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Transforming nursing assessment in acute hospitals: A cluster randomised controlled trial of an evidence-based nursing core assessment (the ENCORE trial)

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ABSTRACT

Background: Patient safety is threatened when early signs of clinical deterioration are missed or not acted upon. This research began as a clinical–academic partnership established around a shared concern of nursing physical assessment practices on general wards and delayed recognition of clinical deterioration. The outcome was the development of a complex intervention facilitated at the ward level for proactive nursing surveillance.
Methods: The evidence-based nursing core assessment (ENCORE) trial was a pragmatic cluster-randomised controlled trial. We hypothesised that ward intervention would reduce the incidence of patient rescue events (medical emergency team activations) and serious adverse events. We randomised 29 general wards in a 1:2 allocation, across 5 Australian hospitals to intervention ($n = 10$) and usual care wards ($n = 19$). Skilled facilitation over 12 months enabled practitioner-led, ward-level practice change for proactive nursing surveillance. The primary outcome was the rate of medical emergency team activations and secondary outcomes were unplanned intensive care unit admissions, on-ward resuscitations, and unexpected deaths. Outcomes were prospectively collected for 6 months following the initial 6 months of implementation. Analysis was at the patient level using generalised linear mixed models to account for clustering by ward.
Results: We analysed 29,385 patient admissions to intervention ($n = 11{,}792$) and control ($n = 17{,}593$) wards. Adjusted models for overall effects suggested the intervention increased the rate of medical emergency team activations (adjusted incidence rate ratio 1.314; 95 % confidence interval 0.975, 1.773), although the confidence interval was compatible with a marginal decrease to a substantial increase in rate. Confidence intervals for secondary outcomes included a range of plausible effects from benefit to harm. However, considerable heterogeneity was observed in intervention effects by patient comorbidity. Among patients with few comorbid conditions in the intervention arm there was a lower medical emergency team activation rate and decreased odds of unexpected death. Among patients with multimorbidity in the intervention arm there were higher rates of medical emergency team activation and intensive care unit admissions.
Conclusion: Trial outcomes have refined our assumptions about the impact of the ENCORE intervention. The intervention appears to have protective effects for patients with low complexity where frontline teams can respond locally. It also appears to have redistributed medical emergency team activations and unplanned intensive care unit admissions, mobilising higher rates of rescue for patients with multimorbidity.
Trial registration number: ACTRN12618001903279 (Date of registration: 22/11/2018; First participant recruited: 01/02/2019).

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What is already known

- Although hospital rapid response systems for clinical deterioration provide a patient safety net, they do not guarantee timely, safe and effective care by frontline teams.
- Ultimately, patient safety depends on nursing surveillance capacity at the ward level.

What this paper adds

- This is the first cluster-randomised trial to examine the impact of strengthening nursing physical assessment at the ward level on the rate of medical emergency team activations and serious adverse events.
- We found intervention effects depended on patient complexity, based on the number of comorbid conditions.
- Optimising the contribution of ward nursing physical assessment for early changes and trends in patient condition would enhance hospital safety.

1. Introduction

Hospital rapid response systems were designed to improve timely recognition of at-risk patients and to overcome delays in initiating treatment within the traditional hierarchical chain-of-command medical model (Lyons et al., 2018). While now widely implemented, the impact of rapid response systems on patient outcomes remains uncertain (Hall et al., 2020; Piasecki et al., 2023). Rapid responses may decrease in-hospital cardiac arrests and all-cause mortality (Chan et al., 2010; De Jong et al., 2016; Maharaj et al., 2015; Solomon et al., 2016), although the evidence is debated and how to optimise implementation remains controversial (Lyons et al., 2018; Hall et al., 2020; Piasecki et al., 2023). Yet, from a ward nursing standpoint, a potential problem with the rapid response system is that healthcare facilities are arriving at a solution to a serious problem by focussing on the end of the process (the rescue) rather than analysing the issue as a whole (White et al., 2015). Rapid response call criteria are focussed on late signs of deterioration which can have unintended consequences for patient safety (Harrison et al., 2006; Tan et al., 2021). One consequence is that ward nursing assessment practices become concentrated at the sharp end of acute patient deterioration, a point at which early interventions lose effectiveness and medical rescue is the prevailing model of care (Osborne et al., 2015). Providing ward staff with the resources needed to assess and act upon early changes in patient condition could prevent the need for rescues in the first place (Hamlin et al., 2023).

The ENCORE trial began as a hospital nursing and academic staff collaborative enquiry into missed or delayed recognition of clinical deterioration on general wards at a major hospital in Brisbane, Australia. Hospital staff wanted to interrogate the hospital rapid response system and consequences of current practices including nursing physical assessment. We undertook a critical analysis of the situation to better understand the nature of the problem with a view to developing actionable evidence for acute hospitals.

We undertook multidisciplinary hospital surveys, focus groups, observations and interviews to conceptualise the intervention. Our published and unpublished research concluded that hospital safety systems (such as the rapid response system) produced and reproduced nursing practice that was dependent upon a rescue response (Osborne et al., 2015; Douglas et al., 2014, 2016a). As such, patient assessment was reactive and focussed on late signs of deterioration; ward staff used disparate models and lacked a shared language for clinical assessment; nursing workflow and systems of care were designed for efficiencies which prioritised task-based routines over clinical reasoning; and the contribution of ward nurses to patient assessment was incommensurate with their responsibility for keeping patients safe. The evidence in total supported fundamental changes in ward practice to strengthen nursing surveillance capacity in order to reduce the incidence of patient rescue events and serious adverse events (Osborne et al., 2015; Douglas et al., 2014, 2016a, 2016b).

In response to the above work, we conducted a multi-stage Delphi process to develop a structured acute care nursing surveillance model to move practice away from collecting minimal vital signs to a core plus specialty-specific assessment model (Douglas et al., 2016b). We established consensus on structured core physical assessment to detect early changes in patient status and on core skills at the ward level (Douglas et al., 2016b). We also developed participatory facilitation approaches for ward-level practice change to embed the innovation and optimise early intervention for preventable deterioration (Peet et al., 2019, 2022). The evidence-based nursing core assessment (ENCORE) was successfully piloted for feasibility on a surgical ward and proposed as a complex intervention to transform nursing assessment in acute hospitals.

Real transformation in hospital safety is difficult to achieve. Implementation efforts for preventable clinical deterioration on general wards commonly emphasise what Kemmis (2022) calls technical transformation: more efficient and productive systems, roles and rules (Burke et al., 2022). By contrast, we sought to focus on social processes to achieve critical transformation in nursing practice (Kemmis, 2022). Our objective was to empower wards to alter the organisation of nursing work in ways that might avoid preventable rescue situations. Central to the ENCORE trial, therefore, were systemic changes to ward practices designed to keep patients safe and to ensure nursing core assessment was visible and valued. The implementation approach was critical and participatory (Kemmis et al., 2014, 2019) and thus gave primacy to collective engagement in a social analysis of nursing practices to determine a shared vision for transformation; to collective deliberation and decisions for context-specific solutions, with a focus on function over form; and to collective action at the level of the ward microsystem.

To evaluate this complex intervention, the ENCORE trial was designed to determine effectiveness and implementation outcomes using a cluster-randomised controlled trial design with embedded process and economic evaluations. This article reports on the effectiveness of the ENCORE intervention for patient outcomes. The hypothesis was that intervention would reduce the rate of patient rescue events (medical emergency team activations) and serious adverse events (unplanned intensive care unit admissions, on-ward resuscitations, and unexpected deaths).

2. Methods

2.1. Trial design

We evaluated ward-level intervention with a parallel-group cluster-randomised controlled trial using unequal allocation (1 intervention ward to 2 control wards) with seven acute hospital partners. Hospital wards (clusters) were randomised to either intervention or control wards with outcome measures at the patient admission level. Randomisation was at the ward rather than hospital level which allowed for a greater number of clusters and hospitals to act as their own control. The trial protocol was prospectively registered (Australian New Zealand Clinical Trials Registry number: ACTRN12618001903279; registered 22/11/2018) and the study period was 1 February 2019 to 30 June 2020. Reporting follows the CONSORT extension for cluster trials (Campbell et al., 2012).

2.2. Setting and participants

The trial involved four major public hospitals in Metro North Hospital and Health Service in South-East Queensland and one major public hospital and two private hospitals from the St Vincent's Health Australia network in Sydney, New South Wales. All hospitals had established medical emergency teams with two-tiered rapid response systems (first tier: clinical review within 30 min; second tier: immediate medical emergency team response).

Clusters were general acute care wards, with at least 20 beds and greater than 70 % permanent nursing staff. Specialist units (e.g., intensive care, operating theatres) were ineligible to participate. In total, 34 eligible wards were stratified by (1) hospital and (2) ward type (medical/surgical) and randomised to either intervention or control groups. Hospital Executive and Directors of Nursing gave organisational consent for implementation in eligible wards prior to randomisation. All staff working in the trial wards were involved in the project.

Patient outcome data collection commenced immediately after six months of implementation at each hospital. All patients ≥18 years old admitted to trial wards during a six-month period were prospectively recruited using an opt-out approach for access to health records. Patients were blind to ward allocation or the nature of the intervention.

2.3. The ENCORE intervention

Ward practice change was grounded in a participatory and action-oriented approach to implementation (Kemmis et al., 2014, 2019) reflected in key assumptions guiding facilitation (Table 1). We developed simple principles about how the intervention was designed to work that informed collective action across intervention wards and encouraged local adaptation and experimentation. Skilled external and internal facilitation activated and aligned these principles for theoretical fidelity (Hawe et al., 2004) by standardising the purpose of intervention components rather than the form of components themselves. We provided structure to the steps of the change process and the frontline teams decided how to implement change in their respective contexts.

2.3.1. Strengthening proactive nursing surveillance

The first principle to shift practice from rescue to prevention of patient deterioration was building ward consensus on a model of nursing physical assessment. Intervention wards adopted a structured core nursing physical assessment for general wards to recognise *early changes and trends* in patient status and to enhance *clinical reasoning* at the bedside (Douglas et al., 2016b). The core assessment comprised activities common across all clinical areas plus physical assessment activities that were determined by ward consensus as core for their specialty area. In each ward the emphasis was on manual patient assessment (i.e., inspection, palpation, auscultation) over electronic vital signs monitoring. A primary survey approach (ABCDE) was also adopted for synthesis of patient data to trigger further focussed assessment and/or ongoing care decisions, such as frequency of clinical monitoring.

2.3.2. Bringing registered nurses to the centre of decision-making for patient assessment

Two further simple principles situated core assessment to inform nursing care planning and multidisciplinary team communication. Intervention wards embedded practices that enabled: (1) structured core assessment of every patient at the beginning of every shift; and (2) responsible RN involvement in reviewing patient status and goals of care at ward rounds. Both changes represented a major shift in ward practice that required action planning and iterative cycles of change.

Several months of engagement at all levels of hospital leadership occurred to facilitate organisational readiness and to enable practitioner-led change on intervention wards. Implementation occurred over a 12-month period where the first 6 months embedded ward practice change and the second 6 months supported sustainment. We adopted an external-internal model of facilitation (Harvey and Kitson, 2015). Expert and experienced external facilitators (research team) worked with novice internal facilitators (ENCORE leads) to enable frontline teams to move forward with implementation. Each intervention ward internally appointed an ENCORE lead (clinical nurse) who was employed 2 days per week for the first 6 months of implementation.

External facilitators (one full-time and one part-time, 2 days per week employed in each state) maintained engagement with ward staff over 12 months, focussed on developing ways of working that were collaborative, inclusive and participative. Over the first month of implementation, we achieved high levels of engagement with intervention wards (>90 % of permanent nursing staff attendance) at face-to-face, facility-based (4 h) and ward-based (2 h) ENCORE workshops co-facilitated by the project team. Workshops were educative only in the sense of raising awareness of the power of the status quo, or “the way things are done around here,” and to develop a shared vision for transformation. We provided visual representations of the innovation (e.g., videos of local staff enacting the innovation and visual design of intervention components) that promoted critique and development rather than replacing existing practices and resisted formulations of “new checklists” or assessment tools. Likewise, wards developed their own visual intervention resources to support shared understanding (e.g., ward-specific posters, lanyard-sized cards, core assessment visualisations at the bedside). Wards reconfigured bedside monitoring equipment for manual core assessment and we provided each RN a professional stethoscope.

Implementation was iterative and cyclical and responsive to local context. We established a shared network of ENCORE leads across facilities to support their development as facilitators and to share learning through critical reflection. Most importantly, we continued to create opportunities on and off the wards for teams to discuss and debate the ENCORE intervention, to build mutual understanding and to agree on practical action to move forward.

Table 1
Assumptions informing implementation (based on Walsh et al. (2017)).

- Respecting nurses as intelligent, knowledgeable and skilled professionals—and recognising nurses as the experts in their own context.
- Skilled facilitation is enabling and supporting others to act, rather than telling, persuading or coercing people into action.
- Engaging in a genuine puzzle to be solved, rather than a predetermined solution to be implemented and drawing out the practice wisdom of the collective in generating solutions for the context.
- Seeking to understand what goes right and why, rather than just what goes wrong and supporting frontline teams to take action within their sphere of influence.

2.4. Control wards

Control ward conditions reflected usual patient care practices. Control wards did not receive any detailed information or implementation support for systems change around nursing assessment practice.

2.5. Outcomes

The primary outcome was patient rescue events on the ward measured by the rate of medical emergency team activations collected from hospital switchboard records. Typically, this is reported in the literature as a medical emergency team call rate per 1000 admissions (Lyons et al., 2018). Hospital call criteria provide a clinical definition for acute deterioration that includes threatened airway, critically abnormal breathing, circulation or level of consciousness (Lyons et al., 2018). Clinical staff activate a medical emergency team call by phoning a central switchboard which provides a definitive record of medical emergency team events including ward and patient details. Ward medical emergency team call data were also cross-checked for verification by comparison with audit records that were completed at the bedside by the response team and separately recorded in each hospital's safety and quality database.

Secondary outcomes were serious adverse events including unplanned intensive care unit admissions, on-ward resuscitations, and unexpected deaths. An unplanned intensive care unit admission was defined as patients admitted to intensive care following deterioration or any emergency response on a general ward (ANZICS Centre for Outcome and Resource Evaluation, 2022). Resuscitation was defined as the need for chest compressions and/or defibrillation (Peberdy et al., 2007). Unexpected deaths included patient deaths without a documented do not attempt resuscitation order (MERIT Study Investigators, 2005). Ward resuscitations were collected from the hospital switchboard code blue calls. Intensive care unit admissions and deaths were obtained from discharge codes using linked admitted patient data.

All patients who had an outcome of interest had their medical records audited by a team of research assistants to verify events against outcome definitions. Outcome evaluators were independent of study hospitals and blinded to ward assignment. We linked hospital admitted patient data to outcomes to construct comprehensive patient characteristics for each ward admission, such as length of stay and clinical covariates. The Elixhauser comorbidity index (Elixhauser et al., 1998) for 31 conditions was scored with ICD-10-AM codes based on Quan et al. (2005) and confirmed with study hospital clinical coders. It has been shown to outperform other comorbidity indices for predicting patient outcomes such as mortality (Yurkovich et al., 2015).

2.6. Sample size

We planned to recruit 36 wards (1:2 allocation intervention to control) and from each ward expected an average of 1000 patient admissions over a 6-month period resulting in a target sample size of 36,000 admissions. Accounting for a design effect (Rutterford et al., 2015) we estimated the trial would have 80 % power to detect at least a 25 % reduction in the control event rate of 0.075 (7.5 %) for medical emergency team activations (based on local hospital data), assuming a two-sided 5 % significance level and an intra-cluster correlation (ICC) of 0.005. We also generated power curves with a range of cluster sizes and ICC values to inform sample size determination. Small increases in ICC substantially increased sample size estimates. Increasing cluster sizes (number of patient admissions) yielded marginal gains in study power, which was primarily determined by the number of wards (Hemming et al., 2017).

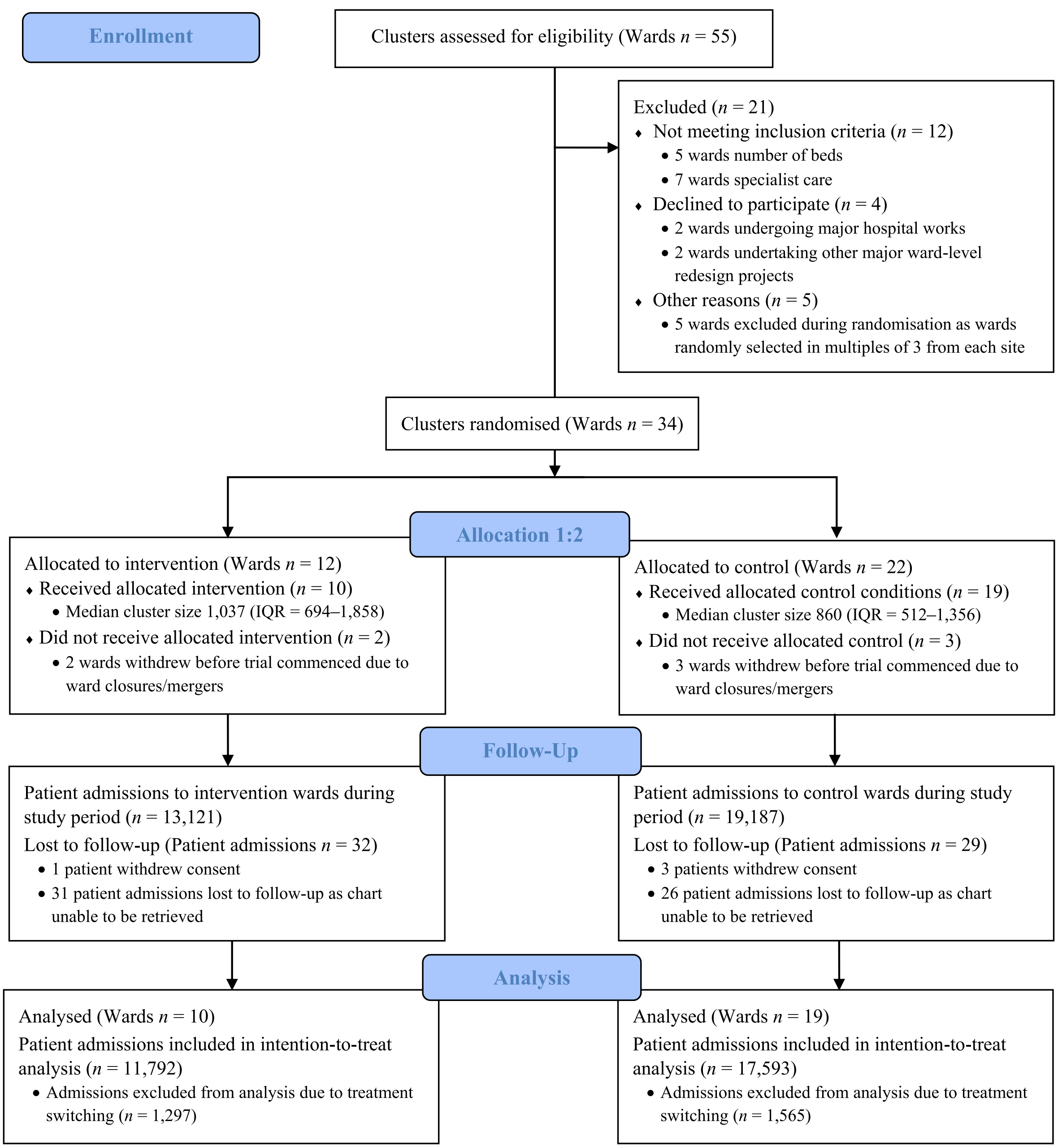

Fig. 1. Participant flow.

2.7. Randomisation and blinding

A stratified random allocation sequence was computer-generated and wards were assigned to intervention or control conditions by a trial biostatistician not involved in analysis of outcomes. Wards were randomly assigned in multiples of 3 within each hospital to achieve a 1:2 allocation. Ward allocation was concealed until implementation was ready to begin at each facility. Nurses were not masked to ward randomisation on assignment, and there may have been some movement of staff across wards reflective of a pragmatic trial. However, given the collective effort required to embed and sustain practice change in intervention wards, we expect individual nurses who moved to control wards had limited impact on ward-level practice.

2.8. Statistical analysis

First, we investigated the trial clusters to inform our data modelling choices. The unit of observation was a patient admission, meaning that although most patients had a single ward admission (80 %), some contributed multiple observations over the study period. Further cluster characterisation is reported in Supplementary Table 1. To account for clustering of patients within wards, we used mixed-effects models that included a random effect for ward. We clustered errors at ward level which accounted for repeated admissions by the same patient.

We used an intention-to-treat analysis. The count of medical emergency team activations was analysed with mixed-effects Poisson regression, including ward length of stay as an offset to account for different exposure times for each admission. Binary outcomes for unplanned intensive care unit admission, resuscitation and unexpected death were analysed with mixed-effects logistic regression. A priori, we included hospital and ward type (surgical/medical) fixed effects to account for stratified randomisation using these variables. All models were adjusted for patient age (years), comorbidities (sum of Elixhauser comorbidities) and hospital admission from emergency department (yes/no). To account for intra-year seasonality over the study period, we also included month-fixed effects. Consistent with Medical Research Council guidance on evaluating complex interventions (Skivington et al., 2021), we also conducted planned analyses for effect modification by ward type and patient characteristics (i.e., comorbidities) by interactions with the intervention group variable.

For all outcomes, we report intervention effect measure estimates with 95 % confidence intervals (CIs) and interpret CIs in relation to clinically important effect sizes (Hemming and Taljaard, 2021). We used interval estimation rather than *p*-values for interpretation of effect sizes in line with the position statement of this journal (Griffiths and Needleman, 2019). All analyses were conducted in Stata release 17 (StataCorp, 2021).

2.9. Ethical approval

The trial protocol was approved for all sites by The Prince Charles Hospital Human Research Ethics Committee (EC00168) as a lead committee for multicentre research (HREC/18/QPCH/1). An opt-out consent approach was used to access medical records. Approval was granted under the Queensland *Public Health Act* 2005 to access hospital admitted patient data (QCOS/032227/RD007608).

3. Results

3.1. Participant characteristics

Fig. 1 shows the flow of ward clusters and patient admissions throughout the trial. The final allocation ratio was not exactly 1:2 because two hospitals each contributed two wards. Before trial commencement two private hospitals withdrew ($n = 5$ clusters) due to ward closures or ward mergers across trial arms. Thus, of the 34 wards assigned, the final sample ($n = 29$ clusters) included 10 intervention wards and 19 control wards across five hospitals. We completed the trial by 30 June 2020 during the early stages of the COVID-19 pandemic. Both Queensland and New South Wales implemented various general restrictions on public gatherings and movement by April 2020 which restricted patient visiting but did not affect ward staffing. Four wards (2 intervention and 2 control) at one hospital merged and closed in preparation for the COVID-19 response towards the end of the trial.

Given the pragmatic sampling design, some patients were admitted to both intervention and control wards over the study period. We therefore excluded from the analysis admissions where the patient's ward assignment differed from the ward of their first admission (and all subsequent ward admissions). This reduced the total number of patient admissions from 32,247 to 29,385.

Table 2 presents a summary of baseline characteristics. There was some imbalance in covariates that may be prognostic for outcomes. Compared with control ward admissions ($n = 17{,}593$), the intervention ward admissions ($n = 11{,}792$) represented younger patients (median age, 62.6 vs 66.3 years) with fewer comorbidities overall (no comorbidities, 38.3 % vs 34.9 %), although at the level of specific comorbidities the direction of imbalance was inconsistent. Intervention wards received more hospital admissions originating from the emergency department (68.9 % vs 60.2 %). All subsequent analyses adjusted for these covariates.

Table 2
Patient admission characteristics.

Characteristic	Patient admissions, *n* (%)	
	Intervention wards ($n = 11{,}792$)	Control wards ($n = 17{,}593$)
Age, median (IQR), years	62.6 (46.6–75.0)	66.3 (49.5–78.2)
Sex, female	5450 (46.2)	8163 (46.4)
Socioeconomic index (SEIFA)[a], median (IQR)	1010 (936–1062)	994 (929–1054)
Elixhauser comorbidities		
Congestive heart failure	809 (6.9)	1580 (9.0)
Cardiac arrhythmias	1397 (11.9)	2338 (13.3)
Hypertension	678 (5.8)	1301 (7.4)
Chronic pulmonary disease	1064 (9.0)	959 (5.5)
Diabetes	875 (7.4)	1232 (7.0)
Diabetes with complications	1502 (12.7)	2707 (15.4)
Kidney failure	693 (5.9)	1323 (7.5)
Solid tumour without metastasis	846 (7.2)	978 (5.6)
Weight loss	968 (8.2)	1414 (8.0)
Fluid and electrolyte disorders	2022 (17.2)	3171 (18.0)
Alcohol abuse	553 (4.7)	805 (4.6)
Other[b]	2834 (24.0)	5078 (28.9)
Total number (sum) of comorbidities		
None (0)	4513 (38.3)	6137 (34.9)
One (1)	3264 (27.7)	4940 (28.1)
Two (2)	1997 (16.9)	3116 (17.7)
Three or more (≥3)	2018 (17.1)	3400 (19.3)
Ward type		
Medical	5222 (44.3)	7927 (45.0)
Surgical	5509 (46.7)	9160 (52.1)
Mixed medical-surgical	1061 (9.0)	506 (2.9)
Length of stay, median (IQR), days		
Study ward admission	1.8 (0.8–3.8)	2.0 (0.9–4.7)
Hospital admission	3.0 (1.4–6.9)	4.0 (1.8–9.1)
Ward immediately prior to study ward admission		
Emergency department	3281 (27.8)	4625 (26.3)
Intensive care unit	457 (3.9)	1067 (6.1)
Emergency department hospital admission	8120 (68.9)	10,594 (60.2)

Note:
[a] SEIFA = Socioeconomic Indexes for Areas (Australian Bureau of Statistics, 2018); we report the Index of Relative Socio-economic Advantage and Disadvantage (IRASD).
[b] Other comorbidities that were each present for fewer than 5 % of patient admissions overall, including: valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hypertension with complications, paralysis, other neurological disorders, hypothyroidism, liver disease, peptic ulcer disease excluding bleeding, HIV/AIDS, lymphoma, metastatic cancer, rheumatoid arthritis/collagen vascular diseases, coagulopathy, obesity, blood loss anaemia, deficiency anaemia, drug abuse, psychoses, depression.

3.2. Patient outcomes

We observed a total of 2614 medical emergency team activations over the study period from 1671 (5.69 %) of 29,385 patient admissions. This event rate was lower than expected. For secondary outcomes, there were 276 (0.94 %) unplanned intensive care unit admissions, 34 (0.12 %) resuscitations and 222 (0.76 %) unexpected deaths. The crude rate of events per 1000 ward admissions was consistently lower for the intervention versus control wards: 86.8 vs 90.4 medical emergency team activations/1000 admissions; 8.6 vs 9.9 unplanned intensive care unit admissions/1000 admissions; 0.9 vs 1.3 resuscitations/1000 admissions; and 6.2 vs 8.5 unexpected deaths/1000 admissions.

Table 3 reports the adjusted effect measures of the ENCORE intervention on primary and secondary patient outcomes. For medical emergency team activations, while the point estimate suggests a rate increase of 31.4 % in intervention versus control wards, the confidence interval was also compatible with a marginal decrease of 2.5 % to a substantial increase of 77.3 %. Data for serious adverse events are most compatible with intervention effect estimates that widely span clinically important benefit and harm. Taken together, the interpretation of trial outcomes based on 95 % confidence intervals (Hemming and Taljaard, 2021) indicates the overall intervention effects are inconclusive. A sensitivity analysis that retained all admissions after treatment switching also showed the magnitude and direction of estimates were similar (<5 % change in estimates; data not shown).

Next, and to contextualise the above findings, we planned to examine if intervention effects varied across subgroups of ward or patient characteristics (Supplementary Tables S2–4). We found no evidence that effects differed by ward type (medical/surgical) for any outcome. However, we observed that intervention effects were associated with the level of patient comorbidity.

As a measure of patient comorbidity and complexity, the Elixhauser score ranged from 0 to 9. To ensure adequate cell counts for subgroup analysis, for medical emergency team activations we collapsed the highest comorbidity scores ≥7 into one category. Fig. 2 shows that compared with the control wards, intervention decreased the rate of medical emergency team activation for patients without comorbidities (adjusted incidence rate ratio 0.604; 95 % CI, 0.422, 0.864), while the intervention increased activation rates for patients with 3 or more comorbidities.

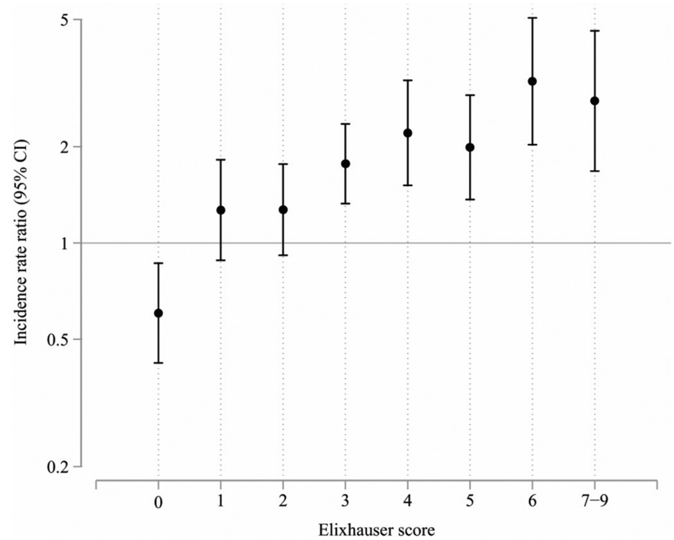

Fig. 2. ENCORE intervention effect on Medical Emergency Team activations by number of patient comorbid conditions.
Note: Adjusted incidence rate ratios when intervention is interacted with levels of Elixhauser comorbidity score. An incidence rate ratio of 1 is no effect.

We further investigated if the same pattern held for secondary outcomes. Due to the rarity of realised secondary outcomes and their unequal distribution by comorbidity score, we dichotomised the Elixhauser score. Ultimately, our model distinguished the effect on patients with multimorbidity (≥2) from those without or with one comorbidity. Consistent with the pattern in Fig. 2, the intervention increased the likelihood of unplanned intensive care unit admissions for patients with multimorbidity (adjusted odds ratio (OR) 2.791; 95 % CI, 1.424, 5.472), but not without multimorbidity (adjusted OR 0.571; 95 % CI, 0.226, 1.445). The protective effects of intervention also appeared strengthened for patients without multimorbidity in terms of resuscitation (adjusted OR 0.326; 95 % CI, 0.105, 1.009) and unexpected death on the ward (adjusted OR 0.600; 95 % CI, 0.364, 0.989).

Table 3
ENCORE Intervention effect estimates for patient outcomes.

Medical emergency team activations	
Incidence rate ratio	1.314
95 % CI	(0.975, 1.773)
ICC[a]	0.011
n	29,385
Unplanned intensive care admissions	
Odds ratio	1.367
95 % CI	(0.732, 2.553)
ICC	0.182
n	29,385
On-ward resuscitations	
Odds ratio	0.648
95 % CI	(0.363, 1.156)
ICC	3.57×10^{-33}
n[b]	21,112
Unexpected deaths	
Odds ratio	0.939
95 % CI	(0.604, 1.459)
ICC	0.037
n	29,385

Note: Generalised linear mixed models with ward (cluster) random effect. Adjusted for patient age, comorbidities, hospital admission from emergency department, study month, hospital and ward type. Ward clustered standard errors were used for 95 % CIs.
[a] Intra-cluster correlation (ICC) was estimated using exact calculations (Austin et al., 2018) with averages for continuous covariates and zeros for binary covariates. ICC ranges from 0.005 to 0.41, increasing with the length of ward stay. The value corresponding to the median length of stay is reported.
[b] As in-hospital cardiac arrest is a very rare outcome, there were zero resuscitation events for one hospital and at several time points (month time effects variable). These zeros caused separation problems and therefore observations in these categories were dropped from the logistic regression model (Mansournia et al., 2017).

4. Discussion

The ENCORE trial facilitated practitioner-led, ward-level practice change for proactive nursing surveillance to keep patients safe. We demonstrated in a large-scale cluster-RCT the impact of working with frontline teams to transform the social practice of nursing physical assessment on patient outcomes. We found that while overall intervention effects were imprecise, subgroup analysis by levels of patient comorbidity suggested large differences in outcomes between groups with or without ward intervention. For patients with multimorbidity, intervention wards mobilised a higher rate of medical emergency team response and intensive care unit admissions. For patients with low complexity, ward intervention appears to have reduced the rate of medical emergency team response and risk of unexpected death.

The findings have challenged our assumptions about how the ENCORE intervention would work and produce its intended outcomes in general wards. We hypothesised a global reduction in rescue events for patients with preventable deterioration and made strong assumptions about the kind of preventative action to be taken by nurses if deterioration was detected early. It may be that frontline teams can prevent rescue events with autonomous and local action when patient complexity is low. But as patient complexity and risk for poor outcome increases, activating a medical emergency team response may be a first-line intervention and indeed the most appropriate action to keep a patient safe. In this way the ENCORE intervention appears to have redistributed medical emergency team response effort to where it was needed most.

General ward staff often care for deteriorating patients with complex acuity and dependency profiles typical of intensive care where nurse-to-patient ratios are one-to-one (Batterbury et al., 2023a). We have recently shown that deteriorating patients on general wards could be clustered by levels of clinical acuity and dependency with distinct risk profiles for subsequent clinical deterioration, unplanned intensive care admission and in-hospital mortality (Batterbury et al., 2023b). Our trial findings reflect this gradient of care complexity, where the intervention effects indicate that clinical decision-making was responsive to levels of patient comorbidity.

We add to other recent ward-level cluster-RCTs of facilitated safety interventions where the overall intervention effects on the primary outcome are not directive, but where holistic interpretation of outcomes and context are more informative (Mudge et al., 2022; Bucknall et al., 2022). As a complex intervention, unbiased estimates of effectiveness offer an important but incomplete evaluation of impact for decision-makers (Skivington et al., 2021). We considered responsiveness to context and the more practice-relevant findings generated with a participatory approach as key strengths of the trial (Harvey et al., 2023). Although not the focus of this article, we included rigorous process and economic evaluation methods in the evaluation study design to allow for broader questions about the impact of ENCORE intervention to be examined and reported elsewhere.

Our external-internal model of skilled facilitation was the primary implementation strategy and a powerful catalyst for ward transformation. Facilitation focussed on building safety cultures with frontline teams at the microsystems level, where care is experienced and provided, while aligning support from organisational enablers (Manley et al., 2019; Manley and Jackson, 2020). Creating spaces for democratic conversation was central to the participatory approach to implementation, where ward staff learned to seek mutual understanding of viewpoints and came to unforced consensus on change (Kemmis et al., 2019). Having embedded facilitators enabled ongoing conversations to include as many ward staff as possible. This process gave legitimacy to collective decisions reached through ward consensus by allowing for contestation and debate over what would work locally to enact the ENCORE intervention.

The generalisability of our findings at the patient and ward level is supported by the pragmatic trial design with broad eligibility criteria and testing intervention effects in real-world practice conditions. The principles guiding implementation in this trial are transferable for acute care wards so that the intervention can be contextualised to the setting. We agree with Walsh et al. (2017) that for clinical research "… it is sometimes essential that clinical teams invent their own wheel rather than use one designed for somewhere else. The process of construction can be as important as the wheel itself." The ENCORE trial also offers a successful model of academic engagement and partnership with hospital staff to transform health services with large-scale acute hospital research on systems change and patient safety.

4.1. Limitations

We acknowledge several potential limitations. Having fewer clusters recruited and retained than planned, a higher ICC than estimated and the rarity of serious adverse events (secondary outcomes) reduced the precision of our findings, as evidenced by the width of confidence intervals (Hemming et al., 2017; MacKinnon et al., 2023). While the patient outcomes measured were important to patients and staff, they were late endpoints in the deterioration trajectory. Extending outcomes to an earlier point in the trajectory to include urgent clinical reviews or hospital-acquired complications (e.g., pressure injury, falls with injury, delirium) that may precede a medical emergency would also capture the impact of quality of ward care. Further work on developing a core outcome set for trials of nursing intervention for preventable clinical deterioration on general wards would be a valuable contribution to the field. We used a definition of unexpected death consistent with earlier trials (MERIT Study Investigators, 2005) but note broader definitions have been used by others (Haegdorens et al., 2018).

Although ward-level randomisation fitted the intervention and had design advantages, conducting a parallel-group cluster trial with general hospital wards was challenging. General wards were more fluid and changeable work units than anticipated. Several wards withdrew early in the trial due to closures and ward mergers. Acute care frontline teams also had multiple hospital quality and safety initiatives implemented at once. We were interested in the intervention effects over and above these standard improvement practices, but we acknowledge that without alignment of purpose, intervention effectiveness may have been diminished.

Cluster-randomisation can be vulnerable to imbalance in baseline characteristics and therefore we adjusted for potential confounding in all analyses (Hayes and Moulton, 2017). Our design also gives valid estimates of intervention effect modification without the need for further controls in subgroup analyses (VanderWeele and Knol, 2011). However, without a large number of clusters it is prudent to remain tentative about conclusions (MacKinnon et al., 2023; Rothwell, 2005).

5. Conclusion

Although hospital-level systems for recognition and response to clinical deterioration provide a patient safety net, they do not guarantee timely and effective care by frontline teams. Safe care depends acutely on nursing surveillance capacity where it matters most, on the ward where care is provided and experienced. The ENCORE trial represents a large collaborative effort to rigorously evaluate, for the first time, the impact of strengthening nursing physical assessment at the ward level on patient safety outcomes. We found that intervention effects depended on patient complexity where among patients with low levels of comorbidity there was a lower medical emergency team activation rate and decreased odds of unexpected death, and among patients with multimorbidity there were higher rates of medical emergency team activation and intensive care unit admissions. Patient safety would be enhanced by participatory engagement with frontline teams for the development of proactive nursing surveillance.

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CRediT authorship contribution statement

Clint Douglas: Writing – review & editing, Writing – original draft, Supervision, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Sergey Alexeev:** Writing – review & editing, Formal analysis, Data curation. **Sandy Middleton:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Glenn Gardner:** Methodology, Funding acquisition, Conceptualization. **Patrick Kelly:** Methodology, Funding acquisition, Data curation, Conceptualization. **Elizabeth McInnes:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **John Rihari-Thomas:** Writing – review & editing, Project administration. **Carol Windsor:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Rachael L. Morton:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization.

Data availability

Data are not publicly available due to confidentiality restrictions.

Declaration of Competing Interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2024.104690.

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