interpreted and acted on to trigger an appropriate response. In RRS, VS thresholds dictate a predetermined action. Depending on the level of deterioration, the response varies and includes nursing intervention, local medical unit review or intensive care team review.

One of the only randomised controlled trials of RRSs to date, the *Medical Early Response, Intervention and Therapy* (MERIT) study, involving 23 Australian hospitals, demonstrated that the implementation of a medical emergency team (MET) resulted in no reduction in the composite outcome of cardiac arrest, unexpected death or unplanned intensive care unit (ICU) admission.[11] However, further analysis identified a high incidence of failed MET activation in eligible patients in the intervention hospitals. Failures to trigger the MET as intended meant that MERIT researchers were unable to measure MET effectiveness because the intervention was not delivered to the patient as intended. Thus, the 'MET dose' was inadequate to effect change.[12] Delayed or failure to trigger the MET counteracts one of the most important tenets, that early recognition and response to deterioration improve patient outcomes.

After decades of research on recognition and response to clinical deterioration, raised international awareness and implementation of new models of response, the problem of failure to rescue remains. Individual-level and organisational-level barriers have been offered as explanations for the continued suboptimal care in hospitals. Individual knowledge, education, fear of criticism, professional hierarchies, excessive workloads, low staffing levels, variable RRS implementation across units, inadequate surveillance systems and high patient turnover have all been described as impacting patient outcomes following clinical deterioration.[1 13] However, there has been a lack of focus on interventions addressing patient deterioration that promote change in clinician behaviour.

The field of implementation science has focused on strategies to promote individual, team and organisational behaviour change. Researchers, decision makers and clinicians have used the Promoting Action on Research Implementation in Health Services (PARIHS) Framework[14–17] to inform research translation into practice. The proposition is that successful implementation is determined by the nature and type of evidence, characteristics of the context in which the evidence is being implemented and the process of facilitation.[14] Facilitation encompasses both a role and a process. Usually, one or more individuals with the appropriate skills and knowledge are assigned as facilitators and use enabling facilitation skills to help individuals, teams and organisations apply evidence into practice.[15] Previous research has demonstrated positive impacts of using this facilitated approach to support implementation.[18]

This study aimed to determine the effectiveness of a facilitation intervention to improve nurses' adherence to a clinical practice guideline (CPG) aimed at early recognition and response to clinical deterioration and measured by escalation of care as per hospital policy. The CPG comprised the Australian National Consensus Statement detailing the requirements to meet a national clinical deterioration standard for hospital accreditation and an accompanying implementation guide[19] (online supplemental file 1).

Hospital policy specified actions to operationalise the CPG, mandating a complete set of VS at least every 8 hours with prescribed responses and timeframes by nurses and doctors depending on the level of patient deterioration. VS assessment precedes data interpretation and recognition of clinical deterioration. VS assessment and interpretation underpin clinical decisions about the most appropriate escalation of care pathway (pre-MET, MET or CAT), followed by escalation of care to the selected team (online supplemental file 2).

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METHODS

Prioritising Responses Of Nurses To deteriorating patient Observations (PRONTO) was a pragmatic cluster randomised controlled trial (CRCT) with an embedded process evaluation and cost consequence analysis. A CRCT design was selected because the intervention targeted a group of participants and avoided contamination. This article follows the CONSORT extension for Cluster Trials recommendations for reporting. The detailed protocol for this study was published before study completion.[7] The trial commenced in June 2016.

Study setting and participants

PRONTO was conducted in 36 wards at four university-affiliated, metropolitan hospitals in Victoria, Australia (online supplemental file 3). Chief executive officers consented to hospital participation. The wards received support from the hospital's MET and ranged in size from 20 to 46 beds (online supplemental file 4). Critical care, emergency, paediatrics, maternity, perioperative and psychiatric areas were excluded as they use an alternative response system for patient deterioration.

All four hospitals had a three-tier RRS consisting of: the pre-MET response that activated a local response from the parent unit and ward nursing staff; an ICU-led MET response; and the cardiac arrest team (CAT) response.

All nursing staff working in the study wards were involved in the study. Nurse to patient ratios were 1:4 on morning and afternoon shifts and 1:8 overnight. All patients within the study wards were included in audits at three time points: baseline (time 0) and at 6 months (time 1) and 12 months (time 2) post-intervention. Data were collected over three randomly selected 24-hour periods for 1 week. A single patient could have multiple audit days. Patients were followed for the duration of their stay, and data were analysed according to ward at commencement.

Randomisation and masking

Wards (clusters) within hospitals were randomised to either intervention or control groups in a 1:1 block randomisation by an independent service. Patient audit dates were randomly selected by a statistician within each audit week. Although facilitators were aware of the intervention, ward nurses were unaware of the comparator. Patients were unaware of the intervention. Allocated groups were concealed from the statistician until data set closure.

Implementation intervention

Our implementation intervention was multi-level facilitation for 6 months. It was comprised of three facilitator roles that employed facilitation methods to enable the implementation of the CPG. Consistent with the theoretical framing of the study, our proposition was that a multi-level facilitation model would increase adherence to CPG recommendations through assessment and response to barriers that related to views about the innovation/evidence (the CPG), the target group for implementation (the nursing staff on intervention wards) and contextual factors at the ward and hospital level.

Table 1 Intervention components

Type	Intervention components
Core components	*Training:* Being a facilitator, processes of facilitation, toolkit of techniques, knowledge of the patient problem and national guideline requirements. Review of hospital policy, VS triggers for escalation and nursing interventions. *Identification of ward barriers and enablers:* individual, discipline, ward and organisation. Monthly ward audits with feedback of results to nurse managers and staff via posters, presentations and discussions of areas for improvement. *Monthly HFLIP facilitation support* by external expert facilitator reviewing audit results, how to respond to ward issues, questions and concerns. *Toolkit of facilitation techniques (Harvey and Kitson, 2015) provided to HFLIPs:* Clarify and engage; assess and measure; action and implementation; review and share. Techniques included: interactive education, case presentations, individual discussions, reminder posters, working with clinicians during assessments, interdisciplinary discussions and ward audits with feedback. Each facilitator used the same techniques.
Adaptable components	Facilitation techniques were selected from the toolkit and tailored depending on the context such as patient management problems, ward audit results, ward staff needs and their availability.

HFLIPs, hospital facilitators; VS, vital signs.

In the intervention wards (n=18), the nurse managers (NMs) disseminated information on the CPG to staff at ward meetings, providing online information links on where to access the CPG and free education (online supplemental file 1). In addition, the intervention wards received a *Faci*litation *I*ntervention for *P*ractice improvement (FLIP), informed by the i-PARIHS theoretical framework.[20] Facilitation provides a way of enabling and supporting people to change their attitudes, habits, skills, ways of thinking and working to achieve implementation.[20] The FLIP consisted of an external facilitator, an internal hospital facilitator (HFLIP) and two ward facilitators (WFLIPs) per intervention ward. Table 1 outlines intervention components. FLIPs identified barriers and enablers in each ward, then used facilitation methods and processes to promote use of the CPG in ward practice. For example, missed VS could be addressed through an individual or NM discussion of the hospital policy, how to use the hospital policy or reminder posters in common areas. WFLIPs used teachable moments to promote learning. HFLIPs could do a presentation on the hospital policy and requirements of nursing staff.

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Facilitators targeted three nursing components of the CPG:

1. Vital sign assessments at least 8 hourly on every patient.
2. Recognition of abnormal VS and activation of the appropriate response for escalation as per policy.
3. Implement appropriate nursing interventions in response to the deterioration.

HFLIPs (n=4) had oversight of four or five wards each and acted as the lead facilitator in each hospital, co-ordinating and mentoring two WFLIPs per ward (n=36). Supervising and advising all facilitators were undertaken by an external expert facilitator. Facilitators were given training on the subject matter, the evidence supporting targets, how to identify barriers and activities to address barriers. All facilitators were trained by experts in the CPG and facilitation process and given a toolkit of techniques (table 1) to promote CPG adherence. HFLIPs gave 5 hours of support per week to each intervention ward for 6 months using multiple strategies including interactive education, case presentations, individual discussions, reminders and audit with feedback. WFLIPs were given 1 day per fortnight of protected time to liaise with the HFLIP, review audits and work with staff in applying the CPG. HFLIP positions required registered nurses with prior education experience, were advertised in hospitals and incumbents were selected following interviews. WFLIPs were registered nurses identified by NMs to support the HFLIP and enable staff to apply the CPG. All facilitators had to have knowledge of hospital policy, hold clinical leadership roles and possess good communication skills.

All facilitators received training prior to commencing the study. HFLIPs received 3 days of training with experts in recognition and response to clinical deterioration and advanced facilitation skills, a monthly teleconference with the external facilitator and project manager, one site visit and face-to-face meeting with the external facilitator. WFLIPs received 1 day of training, and face-to-face and email support from the HFLIP for the duration of the study. HFLIPs kept electronic activity logs and audits of practice to enable ward-level feedback.

Control

In the control wards (n=18), ward nurses received the CPG information disseminated by the NMs in the same manner as the intervention group (online supplemental file 1).

Outcomes

The primary outcome was measured escalation of care as per hospital policy, defined as activation of the pre-MET, MET or CAT, as a percentage of all patients with triggers by prescribed pre-determined criteria (online supplemental file 2).

Secondary outcomes included nursing practice outcomes and clinical outcomes for patients. Nursing practice outcomes were measured by the proportions of: at least 1 VS measurement every 8 hours, complete sets of VS documented; VS repeated within 30 min of obtaining an abnormal VS; and documented nursing interventions in response to abnormal VS clinical outcomes included: cardiac arrest rates, unplanned ICU admissions, in-hospital mortality,and hospital length of stay (LOS).

Sample size and power calculations

Sample size calculations were based on a 50% rate of adherence to escalation as per hospital policy, informed by previous research.[21] For 90% power to detect a 20% improvement in the intervention group, 270 patient audits with abnormal VS triggers were required for each study arm at 6 months (T1) and 12 months post-intervention (T2). The sample size accounted for within ward clustering effect and within patient autocorrelation, by inflating the sample size for a design effect of 1.5. To account for multiple comparisons, type I error was set at a 1% significance level. To determine an improved adherence rate in post-intervention comparisons between the intervention and the control groups, we set 80% power to detect an OR of at least 1.8 for secondary outcomes.

Statistical analysis

Characteristics of patients and audits were summarised at each time point using mean and SD for continuous variables and frequency and percentage for categorical variables. The main outcome and all secondary analyses followed an intention-to-treat approach, that is, wards and patients within wards were analysed according to the group to which they were randomly allocated. For the primary outcomes' analysis, escalation per hospital policy, we employed logistic models using a generalised estimating equations (GEE) technique with an exchangeable working correlation structure and robust SEs to account for the cluster nature of data. Study group (intervention vs control), time point (T0, T1 and T2) and a study-group-by-time point interaction were specified as independent variables in each model. The relative between-group change from T0 to post-intervention T1 and T2 (ie, ratio of OR) was estimated from the study-group-by-time point two-way interaction. Additional GEE models were employed to estimate change over time in the intervention and control groups separately. All other dichotomised secondary outcomes followed the same analytical method as the main outcome.

Further adjustments for sex, age, admission status (emergency or non-emergency), diagnosis-related group (DRG) weight and hospital site were implemented via multivariable logistic GEE models for the clinical outcomes. Mean LOS was also compared and reported using GEE model with Gaussian outcome and identity link while accounting for the ward clustering effect and adjusted for sex, age, admission status, DRG

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Table 2 Characteristics of patient audits, by intervention and control groups at T0, T1 and T2

Time	Characteristic	Intervention	Control	P value
Time 0	Number of audits	1716	1654	–
	Male audits, N (%)	933 (49)	962 (51)	0.022
	Emergency admissions audits*, N (%)	1476 (86)	1363 (82)	0.005
	Surgical procedures, N (%)	375 (39)	329 (36)	0.352
	Mean age, years (SD)	65.6 (18.8)	65.5 (18.0)	0.872
	Mean DRG† weight (SD)	4.18 (8.69)	4.62 (8.48)	0.218
Time 1	Number of audits	1778	1757	–
	Male audits, N (%)	928 (49)	984 (51)	0.048
	Emergency admissions audits, N (%)	1543 (84)	1433 (82)	<0.001
	Surgical procedures, N (%)	414 (38)	388 (38)	0.832
	Mean age, years (SD)	64.7 (19.6)	66.2 (17.6)	0.002
	Mean DRG† weight (SD)	3.40 (5.09)	3.89 (6.28)	0.051
Time 2	Number of audits	1747	1731	–
	Male audits, N (%)	914 (48)	989 (52)	0.005
	Emergency admissions audits, N (%)	1521 (87)	1449 (84)	0.004
	Surgical procedures, N (%)	390 (38)	359 (36)	0.802
	Mean age, years (SD)	63.7 (20.4)	66.2 (18.5)	<0.001
	Mean DRG† weight (SD)	3.39 (5.26)	4.40 (8.23)	0.001

*Elective admissions are the alternative to emergency admissions.
†Diagnosis-related group (DRG) weight represents an estimate of the relative resource intensity of each DRG.

weight and hospital site. All p values were two-sided. Level of significance was set at 0.01 for between-group escalation per hospital policy outcomes and 0.05 for all other secondary comparisons and within-group comparisons. Data pertaining to unplanned ICU admission, in-hospital mortality and LOS were from the hospital administrative data set which contained information about the entire period of hospitalisation (from hospital admission to discharge) for each patient. Stata V.16[22] was used for all calculations.

RESULTS

Participants

A total of 6065 patient records were reviewed. Some patients had multiple audit days (N=10 383): T0 patients (n=1894) were audited in June 2016; T1 patients (n=2126) in December 2016; and T2 patients (n=2045) in June 2017. Table 2 shows characteristics of patient audits per study arm at each time point. The intervention group had significantly more emergency admissions at all time points. The control group had significantly more males at each time point, and higher mean age and DRG weights at T1 and T2 indicating more chronic disease. Several differences were noted within groups over time. From T0 to T2, mean age and DRG weight decreased in the intervention group, and emergency admissions increased in both groups.

Primary outcome

Of 2680 audits with pre-MET, MET or CAT triggers, 719 (26.8%) had activated pre-MET or MET calls and four had activated CAT calls. Table 3 shows the frequency (%) of the audits with escalation per policy across the three time points. The intervention group showed an improvement in escalation of care as per policy from T0 to T1 (OR 1.47, 95% CI (1.06 to 2.04)), although it was not sustained at T2. There were no significant changes between groups at either T1 (ratio of ORs 1.24, 99% CI (0.69 to 2.30); p=0.355) or T2 (ratio of ORs 0.92, 99% CI (0.51 to 1.65); p=0.735).

Of the audits with pre-MET triggers present, there was improvement in pre-MET activation comparing T0 to T1 in the intervention group (OR 1.53, 95% CI (1.07 to 2.19)). A significant change was also found at T2 (OR 1.37, 95% CI (1.02 to 1.86)) in the control group compared with T0. Of the audits with MET triggers present, there were no significant changes within or between groups from T0 compared with T1 (ratio of ORs 1.11, 99% CI (0.22 to 5.63); p=0.873) or T2 (ratio of ORs: 0.78, 99% CI (0.15 to 4.16); p=0.704).

Nursing practice outcomes

A total of 26 512 vital sign measurements were recorded in 10 383 audits with an average of 2.55 sets of vs measurements per audit. More than 90% of audits had at least one VS measurement every 8 hours, in accordance with hospital policy. Table 4 highlights that there was a significant improvement in the VS measurement every 8 hours in the intervention group at T2 (OR 1.36, 95% CI (1.08 to 1.72)). Comparing between-group relative change from T0 to T1 and T2, the difference between the intervention and control group was not statistically significant (table 4).

As per hospital policy, over 80% of audits had at least one complete set of VS measured every 8 hours

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Table 3 Comparing proportion of total audits with activated pre-MET, MET or CAT call and escalation per hospital policy by intervention and control groups at T0, T1 and T2

Group	Time 0 n/N (%)	Time 1 n/N (%)	Time 1 vs Time 0* OR (95% CI)	Time 2 n/N (%)	Time 2 vs Time 0* OR (95% CI)	P value†
Proportion of audits with escalation of care to pre-MET, MET or CAT as per hospital policy (N=2680)‡						
Both	197/848 (23.2%)	247/874 (28.3%)	1.30 (1.05 to 1.62)	279/958 (29.0%)	1.35 (1.09 to 1.67)	
Intervention	82/439 (18.8%)	107/424 (25.2%)	1.47 (1.06 to 2.04)	110/470 (23.2%)	1.32 (0.96 to 1.82)	0.102
Control	115/409 (28.1%)	140/450 (31.1%)	1.15 (0.86 to 1.55)	169/488 (34.6%)	1.35 (1.02 to 1.80)	0.055
		Time 1 vs Time 0§ OR (99% CI)		**Time 2 vs Time 0§ OR (99% CI)**		
		1.24 (0.69 to 2.30)		0.92 (0.51 to 1.65)		
		p=0.355		p=0.735		
Proportion of audits with pre-MET triggers where pre-MET was activated (N=2403)						
Both	168/753 (22.3%)	213/778 (27.4%)	1.31 (1.04 to 1.66)	251/872 (28.8%)	1.41 (1.12 to 1.77)	
Intervention	66/387 (17.1%)	90/376 (23.9%)	1.53 (1.07 to 2.19)	96/425 (22.6%)	1.42 (1.00 to 2.02)	0.057
Control	102/366 (27.9%)	123/402 (30.6%)	1.14 (0.84 to 1.56)	155/447 (34.7%)	1.37 (1.02 to 1.86)	0.055
		Time 1 vs Time 0§ OR (99% CI)		**Time 2 vs Time 0§ OR (99% CI)**		
		1.29 (0.68 to 2.45)		0.96 (0.52 to 1.88)		
		p=0.311		p=0.871		
Proportion of audits with MET triggers where MET was activated (N=273)						
Both	29/95 (30.5%)	32/94 (34.0%)	1.17 (0.64 to 2.17)	26/84 (31.0%)	1.02 (0.54 to 1.94)	
Intervention	16/52 (30.8%)	17/48 (35.4%)	1.23 (0.53 to 2.87)	12/43 (27.9%)	0.87 (0.35 to 2.14)	0.791
Control	13/43 (30.2%)	15/46 (32.6%)	1.11 (0.45 to 2.78)	14/41 (34.1%)	1.19 (0.47 to 3.04)	0.707
		Time 1 vs Time 0§ OR (99% CI)		**Time 2 vs Time 0§ OR (99% CI)**		
		1.11 (0.22 to 5.63)		0.78 (0.15 to 4.16)		
		p=0.873		p=0.704		

*OR (95% CI) compares within-group difference across times in each study group.
†P value for trend tests the changes in the outcome across times (T0, T1 and T2) in each study group.
‡Number of CATs identified in audits were too small to analyse separately.
§Intervention effect: OR (99% CI) comparing changes over time from T0 between intervention and control at Time 1 and Time 2.
CAT, cardiac arrest team; MET, medical emergency team.

(table 4). The proportion of audits with at least one VS measurement every 8 hours increased in the intervention group at T2 (OR 1.22, 95% CI (1.02 to 1.47)), while it remained unchanged in the control group. Comparing the between-group relative change from T0 to T1 and T2, the differences were not statistically significant.

The ratio of ORs of repeated VS measurement within 30 min after recording an abnormal VS at T1 compared with T0 showed a 71% increase in the intervention group that was not sustained at T2. These differences were not statistically significant. The proportion of audits with nursing intervention documented after triggering pre-MET or MET remained unchanged in the control group, while a non-significant increasing trend in T1 and a declining trend in T2 relative to T0 rate were observed. Similarly, an improvement trend was shown in nursing interventions documented for abnormal VS and medical team reviews within 30 min in the ratios of ORs in T1, reducing in T2. These differences were not statistically significant (table 4).

Patient outcomes

In total, 187 (3.1%) in-hospital deaths and 226 (3.74%) unplanned ICU admissions were recorded over the study period. There were no significant within-group or between-group changes in unplanned ICU admissions over time (table 5). The within-group change in mortality over time was non-significant for both intervention and control groups. However, the between-group change in mortality rate was statistically significant at T2 (adjusted ratio of ORs T2 vs T0 1.89, 95% CI (1.05 to 3.38)).

There were significant within-group adjusted mean changes in hospital LOS over time within the intervention and control groups (table 5). In the intervention group, adjusted mean LOS decreased at T1 (−1.31 days, 95% CI (−2.18 to –0.45)) compared with T0; while in the control group there was an increase in adjusted mean LOS at T2 (1.51 days, 95% CI (0.54 to 2.49)) compared with T0. There was no statistically significant difference in adjusted between-group changes (ie, adjusted differential change) in LOS at T1 compared with T0 (−1.10 days, 95% CI (−2.44 to

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Table 4 Comparing proportions of total audits (N=10 383) with nursing interventions by intervention and control groups at T0, T1 and T2

	Time 0	Time 1	Time 1 vs Time 0 *	Time 2	Time 2 vs Time 0 *	
Group	**n/N (%)**	**n/N (%)**	**OR (95% CI)**	**n/N (%)**	**OR (95% CI)**	**P value†**
Proportion of audits with at least one vital sign measurement every 8 hours						
Both	3072/3370 (91.2%)	3236/3535 (91.5%)	1.05 (0.89 to 1.24)	3206/3478 (92.2%)	1.14 (0.96 to 1.36)	
Intervention	1537/1716 (89.6%)	1611/1778 (90.6%)	1.12 (0.90 to 1.40)	1609/1747 (92.1%)	1.36 (1.08 to 1.72)	0.010
Control	1535/1654 (92.8%)	1625/1757 (92.5%)	0.95 (0.74 to 1.23)	1597/1731 (92.3%)	0.92 (0.71 to 1.19)	0.689
		Time 1 vs Time 0 OR (95% CI)‡		**Time 2 vs Time 0 OR (95% CI)‡**		
		1.14 (0.79 to 1.65)		1.43 (0.98 to 2.09)		
		p=0.471		p=0.064		
Proportion of audits with a complete set of vital sign measurements every 8 hours						
Both	2782/3370 (82.6%)	2930/3535 (82.9%)	1.02 (0.90 to 1.16)	2919/3478 (83.9%)	1.10 (0.97 to 1.25)	
Intervention	1418/1716 (82.6%)	1483/1778 (83.4%)	1.06 (0.89 to 1.26)	1491/1747 (85.3%)	1.22 (1.02 to 1.47)	0.034
Control	1364/1654 (82.5%)	1447/1757 (82.4%)	0.99 (0.83 o 1.18)	1428/1731 (82.5%)	1.00 (0.84 to 1.20)	0.912
		Time 1 vs Time 0 OR (95% CI)‡		**Time 2 vs Time 0 OR (95% CI)‡**		
		1.06 (0.80 to 1.39)		1.23 (0.93 to 1.63)		
		p=0.697		p=0.154		
Proportion of audits with repeated measurement in 30 min after at least one abnormal vital sign						
Both	51/845 (6.0%)	60/861 (7.0%)	1.17 (0.79 to 1.72)	32/909 (3.5%)	0.57 (0.36 to 0.89)	
Intervention	22/437 (5.0%)	33/416 (7.9%)	1.62 (0.93 to 2.87)	14/452 (3.1%)	0.61 (0.30 to 1.19)	0.169
Control	29/408 (7.1%)	27/445 (6.1%)	0.84 (0.49 to 1.46)	18/457 (3.9%)	0.54 (0.29 to 0.98)	0.109
		Time 1 vs Time 0 OR (95% CI)‡		**Time 2 vs Time 0 OR (95% CI)‡**		
		1.71 (0.81 to 3.62)		0.97 (0.39 to 2.40)		
		p=0.158		p=0.947		
Proportion of audits with nursing intervention documented after triggering pre-MET or MET						
Both	271/845 (32.1%)	290/861 (33.7%)	1.08 (0.88 to 1.32)	273/909 (30.0%)	0.91 (0.74 to 1.11)	
Intervention	144/437 (33.0%)	152/416 (36.5%)	1.17 (0.88 to 1.55)	130/452 (28.8%)	0.82 (0.62 to 1.09)	0.197
Control	127/408 (31.1%)	138/445 (31.0%)	0.99 (0.74 to 1.33)	143/457 (31.3%)	1.01 (0.76 to 1.35)	0.958
		Time 1 vs Time 0 OR (95% CI)‡		**Time 2 vs Time 0 OR (95% CI)‡**		
		1.17 (0.77 to 1.79)		0.81 (0.53 to 1.23)		
		p=0.465		**p=0.320**		
Proportion of audits with medical team review in 60 min of triggering pre-MET or MET						
Both	63/845 (7.5%)	65/861 (7.5%)	1.01 (0.71 to 1.46)	78/909 (8.6%)	1.16 (0.82 to 1.65)	

Continued

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Table 4 Continued

Group	Time 0 n/N (%)	Time 1 n/N (%)	Time 1 vs Time 0 * OR (95% CI)	Time 2 n/N (%)	Time 2 vs Time 0 * OR (95% CI)	P value†
Intervention	24/437 (5.5%)	32/416 (7.7%)	1.43 (0.83 to 2.50)	30/452 (6.6%)	1.22 (0.70 to 2.15)	0.471
Control	39/408 (9.6%)	33/445 (7.4%)	0.76 (0.46 to 1.23)	48/457 (10.5%)	1.11 (0.71 to 1.74)	0.606
		Time 1 vs Time 0 OR (95% CI)‡		**Time 2 vs Time 0 OR (95% CI)‡**		
		1.75 (0.82 to 3.73)		1.05 (0.50 to 2.21)		
		p=0.144		p=0.890		

*OR (95% CI) compares within-group difference across follow-ups.
†P value for trend tests the changes in the outcome across time points (T0, T1 and T2) in each study group.
‡Intervention effect: OR (95% CI) comparing changes over time from T0 between intervention and control at Time 1 and Time 2.

0.24)). However, the adjusted between-group changes in mean LOS at T2 compared with T0 showed a statistically significant difference (−2.18 days, 95% CI (−3.53 to −0.82).

DISCUSSION

This is the first CRCT to study the effectiveness of a multi-level facilitation intervention designed to improve recognition and response to clinical deterioration in acute care. VS assessment is the necessary precursor to the interpretation of data and thus recognition of clinical deterioration. This study used an intervention to facilitate frequent VS assessment, the interpretation of which underpins decisions and actions regarding the most appropriate escalation of care pathway (pre-MET, MET or CAT). We found a significant increase in escalation as per hospital policy after 6 months of facilitation in the intervention group that was not sustained at 12 months. In contrast to the control group, VS assessments increased significantly at 12 months in the intervention group. However, practice changes between groups were not statistically significant at either time point.

Despite a 6-month facilitation intervention, the gap between conducting VS and escalating care remains. Changing clinicians' behaviour is difficult to achieve.[23] Grimshaw *et al*[23] argued that multi-faceted interventions built on an assessment of barriers and theory were more likely to be effective than single interventions. We designed a multi-level facilitation intervention using the i-PARIHS theoretical framework to guide our approach.[7 24] Despite an understanding of the barriers, patient case-mix, shift leadership and staffing resources varied across wards and likely impacted outcomes. Nurses face numerous challenges, including dealing with uncertainty, getting a timely and appropriate medical response, high workloads, shift leadership, hospital hierarchies and patient case-mix indicating that a more explicit interdisciplinary approach to escalation may be warranted.[13 25 26]

Failure to escalate care of deteriorating patients, often referred to as afferent limb failure, has been found in numerous studies.[6 11 27 28] In the trial hospitals, mandatory escalation was in place, yet failure to escalate continued to be problematic. We believed that if nurses had facilitation support, conducted more frequent observations and performed clinical interventions within their scope of practice to mitigate early signs of deterioration, then improved escalation and patient outcomes would result. Although we observed a significant improvement in the frequency of nurses' VS assessment within the intervention group at T2 vs T0, it did not improve escalation of care. This may indicate that the duration of the intervention was too short to embed and routinise practice changes. Embedding clinical changes has been shown to be problematic in implementation studies.[29] Given the changes were moving in the right direction at 6 months, extending

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Table 5 Patient level (mortality, unplanned ICU and length of stay) outcomes: comparing proportional change from Time 0 between the intervention and control group at Time 1 and Time 2

Group	Time 0	Time 1	Time 1 vs Time 0*	Time 2	Time 2 vs Time 0*	P value†
Mortality						
	n (%)	**n (%)**	**Adjusted OR (95% CI)‡**	**n (%)**	**Adjusted OR (95% CI)‡**	
Both	60 (3.2)	66 (3.1)	1.06 (0.75 to 1.49)	61 (3.0)	0.96 (0.68 to 1.37)	0.809
Intervention	23 (2.4)	33 (3.0)	1.33 (0.87to 2.02)	32 (3.1)	1.35 (0.90 to 2.01)	0.250
Control	37 (4.0)	33 (3.2)	0.88 (0.53 to 1.44)	29 (2.9)	0.70 (0.46 to 1.07)	0.116
		Time 1 vs Time 0 OR (95% CI)§		**Time 2 vs Time 0 OR (95% CI)§**		
		1.63 (0.82 o 3.24)		1.89 (1.05 o 3.38)		0.102¶
		p=0.166		p=0.033		
Unplanned ICU admission						
	n (%)	**n (%)**	**Adjusted OR (95% CI)‡**	**n (%)**	**Adjusted OR (95% CI)‡**	
Both	78 (4.1)	71 (3.3)	0.93 (0.68 to 1.23)	77 (3.8)	1.03 (0.76 to 1.39)	0.856
Intervention	33 (3.5)	36 (3.5)	1.13 (0.70 to 1.85)	30 (2.9)	1.02 (0.68 to 1.51)	0.873
Control	45 (4.9)	35 (3.2)	0.79 (0.48 to 1.30)	47 (4.7)	1.03 (0.64 to 1.66)	0.582
		Time 1 vs Time 0 OR (95% CI)§		**Time 2 vs Time 0 OR (95% CI)§**		
		1.43 (0.74 to 2.76)		0.99 (0.56 to 1.78)		0.528¶
		p=0.294		p=0.992		
Hospital length of stay**						
	Mean (SD)	**Mean (SD)**	**Adjusted mean difference (95% CI)‡**	**Mean (SD)**	**Adjusted mean difference (95% CI)‡**	
Both	13.40 (20.99)	10.52 (13.96)	−1.18 (−1.86 to −0.51)	12.71 (18.00)	0.53 (−0.15 to 1.21)	<0.001
Intervention	13.61 (24.37)	10.32 (14.62)	−1.31 (−2.18 to −0.45)	11.40 (16.41)	−0.17 (−1.04 to 0.71)	0.005
Control	13.18 (16.76)	10.74 (13.24)	−0.91 (−1.87 to 0.06)	14.06 (19.47)	1.51 (0.54 to 2.49)	<0.001
		Intervention vs control differential change (Time 1 vs Time 0) Mean (95% CI)§		**Intervention vs control differential change (Time 2 vs Time 0) Mean (95% CI)§**		
		−1.10 (−2.44 to 0.24)		−2.18 (−3.53 to −0.82)		0.007¶
		p=0.106		p=0.002		

*OR (95% CI) compares within-group difference across follow-ups.
†P value for trend tests the changes in the outcome across time points (T0, T1 and T2) in each study group.
‡Adjusted for age, sex, hospital site, admission type and DRG weight.
§Intervention effect: OR (95% CI) (mortality, unplanned ICU and mean LOS) comparing changes over time from T0 between intervention and control at Time 1 and Time 2. Ratio of OR estimated from two-way interaction between time points and intervention group from a GEE model that included audit time point and intervention group as factors and the two-way interaction between time points and intervention group and adjusting for age, sex, hospital site, admission type and DRG weight; intervention vs control. Mean LOS estimated from two-way interaction between time points and intervention group from a GEE model with same adjustments as for mortality and unplanned ICU admissions.
¶Simultaneously testing intervention effect across T1 and T2 using a likelihood ratio test with 2 degrees of freedom.
**Missing hospital length of stay data (0.8%) were imputed using mean for study group (intervention or control) and time (T0, T1, T2).
DRG, Diagnosis-Related Group; GEE, generalised estimating equations; ICU, intensive care unit; LOS, length of stay.

the intervention time may offer further insight into the strength of the evidence.

Our multi-level facilitation intervention had variable impact. This is consistent with other recent studies that investigated facilitation as an implementation strategy and highlighted a complex facilitation-context dynamic.[30 31] Although facilitation is popular for improving decision making and practice, outcomes fluctuate, with little known about why they vacillate across contexts.[32–34] An embedded process evaluation, to be reported separately, will extend our understanding of how and why the facilitation strategy worked across different contextual settings to provide further insights into key mechanisms of action.

LOS was significantly reduced for both groups at T1 compared with T0, however, at T2 only the intervention group had a sustained reduction. Between-group comparison at T2 showed the intervention group had a statistically significant and clinically meaningful reduced LOS compared with patients in the control group. We found no significant differences in unplanned ICU admissions within or between groups.

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However, a between-group difference favoured a lower mortality in the control group at T2. LOS may be influenced by unplanned ICU admissions and mortality, this warrants further investigation. Early recognition and response have been shown to positively impact patient outcomes,[1 6] whereas delayed escalation has been associated with increased unplanned ICU admissions and death.[12] Other studies comparing patient outcomes have also shown significantly decreased LOS in non-automated vital sign capture[35] and in automated vital sign capture and alerts[36 37] with no decrease in mortality. Bed availability is a global problem, so interventions that support a reduced LOS in hospital require further examination.

The focus of this trial was limited to nurses' role in detection of clinical deterioration. What remains unknown is the impact of ward medical staff on the treatment of ward patients and escalation to external teams for clinical support. Studies have reported challenges encountered by nurses with ward medical staff and nurses' fear of escalating without approval.[38 39] One study showed nurses bypassing ward medical staff by manipulating VS and calling the external RRS.[26] Another study highlighted intraprofessional issues between different levels of nurses as potentially preventing timely escalation.[40] The impact of the bypass was not measured in our study and remains unknown. Electronic capture of VS may be used to determine such an effect. Artificial intelligence also offers opportunities to refine the escalation thresholds to increase predictive validity.[6]

The importance of knowing what response occurred once the VS were taken is critical. However, capturing the complex decision making, dynamic interactions and scope of interventions during patient deterioration remains elusive and is resource-intensive to study. We captured only interventions that were documented by nurses; this may reflect inaccurately on what actually occurred. Potentially, nurses may have mitigated the risk by intervening successfully within their scope of practice; thus, addressing the clinical deterioration and using their clinical judgement about the need to call a team in for further treatment. Studying the impact of clinical decisions in this context would provide much needed insight into the gap between recognition and escalation.

Nurses' decision making during clinical deterioration has been under-represented in research, which has focused on the failure to escalate when indicated. However, recognition of the various roles and responsibilities of health professionals within the clinical context is long overdue in studies investigating clinical deterioration.[38 40] Mackintosh *et al*[41] used a sociological framework to challenge the idea of rescuing patients as a technical fix to suggest that structural and professional inequalities require closer scrutiny. They suggested that a failure to rescue is not only an individual responsibility but spans the collective across various hierarchies. Similarly, a sociocultural framework developed after interviewing 30 clinicians explained the impact of intraprofessional and interprofessional factors and context on escalation.[38] Bingham *et al*[26] interviewed 30 nurses who reported balancing uncertainty and managing complex interdisciplinary team dynamics for deteriorating patients. Nurses also described complex decision making and interventions to counter deterioration, which preceded escalation decisions. Closer examination of the patient pre-MET situation, the patient and interdisciplinary interactions and responses to the situation is warranted to advance our understanding.

Strengths and limitations

Few CRCT studies have measured outcomes to recognise and respond to clinical deterioration, none to our knowledge have focused on facilitation to improve suboptimal decision making and escalation. A large sample across multiple hospitals, using randomisation and blinding of outcome assessors to improve internal validity, conducted in the context of service delivery, maximises external validity. However, there were limitations. The dose of the intervention was controlled at the hospital ward level. This meant that each hospital facilitator had the same time allocation despite variations in ward beds and nurses. The audit sample at time points selected the whole ward population only on audit days; however, it did not reflect the whole ward population for 12 months (ie, every patient in the wards beginning at T0 and finishing at T2). Nevertheless, access to hospital administrative data meant that patient-level outcomes such as in-hospital mortality, ICU admission and hospital LOS were included. Randomisation at the ward level, not the patient level, meant some differences between groups were evident at the ward cluster level (table 2 and online supplemental file 4). Some heterogeneity at the patient level was expected which is not uncommon in cluster randomised control trials. These differences were adjusted for and highlighted the importance of measuring within-group differences over time. We were unable to perform robust models to estimate ORs and ratio of ORs for cardiac arrest rates due to very low numbers. Documentation may also not reflect actual clinician behaviour. However, nurse observations are resource-intensive, based on small samples and to study escalation would require individuals to be followed 24 hours a day. As a legal requirement, documentation is meant to reflect clinical interventions and is widely used in studies of quality of care.

CONCLUSION

This study set out to measure the effectiveness of a multi-level facilitation intervention targeted at nurses' early recognition and response to clinical deterioration in patients. There was evidence of increased guideline adherence by nurses in the intervention group,

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including some sustained change. Compared with the control group, the demonstrated reduced LOS for patients in the intervention group is a clinically important outcome for patients and health services. Further research on the dosage of facilitation, responsiveness to context and mechanisms of action in healthcare improvement is warranted. Leveraging electronic decision support systems to track and trigger escalation decisions and interventions offers further potential for improvement but risks alert fatigue. Digital architecture or 'nudging' to assist nurses to make the optimal choice for interventions and escalation may reduce the cognitive burden and should be investigated.

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