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A cluster randomised controlled feasibility study of nurse-initiated behavioural strategies to manage interruptions during medication administration

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Abstract

Objectives: To examine the feasibility of a behavioural e-learning intervention to support nurses to manage interruptions during medication administration.
Design: A cluster randomised feasibility trial.
Setting: The cluster trial included four intervention and four control wards randomly selected across four metropolitan hospitals in Sydney, Australia.
Participants: We observed 806 (402 pre-intervention and 404 post-intervention) medication events, where nurses prepared and administered medications to patients within the cluster wards.
Main Outcome Measures: The primary outcome measured was the observed number of interruptions occurring during administration, with secondary outcomes being the number of clinical errors and procedural failures. Changes in the use of behavioural strategies to manage interruptions, targeted by the e-learning intervention, were also assessed.
Results: No significant differences were found in the number of interruptions ($P = 0.82$), procedural failures ($P = 0.19$) or clinical errors per 100 medications ($P = 0.32$), between the intervention and control wards. Differences in the use of specific behavioural strategies (engagement and multitasking) were found in the intervention wards.
Conclusion: This behavioural e-learning intervention has not been found to significantly reduce interruptions, however, changes in the use of strategies did occur. Careful selection of clinical settings where there is a high number of predictable interruptions is recommended for further research into the impact of the behavioural e-learning intervention. An increase in the intensity of

this intervention is recommended with training undertaken away from the clinical setting. Further research on additional consumer-sensitive interventions is urgently needed.

Key words: experimental research, general methodology, risk management, patient safety, adverse events, practice variations, appropriate healthcare, hospital care, professions, training/education, human resources, medications, intervention, interruptions, behaviour, nursing, cluster trial

Introduction

The relationship between medication errors and interruptions has been established with increased numbers of interruptions being associated with an increase in the number and severity of errors [1, 2]. A 12.1% increase in procedural failures (e.g. failure to check patient identification (ID)) and 12.7% increase in clinical errors (e.g. wrong drug) was associated with each interruption [1]. Interruptions are defined as 'a break in the performance of a human activity initiated by a source internal or external to the recipient' (p.658) [3], however, it may not be possible or desirable to reduce medication interruptions if they relate to important aspects of clinical practice [4, 5]. Major sources of interruptions were recently reported as: nurses (33%), patients (15%) and doctors (11%) [2]. Interventions targeting these key sources of interruptions, with appropriate conceptualisation, methods and measurement (with fidelity, control, generalisability and replicability), are required [6].

There have been two systematic reviews conducted with a range of strategies to prevent and/or manage medication interruptions identified [7, 8]. Researchers implemented 'Drug Round tabards' in a pre–post evaluation and found a reduction in interruptions and medication errors [9]. Several trials to reduce interruptions or errors have been conducted [10–12]. A multifactorial intervention—hourly patient rounds, phone call triage, protected medication time, staff signage, 'No Interruption/Quiet Zone' for medication rooms, 'Do Not Disturb' visible wear and patient/family education materials [11]—found reduced interruptions and errors in one of two intervention units [11]. A cluster randomised trial, in medical and surgical wards, also used a bundled intervention—'Do not interrupt' nurse medication vest, interactive workshops to mitigate local barriers, brief standardised education sessions for other clinical staff [12]—with researchers demonstrating a reduction in non-medication-related interruptions [12].

Although the wearing of 'Do Not Disturb' vests remains a prominent feature of intervention studies, some challenges to this approach have been reported by nurses [13], and health consumers [14, 15]. Palese reported negative responses from patients ($n = 104$) to the tabard messaging ranging from 38.4% to 42.3% [16], while another multimodal intervention including a 'red tabard' with signage stating 'Please, do not interrupt me, I am managing medications,' [17] found reduced patient interruptions, but not staff interruptions. Alternate approaches targeting nurses' behaviours acknowledge that some interruptions require attention from nurses to ensure patient safety [4].

Initial work on behavioural strategies such as blocking (blocking out the interruption or not responding), engaging (stopping the initial task and engaging with the interrupting task), mediating (actions to support resumption of the initial task) and multitasking (undertaking both tasks simultaneously)—was derived from focus groups in paediatric settings [18] and validated in adult medical–surgical settings [19].

Our previous qualitative research identified that experienced nurses used blocking to reduce interruptions but *engaged* with unpredictable interruptions (such as patients falling out of bed) [19]. Also, in this study nurses reported using mediating strategies to reduce the chance of an error occurring when returning to the medication task. Nurses also used multitasking despite an awareness that this could lead to errors [19]. The qualitative research provided details on the types of nurse behaviours that could be modified [19], and the connection between specific types of behavioural strategies for predictable (able to be anticipated and so managed by other staff members without risk of patient harm) and unpredictable (not able to be anticipated and so require immediate action by the nurse to maintain patient safety) interruptions [19]. This framework formed the basis of this behavioural e-learning intervention.

The aim of this study was to conduct a feasibility cluster randomised controlled trial of an educational intervention that taught behavioural strategies to nurses, to manage predictable and unpredictable interruptions, related to medication preparation and administration. We hypothesised that there would be a:

(i) change in the distribution and frequency of use of nurse-initiated behavioural management strategies (fidelity of the intervention);
(ii) reduction in the number of interruptions per 100 medications;
(iii) reduction in the rate of procedural and clinical errors per 100 medications;

in observed medication administration events where nurses undertook the e-learning intervention compared to nurses who received no education.

Methods

Study design

A parallel cluster randomised controlled trial was conducted between August 2015 and May 2016 in eight wards within metropolitan hospitals in Sydney, Australia. The study was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12615000811505). Although nurses were the focus of the intervention (participants within the ward cluster), medications administered as per the medication chart were also collected to allow for standardisation of data per 100 medications. Pre- and post-intervention data collections were undertaken.

Ward and participant selection and randomisation

From an initial request for self-nomination, 15 wards across a local health district agreed to participate, with a final random selection of eight medical–surgical wards located within four hospitals, four wards (intervention), four wards (control), the minimum number recommended for cluster trials and manageable within the resources available. An independent research assistant used a computer-generated block randomisation process [20], whereby six sequences of blocks of 4 were generated (>2), and one sequence was randomly

selected and allocated to four wards as controls and 1–4 wards as intervention settings. Participating wards/units included: three medical wards, one medical–surgical ward, one surgical ward, aged care, haematology oncology and palliative care units. All nurses within the control and intervention wards were encouraged to participate in the study. All participating wards received a 20-min introduction to the study purpose and data collection procedures.

Intervention

Only nurses within the intervention wards had access to the 20-min e-learning intervention via the Learning Management System within the local health district. The module included factual information on the high rate of interruptions (99% of all medication events) [2], behavioural strategies to manage interruptions, simulations of positive and negative management approaches, and a discussion by nursing leaders on changing ward culture [21]. The module targeted key sources of interruptions—nurse-to-nurse communication, patient and other healthcare professional interruptions—and described when and how to use behavioural strategies.

Behaviours such as blocking (non-patient related conversations) were encouraged, while multitasking was discouraged. The intervention used a metaphor of 'texting while driving' [21] to focus nurses on how multitasking could compromise patient safety. The risks associated with engaging in interruptions that threatened patient safety was reinforced [21].

A register of nursing staff completing the intervention was maintained, and only these nurses were observed. Sixty-eight nurses viewed the intervention, with 61.9% (42/68) consenting to be observed preparing and administering medications.

The intervention wards came from Hospitals 1 and 4. The control wards came from Hospitals 2 and 3. Wards were geographically distant from each other, minimising the opportunity for contamination. In addition, ward posters noting 'In the interest of patient safety please do not interrupt nurses administering medications' were placed within patient areas, targeting visitors, allied health and medical staff.

Nurses on the control wards did not receive any educational intervention or placement of posters and continued with normal practice of preparing and administering medications.

Study outcomes

The primary study outcome was the number of interruptions per 100 medications reflecting the effect of the e-learning program targeting nurses' behaviours and the impact of the poster on visitors, allied health and medical staff. Secondary outcomes included observed clinical errors and procedural failures per 100 medications. Clinical errors were defined as the administration of the wrong medication including giving the wrong drug or dose, by the wrong route of administration, to the wrong patient or at the wrong time (>1 h before or after prescribed time) [1]. Procedural failures referred to neglecting or omitting to follow established medication practice standards or polices, e.g. failure to check patient ID, record medication administration on medication chart, failure to read medication label/expiry date, temporary storage of medication in unsecured environment or failure of two nurses to sign the dangerous drug register [1]. Finally, changes in the distribution and frequency of use of nurse-initiated behavioural management strategies (fidelity of the intervention) were also assessed.

Data collection

Data were collected using a structured non-participant observational approach where the 'observer only gathers data without interfering with research participant's activities' [22]. Data items relating to the use of behavioural strategies, the number of interruptions, medications, procedural failures and clinical errors were recorded by research nurses. An observation tool was developed [2] which allowed for manual collection of data relating to the use of behavioural strategies, and one or more interruption(s), clinical errors and procedural failures. Definitions of both clinical errors and procedural failures [1] and behavioural strategies [18, 19] were provided on the tool. Nurse observers logged all interruptions which occurred during medication administration by participant nurses, over a one-month period, prior to and following delivery of the intervention (~50 observations per control and intervention ward).

Observers

Four Registered Nurses, independent of any study site, were trained as observers. Training consisted of an 8-h session led by the principal researcher which included a theoretical introduction to the project, ethical issues and data collection procedures. Practice in coding from video simulated interruptions (including behavioural strategies) followed—no interruption (1), and interruptions from nurse unit managers, patients, nurses, doctors only and doctor/nurse unit manager interaction (6). Checking of inter-rater reliability was then undertaken, which involved viewing medication administration practice (n = 20) in the clinical setting. Inter-rater reliability was assessed for observers with Kappas ranging from 0.60 to 1.0 for clinical errors, 0.64 to 1.0 for procedural failures demonstrating moderate to high inter-rater reliability. As no variability in medication interruptions occurred in a previous observational study (99% of medication events were interrupted) [2], this outcome measure was not assessed.

Procedure

Baseline data were collected prior to the intervention being implemented in 2015. Similar methods for both the baseline and post-intervention data collection, for the control and intervention wards, were used. Nurses who consented to participate were observed in the workplace preparing and administering medications to patients within the ward. Observation commenced when the nurse removed the patient's folder containing the medication chart from the bedside and ceased when the chart was replaced (a medication event). Observers remained ~2 m away from the nurse (viewing medication preparation and administration) but they could view the medication receptacle when required. Trained nurse observers, independent of the study sites, also checked the medication charts after the observation to assess for other failures or errors. Patient rooms for infectious patients or closed patient curtain areas were excluded.

Ethics approval was obtained from the local health district and university Human Research and Ethics Committee Approval No. HREC/15/LPOOL/80. Nurse Unit Managers provided a cluster level consent for their unit, and all nurses observed within both the control and intervention wards provided written informed consent. To reassure staff of anonymity and confidentiality of data or identity, no demographic data were obtained from the nurses participating in the observations. Nurse researchers were trained to intervene if any imminent threat to patient safety occurred during observation.

Analysis procedures

Analyses were conducted using SAS™ Version 9.4 (linear mixed-effects modelling) [23] and SPSS™ Version 25 [24]. Differences in nurse behaviours were analysed using chi-square procedures. Outcome analyses were conducted at both the individual observation and the cluster level. For the observation level, we used linear mixed-effects models (allowing for clustering within wards) to examine the intervention effect on interruptions (including non-patient related and non-medication related), procedural failures and clinical errors per 100 medications. Standardising the rate of interruptions per 100 medications, controlled for the increased opportunity (the more medications the longer the direct contact with the patient and therefore the more likely an interruption would occur) for errors related to a higher number of medications per medication event. One or more medications could be administered within one medication event. Linear mixed-effects modelling is used where the data units (observations) occur within the same clusters (wards) and the data units are likely to be correlated [25]. Modelling of the means, variances and covariances can be considered within this procedure [26].

Results

Use of behavioural strategies by nurses

The e-learning intervention focused on increasing the use of specific behavioural strategies to manage interruptions. Engaging (stopping medication administration and engaging with the interruption/interrupter) was the most common strategy used; 70.87% at baseline and 74.67% at follow-up (control group) and 66.12% at baseline and 77.27% at follow-up (intervention group) (see Table 1). There were no statistically significant differences between the control and intervention group (between groups) in the number and type of interruption-management strategies used at baseline ($\chi^2 = 5.993$, $P = 0.199$). Similarly, there were no statistically significant differences between baseline and follow-up in the types of strategies used by the control group ($\chi^2 = 3.874$, $P = 0.423$). However, in the intervention group, proportionally more nurses engaged with the interruption at follow-up than at baseline (66.12% at baseline, 77.27% at follow-up) with proportionally fewer multitasking (22.73% at baseline, 15.91% at follow-up).

Within-group comparisons of interruptions and errors for groups

Eight-hundred and six observations were undertaken across the eight wards over the 8-month data collection period (pre-intervention $n = 402$; post-intervention $n = 404$).

There were no statistical differences within the control or intervention groups on any of the variables (see Table 2).

Differences in outcomes between groups

No differences were found in the primary outcome measure of interruptions per 100 medications (see Table 3). Similarly, no differences were found in the number of clinical errors or procedural failures per 100 medications.

Further analysis of non-patient related interruptions also found no significant difference ($P = 0.65$).

Further exploration of the types of clinical errors or procedural failures was undertaken.

Types of clinical errors

Table 4 displays the types of clinical errors found at observation. At baseline, no clinical errors, were found in 96% (192/201, control group) and 99.5% (200/201, intervention group) of observations. Similarly, at post-intervention, no clinical errors were found in 100% (203/203, control group) and 98.5% (198/201, intervention group) of observations. Other clinical errors were the most predominant clinical error. Medications being administered at the wrong time were also found.

Types of procedural failures

Table 5 displays the types of procedural failures found at observation. At baseline, no failures were found for 83% (167/201, control group) and 56% (116–201, intervention group) of observations. At post-intervention, no failures were found for 88% (179/203, control group) and 61% (123/201, intervention group) of observations. Failure to check patient ID was the most frequent failure observed. Issues of aseptic technique (non-touch technique when administering medications) and handwashing (infection control) were the next most frequent procedural failures.

Discussion

Unlike other trials, this feasibility study used an educational intervention focused on behavioural change of the administering nurse and other nurses in the unit, with the addition of ward posters. There was no attempt to provide the types of 'Do Not Disturb' vests that are described in previous studies [11, 12]. We were influenced by calls from nurses and consumers [13–15] seeking new approaches to interruptions that were consumer-sensitive. To our knowledge, this is the first study to develop an educational intervention detailing specific behavioural strategies related to predictable and unpredictable interruptions.

Table 1 Frequency and distribution of behavioural strategies to manage interruptions

Strategy used	Control		Intervention	
	Baseline No. (%)	Follow-up No. (%)	Baseline No. (%)	Follow-up No. (%)
Blocking	6 (2.61)	6 (2.67)	10 (4.13)	8 (3.64)
Engaging	163 (70.87)	168 (74.67)	160 (66.12)	170 (77.27)
Mediating	2 (0.87)	4 (1.78)	6 (2.48)	0 (0.00)
Multitasking	55 (23.91)	40 (17.78)	55 (22.73)	35 (15.91)
Other	4 (1.74)	7 (3.11)	11 (4.55)	7 (3.18)

Note: For the Control group, there was no significant difference in the use of the types of strategies at follow-up ($\chi^2 = 3.874$, $P = 0.423$). For the Intervention group, there was a statistical difference in the use of types of strategies ($\chi^2 = 10.936$, $P = 0.028$).

Table 2 Within-group comparisons of baseline and follow-up data on interruptions, procedural failures and clinical errors for control and intervention wards

	Control			Intervention		
	Baseline *M* (SD)	Follow-up *M* (SD)	*t* (*P*)	Baseline *M* (SD)	Follow-up *M* (SD)	*t* (*P*)
Interruptions per 100 medications	41.77 (59.19)	45.37 (81.41)	−0.507 (0.613)	37.48 (80.84)	39.64 (64.07)	−0.296 (0.767)
Number of patient related interruptions per 100 medications	25.45 (44.72)	21.43 (40.70)	0.942 (0.347)	24.81 (65.49)	24.20 (42.96)	0.109 (0.913)
Number of non-patient related interruptions per 100 medications	16.53 (31.96)	17.49 (41.14)	−0.266 (0.790)	14.43 (29.87)	18.66 (47.44)	−1.052 (0.293)
Number of clinical errors	0.11 (0.61)	0.00 (0.00)	2.584 (0.010)	0.00 (0.07)	0.02 (0.14)	−1.350 (0.178)
Number of clinical errors per 100 medications	6.20 (47.68)	0.00 (0.00)	1.852 (0.065)	0.09 (1.20)	0.93 (8.11)	−1.427 (0.154)
Number of procedural failures	0.33 (0.86)	0.23 (0.74)	1.245 (0.214)	0.58 (0.80)	0.70 (0.97)	1.348 (0.179)
Number of procedural failures per 100 medications	11.85 (54.75)	8.38 (45.61)	0.689 (0.491)	16.27 (28.14)	20.96 (41.80)	−1.297 (0.195)

Table 3 Differences in interruptions and interruptions per 100 medications, and procedural and clinical errors for intervention and control groups

Outcome	Mean (SD) (Intervention wards)	Mean (SD) (Control wards)	Difference (Control-Intervention)	95% CI for difference	*P* value*
Interruptions	1.14 (1.14) *N* = 201	1.21 (1.29) *N* = 203	0.07	(−0.17, 0.31)	0.82
Interruptions per 100 medications	43.66 (68.98) *N* = 199	49.41 (85.55) *N* = 201	5.75	(−9.53, 21.04)	0.75
Number of procedural failures per 100 medications	21.33 (42.54) *N* = 199**	8.33 (48.60) *N* = 201	−13.00	(−21.99, −4.02)	0.19
Number of clinical errors per 100 medications	0.94 (8.13) *N* = 199	0.00 (0.00) *N* = 201	−0.94	(−2.06, 0.19)	0.32

**P* value was calculated via individual observation level mixed-effects model to incorporate within cluster (ward) correlation.

***It should be noted that one study site in the intervention group does not routinely use checking the patients name, 'Tell me your name and date of birth' as patients are known to nurses, or are often too ill. This would have been recorded as a procedural error.

Table 4 Types of clinical errors baseline and post-intervention by groups

Clinical errors	Baseline Control	No. = 402 Intervention	Post Control	No. = 404 Intervention	Significance
No. clinical error occurred	192	200	203	198	*P* = 0.145
Wrong drug	1				
Wrong dose	1				
Wrong route					
Wrong patient					
Wrong time (>1 h before or after prescribed time)	2			2	
Other clinical error(dose not documented; dropped medication cap; left medications unattended by bedside)	5	1		1	
Total	201	201	203	201	

Note: Chi-square 6.83, df 4, *P* = 0.145.

Definitions for Clinical Errors Westbrook *et al.* (2010) [1].

This cluster feasibility trial of eight wards did not identify a significant effect on interruptions from this e-learning intervention. However there was a significant change in the use of types of behavioural strategies within the intervention groups, with an increase in engaging and a reduction in multitasking approaches. There was no difference in the rate of interruptions per 100 medications within the intervention and control wards.

A process evaluation of the intervention identified certain clinical units that are potentially unsuitable for behavioural approaches alone, that is, units with a high number of patients with cognitive

Table 5 Types of procedural failures baseline and post-intervention by groups

Procedural failures	Baseline Control	No. = 402 Intervention	Post Control	No. = 404 Intervention	
No failures	167	116	179	123	$P = <0.001$
Failure to check ID	4	55	3	43	
Failure to recognise wrong medication order			1		
Failure to document or wrong document	5	6	1	3	
Failure to check vital signs, Blood glucose level, neurological observations, others		2			
Failure 2 nurses check	4		7		
Failure 2 nurses sign					
Failure of infection control	12	5	9	2	
Failure of aseptic/non-touch technique	9	17	3	30	
Total	201	201	203	201	

Note: Chi-square 63.82, $P < 0.001$.
Definitions for Procedural Failures Westbrook *et al.* (2010) [1].

deficits (e.g. patients with dementia) and/or high number of unpredictable interruptions [21]. It was also noted that there was variation in how well nursing staff engaged in the intervention. Although a target of 65% of ward staff completing the education sessions was sought and obtained, nurses found it difficult to complete the entire education session. In the future, we recommend that clinicians be removed from the clinical setting for this training [21]. In addition, the intensity of the intervention may need to be increased, i.e. 2 or more educational sessions, or repetition over a three-month period.

It would appear that the use of the 'Do Not Disturb' vests, an element in the most recent feasibility study of a bundled approach, may be the critical element in the effectiveness of the intervention [12]. Further qualitative research exploring how the vests deter interruptions is needed to develop other consumer-sensitive approaches.

Our process evaluation did highlight that in a palliative care setting, the response from staff was positive and behavioural change was evident (qualitative data). However, participants from more acute settings did not identify similar change; staff from one aged care unit noted that the patient caseload reduced any opportunity for behavioural strategies to be effective [21].

Clinical errors were infrequent (<1 per 100 medications), requiring large samples to detect a difference, making this a less useful outcome measure. Procedural failures were more frequent, and the high frequency of nurses not checking the patient ID was of concern. For one of the intervention units (hospice environment), routine checking of the patient ID is not always conducted as the patients were well-known to nurses. Aspects of procedural failure, relating to aseptic technique (non-touch of medications) and handwashing, accounted for frequent failures and is an area for ongoing education and audits.

Limitations

Only a small group of general wards has been examined, consistent with the minimum number of clusters required (four per arm) [27] for a feasibility cluster trial. Other estimates were derived using a 40% reduction in interruptions and 25% reduction in clinical errors requiring 8–6 clusters per arm for the larger Cluster trial. This feasibility study, which did not demonstrate significant effectiveness, was undertaken to provide an accurate estimate of the required sample size for a larger cluster trial. Diversity of patient caseload may have contributed to the limited effects of this intervention, requiring matching of the patient caseload in intervention and control groups. There was no assessment of whether nurses from the intervention wards completed all the education module. Observations of clinical errors, such as the wrong drug, may have been underestimated in both the intervention and control wards, in this study.

In conclusion, further trials of multimodal approaches are required in acute settings, while further testing of behavioural approaches in less acute units may also be warranted. This cluster feasibility trial is the first intervention to observe and report nurses' interruption-management behaviours. The need for a set of strategies to be made available, and to be matched to the clinical setting (rate of predictable and unpredictable interruptions) is emerging. Alternative interventions beyond vests are required, and research seeking new consumer-sensitive interventions is needed. Where a greater proportion of predictable interruptions are found, it is likely, that a nurse-initiated behavioural intervention may be effective. However, where unpredictable interruptions are more common, multimodal approaches may be required, although both approaches require further rigorous trials.

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Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

M.J., T.L.J., E.M., G.W. and R.L. were responsible for the study conception and design, the data collection (M.J. and B.E.) and performed the data analysis (M.J., R.L. and W.X.). M.J., G.W., T.L.J. and B.E. were responsible for the development of the e-learning program. M.J. and R.L. were responsible for drafting the manuscript. B.E. and T.L.J., E.M. and G.W. made contributions and critical revisions to the paper for important intellectual content.

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