A realist evaluation of a safe medication administration education programme

Freda Browne [a,*], Ben Hannigan [b], Jane Harden [c]

[a] School of Nursing Midwifery and Health Systems, University College Dublin, Belfield, Dublin 4 353 1 7166402, Ireland
[b] School of Healthcare Sciences, Cardiff University, Cardiff, Wales, United Kingdom of Great Britain and Northern Ireland
[c] Wales Centre for Evidence Based Care, School of Healthcare Sciences, Cardiff University, Cardiff, Wales, United Kingdom of Great Britain and Northern Ireland

ARTICLE INFO

ABSTRACT

Background: Continuing professional education (CPE) for nurses is deemed an essential component to develop, maintain and update professional skills. However, there is little empirical evidence of its effectiveness or factors which may influence its application into practice.

Objective: This paper explores a continuing professional education programme on the safe administration of medication and how new knowledge and skills are transferred into clinical practice.

Design: Realist evaluation provided the framework for this study. Realist evaluation stresses the need to evaluate programmes within "context," and to ask what "mechanisms" are acting to produce which "outcomes." This realist evaluation had four distinct stages. Firstly, theories were built as conjectured CMO configurations (Stage 1 and 2), then these cCMO were tested (Stage 3) and they were then refined (Stage 4).

Methods: Data was collected through document analysis and interviews (9) to build and refine CMOs. The conjectured CMOs were tested by clinical observation, interview (7), analysis of further documents and analysis of data from reported critical incidents and nursing care metric measurements.

Results: This study has shown the significant role of the ward manager in the application of new learning from the education programme to practice. Local leadership was found to enable a patient safety culture and the adoption of a quality improvement approach. The multi-disciplinary team at both organisation and local level was also found to be a significant context for the application of the education programme into practice. Reasoning skills and receptivity to change were identified to be key mechanisms which were enabled within the described contexts.

Conclusion: The findings from this study should inform policy and practice on the factors required to ensure learning from CPE is applied in practice. The realist evaluation framework should be applied when evaluating CPE programmes as the rationale for such programmes is to maintain and improve patient care.

1. Background

Continuing professional education (CPE) is essential to develop, maintain and update professional skills and practice, in order to ensure that nurses respond effectively to care requirements and provide a high standard of patient care (Atack and Luke, 2008; Pool et al., 2016). CPE provides the opportunity for healthcare workers to remain engaged in evidence based practice and best practice guidelines and to update themselves on clinical skills (Katsikitis et al., 2013). There has been significant investment worldwide in CPE to ensure that healthcare professionals, including nurses, have the knowledge and skills to provide effective patient care (Clark et al., 2015). Nevertheless, while the benefits of nurses engaging in CPE are well documented, there is limited empirical evidence of its direct impact on the organisation and an absence of reported evaluations on the clinical and patient outcomes related to CPE (Clark et al., 2015; Hardwick and Jordan, 2002).

There are also numerous methodological and conceptual challenges in undertaking evaluation of CPE (Hegney et al., 2010; Lee, 2011) and the complexities of evaluating their effectiveness is a common theme in the literature (Lahti et al., 2014). Educational systems and healthcare organisations are not simple systems, they are complex and each educational programme exists in a context in the 'real' word of clinical

---

practice (Ellis and Nolan, 2005; Ogrinc and Batalden, 2009; Ogrinc et al., 2007). The tangible outcomes of CPE often prove difficult to measure (Clark et al., 2015) and variables such as organisational culture, and the motivation and ability of individual professionals to influence change also present challenges for evaluation (Lee, 2011). One such element within the organisational culture which has been identified as influencing the transfer of CPE into practice is the role of leadership. Some previous studies have reported how managers can have a negative effect on the transfer of CPE into practice (Hughes, 2005; Tame, 2009). While other work has reported the positive impact of the role of managers in supporting the transfer of CPE into practice (Clark et al., 2015; Lee, 2011; Mann et al., 2009; Stolee et al., 2009).

In an education and healthcare context, where the researcher is dealing with the complexities of learning and attempting to measure its effects in an equally complex clinical environment (Ellis and Nolan, 2005), it is necessary to ensure that an appropriate research approach is utilised to capture the multiple dimensions. As well as contending with the complexity of the clinical practice environment, an educational intervention (singular) in itself, actually consists of multiple components or parts that interact with one another in complex ways, often in a non-linear fashion (Wong et al., 2012). Therefore, the effectiveness of CPE needs to be fully explored through a systematic and methodologically sound programme evaluation which explores the context, involves multiple data collection methods, and involves key stakeholders.

The study reported in this paper utilised Realist evaluation to evaluate an education intervention for the safe administration of medication. Realist evaluation was chosen as it provides for understanding of the complex environment; it acknowledges and accommodates the 'messiness' of real-world interventions where educational programmes are or are not transferred into clinical practice (Wong et al., 2010). Realist evaluation also provided a mechanism for the research to ask 'how' and 'for whom' and following completion will now influence policymakers to tailor educational interventions and policy to particular purposes, target groups and sets of circumstances (Wong et al., 2012). Thus, realist evaluation is particularly relevant to investigating the transfer of education programmes into complex practice environments consisting of layers of actors, social processes, and structure. In the research site many extraneous variables were present that may affect the results of an evaluation.

Safety in relation to medication administration is currently high on the international and national agenda, with education an identified strategy to address this (Department of Health and Children, 2008). While there is an impetus for healthcare organisations to provide CPE for nurses on medication safety, in the age of accountability and finite resources, organisations must ensure that they can obtain a return on their investment (Draper and Clark, 2016; Garafalo, 2016; Lambert, 2012). In order to demonstrate a return on investment and measure activity and efficiency, it is necessary to evaluate educational interventions (Lambert, 2012).

The aim of this study was to identify factors that enable or constrain the application of knowledge and skills gained through a safe medication administration education programme into practice.

The safe medication administration education programme was developed for one organisation at the request of nursing management to address practice concerns in relation to medication administration. The aim of the programme was to enable nurses to update their skills and understanding of evidence-based principles and practice in the safe administration of medications and apply these to everyday practice. The programme was developed as asynchronous e-learning programme designed on *Articulate* e-learning software and was available for all nursing staff through the virtual learning environment. Completion of the programme was a mandatory requirement for all nursing staff new to the organisation. Learners were advised that the programme would take approximately two hours to complete and learners were required to actively engage in the programme to progress. Knowledge checks were embedded in the programme and a final knowledge assessment with a

passing score of 80% was required to achieve certification. Over a two-year period between August 2015 and August 2017 a total 152 nurses completed the education programme. This programme was selected for evaluation as it was a newly developed programme.

The programme contained four learning modules. The first module reviewed the safety aspects of medication administration and the significance of the '5 rights of medication administration'. The second module described the importance of reporting medication incidents and provided examples of incidents which the learner was required to critically review. The third module provided real patient cases and their medication management issues. The learner worked though the medications and responded to the interactive sections, which highlight the importance of medication knowledge and where further information could be obtained. The final module was on medication calculations.

2. Methods

2.1. Research design

Realist evaluation provided the framework for this study as it acknowledges and accommodates the 'messiness' of real-world interventions where educational programmes are, or are not, transferred into clinical practice (Wong et al., 2010). In realist evaluation the evaluator's role was to understand what works, for whom and in what circumstances (Pawson and Tilley, 1997).

This realist evaluation is reported according to the RAMESES II reporting guidelines (Wong et al., 2016) and followed the eight general principles for realist evaluation as seen in Table 1 (Pawson and Tilley, 1997). Following an iterative explanation building process, the study proceeded in four stages depicted in Table 2. The conjectured Context Mechanism Outcome configurations (cCMOs), were developed through document analysis and interviews with policy makers and key stakeholders (Stage 1). A cCMO is a proposed hypothesis which attempts to tease out specific causal pathways, as pre-specified mechanisms which act in pre-specified contexts and spill out into pre-specified and testable outcome patterns (Pawson and Tilley, 1997). These cCMOs were then refined by experts (Stage 2) and then drove the remaining aspects of the evaluation (Pawson and Tilley, 1997; Rycroft-Malone and Bucknall, 2010). Stage 3 involved testing the cCMOs through a case study involving observation, interviews, further document analysis and the gathering of quantitative data. Finally, Stage 4 involved reviewing the findings from Stage 3 to confirm, modify, or reject the cCMOs.

2.2. Participants and data collection

2.2.1. Stage 1 document analysis and interviews

Document analysis was utilised to develop the cCMOs. This entailed the analysis of the 1) the organisation's policies procedures and guidelines 2) national and professional standards and documents in relation to medication management (Nursing and Midwifery Board of Ireland, 2007), Scope of Practice (Nursing and Midwifery Board of Ireland, 2015), Code of Conduct (NMBI, 2014) and 3) curriculum documents. The organisation where the study took place utilises an electronic system for management of local policies, guidelines, and procedures. This system was accessed, and all relevant currently active policies were downloaded in July 2015. No inactive or draft policies were included. Relevant policies were identified by key words. The keywords searched for were a) medication b) error reporting c) patient safety d) education e) training. Thirty-three policies and guideline documents in total were downloaded. Two documents related to education policy, four policies/guideline documents were related to reporting of critical incidents and safety management; two were on occupational health in relation to staff support; the remaining 29 were on medication management. Two documents on medication management were excluded as they were based exclusively on the transplantation services, and pharmacy specific policies were excluded. An example for pharmacy specific policies was any

Table 1
Principles of realist evaluation as applied in this study.

	Realist principle	Application in this study
1	Generative causation	This study examined why the education intervention caused change. It was not about stating that the education intervention caused an outcome, but rather how they were associated.
2	Ontological depth	This study uncovered what is contained below the surface of inputs and outputs. It was not just what was observed that was important to gather information on but also on the cultural and social processes.
3	Mechanisms	To focus was to understand why an education programme for safe medication administration worked by understanding the mechanism. Mechanisms are theories which are based on propositions and are contingent on contexts (Rycroft-Malone et al., 2010), capacities and choices that lead to regular patterns of social behaviour.
4	Contexts	The study set out to understand the context in which the evaluation was conducted so as to identify what mechanisms were successful.
5	Outcomes	The realist evaluation provided an opportunity to understand what the outcomes were and how they come about. Outcomes provide the evidence as to what components, if any, of the programme are successful and allow for adoption, removal or continuation of that programme
6	Context mechanism outcome (CMO) configurations	The CMOs were developed as propositions stating what it is about the safe medication administration education programme that worked for whom and in what circumstances. On completion of Stage 1, conjectured CMO configurations were presented and at the end of Stage 4 refined CMO configurations were presented.
7	Teacher learner process	In order to construct context-mechanism-outcome pattern explanations, a teacher-learner relationship was developed with policy makers, practitioners and participants (Stage 2 and Stage 3). It was essential to elicit stakeholder involvement and engagement.
8	Open systems	This study acknowledged that the safe medication administration education was implemented in an ever changing social world, and that the environment could either positively or negatively impact (Tolson and Schofield, 2012). In other words, the study was unable to provide control mechanism to maintain equilibrium.

Table 2
Evaluation stages.

Stage	Description of stage	Programme theory development	Sources of data and activity	Data analysis
Stage 1	Identification of initial programme theories as conjectured Context Mechanism Outcome configurations	Theory gleaning	Document analysis (33 organisation Policies Procedures and Guidelines, 4 professional standards & course specific documents) Interviews (n = 6)	Thematic analysis (Braun and Clarke, 2006) Thematic maps Formation of cCMO configurations
Stage 2	CMO refinement	Theory refinement	Expert interviews-(n = 3)	Thematic analysis Deductive I coding to cCMO configurations inductive to new data Exploration of linkages between context, mechanism and outcomes in the formation of CMO configurations
Stage 3[a]	Testing the conjectured CMO configurations	Theory testing	Single case study – 3 embedded units (C&M) Observation of practice (n = 4) 35 h (C&M) Interviews with participants & managers (n = 7) (C&M) Quality Care Nursing Metrics (O) Reported Medication incidents (O)	Interview data analysis focused on examining if an identified theme functioned as a context, mechanism or outcome and also about the relationships between them. Observation notes, field notes and reflections coded, inductively for any new emerging themes, and also deductively based on the cCMO configurations
Stage 4	Refining the CMO configurations -programme theory	Mid-range programme theory	Analysis and interpretation Refined CMO configurations	

[a] Stage 3 - sources of data collected is related to context (C), Mechanism (M) or Outcome (O).

policy relating to the aseptic compounding service. All identified policies, procedures and guidelines were entered into NVivo™ (10). These documents determined the characteristics of the organisation which give it its identity (Owen, 2014) and also provided data on the context in which the case study was to take place (Bowen, 2009).

In order to support the document analysis and to assist in the development of cCMOs, semi-structured interviews took place. The sample was based on the expertise of the informant at a local or national level and thus on their cCMO investigation potential (Manzano, 2016). Interviews were for theory gleaning, where the aim of the interview was to collect data and make inferences about the phenomena and processes to be evaluated (Manzano, 2016).

The document analysis provided a template on which questions in the interview were based. The semi-structured interview guide varied for each participant, as different respondents provided information in relation to different aspects of the theory to be built (Manzano, 2016). The interviews provided a contextual understanding of the documents and their significance.

2.2.2. Stage 2 interviews

Each component of the cCMO triggers the need for a different kind of respondent therefore respondent selection was based on their cCMO investigation potential (Pawson and Tilley, 1997). Three purposefully selected experts from the field of CPE, patient safety and medication safety participated. The purpose of this stage was to refine and further develop the programme theory. To do so, the conjectured CMO configurations were presented to three experts for them to comment on. Interview guides were semi-structured, containing exploratory questions based on the cCMOs thus acting as instruments to draw out the

propositions of the general inquiry (Manzano, 2016). At each interview the questions began to evolve, from less standardised and more tailor-made to interview subjects' area of expertise, in order to refine the cCMOs (Manzano, 2016). Experts either confirmed, refuted, or offered new theories.

2.2.3. Stage 3 case study

In Stage 3, the study design involved a single case study of the medication administration education programme, within an acute tertiary hospital, with three embedded cases of hospital wards. A multiple case design was not possible, as the education programme was only available in a single organisation. This single case study is viewed as a critical case and provided for the determination of whether the propositions (that is the conjectured CMO configurations) were correct or whether some alternative set of explanations might be more relevant (Yin, 2018). A single case study can represent a significant contribution to knowledge and programme theory building by confirming, challenging or extending the theory (Yin, 2018). This single case study involved units of analysis at more than one level called embedded units (Yin, 2018). In this study, three embedded units were examined within the case study which involved three different ward areas.

The embedded cases were purposefully selected to maximise what can be learned (Stake, 1995). The use of three embedded cases allowed the cases to be built around context and mechanism (Tolson and Schofield, 2012). Wards were selected from, where five or more registered nurses had completed the medication education programme. Wards in the site under study have approximately 20 whole time equivalent registered nurses on their roster, therefore five would make up approximately 25% of the total population. This purposeful sample was also to allow for different activity types to be compared and different medication needs also. The participants had all completed the programme within the 18 months before the observation. The embedded cases were purposefully selected in order to contribute to the development, support, refutation and refinement of the cCMOs and thus to maximise what can be learned (Stake, 1995).

The case study allowed for the exploration of the complex social phenomenon of transfer of education to practice, while retaining the holistic and meaningful characteristics of real-life events (Yin, 2018). Multiple forms of data were collected which were tailored in order to allow for the testing of the cCMOs (Pawson and Tilley, 1997).

All staff who meet the criteria on three wards were approached by the researcher and provided with the participant information leaflet. The researcher returned at least 1 day after providing the participant information leaflet to obtain consent from participants. Four staff nurses, from three different clinical areas and three nurse managers consented to participate. Non-participant observation of the four nurses during medication administration was utilised and field notes were taken. Mangers were not directly observed and took part in the interviews only. The use of observation provided information on the actual practice of administration of medication, where the outcome could be observed and did not rely on the accuracy of self-reporting. Observation also provided the opportunity to gather further information about the context, which included the physical environment, the culture of the clinical area and compliance with organisation policy, procedure, and guidelines.

A semi structured observation tool allowed for the consistent recording of each observation and mapped observable actions to the conjectured CMO configurations. Thus, for each context, mechanism and outcome, the associated observable action was identified. The observation tool provided a tick box to indicate if pre –identified actions had occurred or not, for example, checking a patient identity band. This also provided some quantitative descriptive data.

While the presence of the researcher can never be fully eliminated, as they will always have an effect on the phenomena being studied (Walshe et al., 2012) some strategies were adapted in the research setting to minimise the effect where possible. For each participant, three periods

of time where spent observing medication administration. This observation period allowed the participant to be become accustomed to the presence of the researcher; which allowed the researcher to blend in and help to reduce this potential effect (Bloomer et al., 2012; Chiesa and Hobbs, 2008). Many authors have debated that most professionals are too busy to maintain behaviour that is radically different from normal (Mulhall, 2003) and become accustomed to the presence of the researcher and thus do not change their normal behaviour (Houghton et al., 2010; Patton, 2015). The follow up interview also provided an opportunity to address the potential impact of the Hawthorne effect. During the interview, participants were asked directly if they changed or modified their behaviour and ask them to explain as to why they did or did not.

To increase the completeness of the data, semi-structured interviews were conducted with each participant who was observed and with the ward manager in each embedded case. The semi-structured interviews were dynamic while adopting realist principles (Manzano, 2016). For the participants who had also been observed, the interview served to: 1) explore any areas that arose following the observation of medication administration 2) provide explanations of how and why activities and behaviours occurred in certain ways and 3) further explore the cCMOs. For the nurse managers the interview schedule varied depending on the observations that had taken place and the development of the cCMO at the time of interview (Manzano, 2016).

Document analysis was also undertaken which helped to verify the data obtained through observation and interview (Yin, 2018). Two external inspections were undertaken during the period of data collection, these reports related to the observation as interview as they are measures of medication safety. Medication Incident Reports (MIRs) and Nursing Quality Care Metrics (QC-M) were also gathered. The QC-M for medication management acts a measure of professional competency in relation to medication management (Office of Nursing and Midwifery Services Director, 2018).

2.3. Ethical considerations

This study received ethical approval from the University School of Nursing and Midwifery Studies, School Research Ethics Committee and from the Ethics and Medical Research Committee of the organisation where the case study took place. All participants received a participant information leaflet when invited to participate in the study and completed a signed consent form. During the observation period in stage 3 patients were required to give verbal consent. To explain the presence of the researcher posters were displayed at the entrances to the ward area where observation was undertaken and on the central notice board and at the Nurses Station. As the researcher who conducted the observation had a dual role as a nurse and researcher an ethical protocol was developed which provided guidance as to if/when the researcher would intervene. This protocol was provided to the participants prior to observation and to the in the nurse managers in the ward areas prior to periods of observation.

3. Data analysis

While data analysis is reported separately for each stage it was conducted as an iterative process by placing nuggets of information (Pawson, 2006) within a wider configuration explanation (Manzano, 2016). NVivo™ (10) was utilised throughout the study. All interview data was transcribed verbatim, quality and accuracy of the transcription was checked. Table 2 illustrates the data analysis methods for each stage.

3.1. Stage 1

The cCMO propositions were developed directly from the document analysis and interviews within stage 1. A framework for thematic

analysis was utilised (Braun and Clarke, 2006) and following the deep analytical work of thematic analysis themes were identified. The themes were then used to identify conjectured Context Mechanism Outcome configurations. Prior to a theme being allocated, to context mechanism or outcome, each theme was reviewed in terms of Pawson's (2006) four layers of context. These layers are: (1) the broader infrastructural system, the outermost layer; (2) the institutional setting, encompassing the cultural aspects of a given contextual domain; (3) the interpersonal relationships which constitute the relational structure within which actors are embedded; and (4) the individual capacities of the key actors (Pawson, 2006). If it fitted any of the four layers it was allocated the context. Each theme was also reviewed based on the fundamental aspects of the concept of mechanism as put forward by Astbury and Leeuw (2010). They identified that mechanisms are: (1) are usually hidden, (2) are sensitive to variations in context, and (3) generate outcomes (Astbury and Leeuw, 2010) This was undertaken while consideration was taken that the mechanism was not the intervention but it may work through changing the reasoning and responses of participants. Outcomes were identified if they were related to medication incident reporting or QC-M. Once completed a coding template was developed which was utilised throughout all stages of analysis.

3.2. Stage 2

The focus of the expert interviews in Stage 2 was to confirm the context and mechanism configurations and linkages between both. Analysis of transcripts utilised the predetermined code template and inductive codes were assigned to sections of the text that were not covered by the coding template.

3.3. Stage 3

The analysis of data in Stage 3 focused on refining the cCMOs. Analysis also focused on understanding the ways in which the proposed mechanisms unfolded or did not unfold in practice, identifying alternative mechanisms and explanations (Wong et al., 2016). Analysis also focused on examining whether an identified theme functioned as a context, mechanism or outcome and also the relationships between the contexts, mechanisms and outcomes (Wong et al., 2016). Following observation and interview, data in relation to nurse managers leadership style was coded based on the descriptors of leadership style put forward by Vann et al. (2014). Quantitative descriptive data collected from the observation tool was also analysed and was incorporated alongside the qualitative findings. Other quantitative data collected included the number of medication incidents reports and the QC-M scores for each ward. The purpose of analysis was not to demonstrate a change in outcomes but to identify a relationship between context, mechanism, and outcomes.

4. Findings

4.1. Stages 1 and 2 - theory gleaning and theory refinement

The initial context mechanism outcome configurations were gleaned through data collected in Stage 1. The cCMO configurations were then refined through an iterative process (Manzano, 2016) with the data from Stage 1 and 2. The three cCMOs brought forward for testing in Stage 3 are presented in Table 3.

4.2. Stage 3 - theory testing

All four staff nurse participants had either qualified as a registered nurse or had commenced work in the organisation as a registered nurse and thus had fulfilled a mandatory training requirement by undertaking the safe medication administration programme.

Table 3
Conjectured CMOs at the end of Stage 2.

Theory area	Conjectured context mechanism outcome configuration
CMO 1-culture	Registered nurses, who undertake a safe medication administration education programme in an acute hospital with a positive patient safety culture, may adopt reasoning skills in medication administration, which may lead to reduced patient harm.
CMO 2-Goverance structure	Registered nurses, who undertake a safe medication administration education programme in an acute hospital with safety focused governance structure, may adopt a quality improvement approach to medication administration, which may lead to reduced patient harm.
CMO 3-Multi-disciplinarily	Registered nurses, who undertake a safe medication administration education programme in an acute hospital where medication safety involves multi-disciplinary collaboration, may develop individual receptivity to change which may lead to reduced patient harm.

4.3. CMO 1 - reasoning skills

Across this study, three varying leadership styles were uncovered, transformational, laissez faire and autocratic (Vann et al., 2014). Leadership styles were determined through observation and during managers responses when interviewed. The transformational leader was seen to lead on quality improvement initiatives and engage staff in critical thinking and reasoning skills about medication administration. The transformational leader was visible on the ward during periods of observation and participants reported the support of their manager. It was further reinforced during the manager interview.

"I think that as nurses, you always need to be thinking, why are these patients on their medications?"

In the ward with the transformational leader 'reasoning skills' as a mechanism was clearly observed and supported through the interviews. Reasoning skills were observed as seeking out further information and problem solving. During observation, the participants were seen to refer to hospital approved medication resources and discuss medications with senior staff and the pharmacist. The nurse participants were also observed discussing decisions in relation to medication administration with the ward manager and other experienced staff.

During this testing stage reporting medication errors was found to be an outcome which contributes to a patient safety culture. On the ward with the transformational leader a culture of openness in relation to reporting medication administration errors was noted. This ward area reported the highest rate of medication errors of all three embedded cases (50 in the year of the observation). The ward manager described how she manages medication error reports:

"You would sit down with them [staff member] and ... you'd go through the form and see... that there was contributing factors to it. ...What could we learn ... from the drug error that had taken place?"

On the ward with the laissez faire leader there were 20 reported medication errors in the year. During interview, when the staff nurse was asked about her experiences of reporting a medication error. While having never reported a medication error, she said that:

"No, not me. But I have seen them made by others but not reported. But there is blame if you make one".

The ward with the autocratic leader similarly had a low rate of reported medication errors reporting just 15. When the manger was asked if she encourages staff to report errors, she responded that:

"Yes, definitely. So if there is any medication error, fill out MIR form and we send it to pharmacy, and we have a pharmacist who helps us as well, like if there is an error. And our reporting system is very

quick and we do it openly, and patient information - like, we inform the patient if there is an error."

A high number of reported errors are a positive aspect for patient safety, as higher incident reporting rates both demonstrate and promote an improved culture of safety (Abstoss et al., 2011). For two of the wards, the number of reported medication incidents was very low for bed capacity of the ward. Therefore, this highlights that a culture of reporting incidents for patient safety may not exist. This is supported by the interview data also. The medication incident reports support the interview data of an open positive culture towards the reporting of medication incidents.

A patient safety culture was recognised to trigger reasoning skills in staff, which led to a positive approach to reporting medication incidents and to the number of reports. The role of the ward manager was found to be pivotal in the development or non-development of a patient safety culture at ward level, and thus the application of learning from the safe medication administration education programme.

4.4. CMO 2 - safety focused

The broader infrastructural system (organisation level), the outer-most layer (Pawson, 1996) was identified as having safety focused governance. A HIQA (Health Information and Quality Authority, 2017) medication review confirmed that the organisation had:

"formalised governance arrangements and organisational structures with clear lines of accountability in place to support the safe use of medications."

During observation, multiple interruptions during medication administration were noted. Interruptions were identified as a cultural aspect of the given contextual domain (Pawson, 2006; Pawson and Tilley, 2006). Interruptions came from a variety of sources; patients, medical staff, physiotherapy, nurses, catering staff, cleaners and the ward clerk. Another common cause of interruptions was medications missing from the medication trolley. During observation in this study, it was found that 58% (44/76) of all medication administrations were interrupted. The number of interruptions observed across all three sites is reported in Table 4.

The organisation's policy outlined the requirement for the use a red apron/tabard and signage to aid in the reduction of interruptions. During observation, there was a range of no compliance to full compliance with wearing the red apron (Table 4). However, during interview, the participant who complied fully did acknowledge that he does not normally wear the apron and was only wearing it because he was being observed. During all observations across the three embedded cases, signage was present but was not used as advised in the organisations policy.

At organisational level, there was safety focused governance (outer context). However, this was not reflected at local level (inner context), where the application of the policies, which were derived to support safety, were poorly applied or not applied at all. Thus, the local context

of a safety focused organisation as was proposed was not found.

A quality improvement approach was proposed as a mechanism; however, no quality improvement approach was identified to be held by participants. A quality improvement approach, where it did exist, was driven by the managers. No outcomes have been associated, as the mechanism failed to activate in all three clinical areas.

4.5. CMO 3 receptivity to change

At an organisational level, medication management and safety were found to be multi-disciplinary. The HIQA (2017) inspection report contained numerous positive references to the multi-disciplinary management of medication safety in the organisation.

"*The Pharmacy Department in conjunction with the Drugs and Therapeutics Committee and Nurse Practice Development Department had developed and implemented a suite of medication management policies, procedures, protocols and guidelines to support safe medication management systems…*"

(Health Information and Quality Authority, 2017, p 12)

Observation and interview in the clinical sites also identified that multi-disciplinary collaboration was present at local level. For example, on one occasion a nurse participant was observed crushing medication for administration through a nasogastric tube. She was then later observed seeking advice from the pharmacist in relation to the medications than were difficult to discuss and they also discussed the availability of the medication in other formats.

Receptivity to change was identified in two of the embedded ward areas. When one participant was asked about doing things differently following the course, she identified that:

"I wouldn't have been able to do them until I did it anyway (laughs). But, yeah. No, I would have just followed the policy because that's whatever way we were taught."

Receptivity to change was also discussed with the managers, one manager identified that undertaking the course had positive benefits for staff. While receptivity to change was seen across two of the embedded case studies, there was no relationship between the multi-disciplinary collaboration as a context and receptivity to change as a mechanism.

The findings from the QC-M illustrated that the ward with the poorest QC-M scores, had the participants which demonstrated the strongest receptivity to change. The QC-M metric scores did not appear to be related to the context or the mechanism which was under test in this CMO configuration.

The context, mechanism and outcome constructs from this cCMO appeared to be valid constructs. However, further review and testing are required to establish appropriate relationships between the constructs.

5. Discussion

This study identified that the transformational is a key enabler for

Table 4
Details of Medication administration observations and compliance with wearing of the red apron.

	Day 1			Day 2			Day 3			Total interrupted	Red apron compliance
	Observed	Interrupted	% interrupted	Observed	Interrupted	% interrupted	Observed	Interrupted	% interrupted		
Ward 1									0%	9/20–45%	7/20–35%
Nurse a	5	2	40%	8	7	88%	7	0			
Nurse b		3	38%	9	5	56%	9	5	56%	13/26–50%	16/26–62%
Ward 2	11	9	82%	5	3	60%	3	3	100%	15/19–79%	0%
Ward 3	6	2	33%	2	2	100%	3	3	100%	7/11–64%	100%
Total										44/76 58%	

the development of patient safety culture at ward level as they enabled a participative, collaborate and inclusive approach which resulted in staff engagement with medication safety. Previous studies have also identified that leadership is one of the key dimensions of a safety culture (Halligan and Zecevic, 2011; Manley et al., 2017) Organisational culture has been identified as a variable which affects the transfer of CPE into practice (Clark et al., 2015); however there is a dearth of evidence of the role of leadership in the transfer of CPE into practice.

The safe medication administration education programme reinforced the need to be knowledgeable about all medications administered and highlighted how this information can be accessed. The range of medications prescribed in an acute hospital is extensive and it may not always be possible for nurses to have full knowledge of all medication. Therefore, the nurse requires information seeking skills (Sulosaari et al., 2011) and also requires clinical reasoning (Rohde and Domm, 2018).

High incident reporting rates demonstrate and promote an improved culture of safety (Abstoss et al., 2011). In this study, the ward which reported the highest rate of medication incidents was also the ward where the transformational leader was present. If leaders encourage a free and open environment of information flow, incident reporting will increase (Westrum, 2004). Similarly, improved cultural measures have been found to be paralleled by higher medication incident reporting but lower medication-related harm (Abstoss et al., 2011). For CPD to be transferred supportive organisations which provide for learning and effective workplace cultures are required (Manley et al., 2018).

Leadership and ward culture were originally proposed as dimensions of a patient safety culture. Considering the findings from this study, leadership and ward culture should be stand-alone contexts and tested independently in future evaluations of transfer of education into practice. While a validated quantitative instrument was not utilised in this study to identify the leadership styles of nurse managers, its inclusion in future studies could make an additional contribution to the literature on the transfer of education to practice.

Interruptions affect staff cognitively by interfering with working memory and causing lack of focus (Potter et al., 2005). If a nurse is required to stop administering medication so as to perform another task, an error was 48% more likely to occur (Cottney and Innes, 2015). The high rate of interruptions of 45–100% of all medication administrations in this study was seen to significantly interfere with the nurses' work. Similarly to another Irish study (Relihan et al., 2010) this study reported that the greatest source of interruptions of medication rounds were nurses themselves. However, it is difficult to compare this rate with those in the literature, as the literature reports the number of interruptions observed: (a) per hour, (b) per medication activity sampling unit, or (c) per communication event (Hopkinson and Jennings, 2013). Nurse interruptions have been quantified as forming 17.8% of all interruptions (Biron et al., 2009) and staff interruptions as occurring 2.5 times more frequently than any other interruption (Craig et al., 2014).

The use of the alert aprons and signage is a widespread intervention, which is thought to reduce the number of interruptions during medication rounds (Craig et al., 2014; Verweij et al., 2014; Westbrook et al., 2017). Relihan et al. (2010) also reported that strategies to reduce interruptions led to a significant reduction in interruptions. However, the post-implementation data collection was completed approximately two months after the introduction of the intervention, and thus, it is not evident that the strategy is sustainable and will impact over time.

The safe medication administration education programme was developed with the underlying assumption that the strategies recommended in the policy documents for reduction of interruptions were implemented. The policy and strategies for the reduction of interruptions had been implemented more than two years before this study. However, in the three ward areas, there was minimal to no adherence with recommended strategies ~~to reduce interruptions~~, and thus participants were unable to adopt a quality improvement approach. This effected the activation of the proposed mechanism as a mechanism will only activate in the right conditions (Pawson and Tilley, 1997), thus

the context needs to be suitable in order to activate the mechanism. Participants reported that the application of strategies to reduce interruptions were not effective. There needs to be a whole organisation approach to ensuring the adherence to policies and practices in the reduction of interruptions during medication administration. Participants were unable to put new learning into practice because the context was not enabling them to do so as the context proposed, which was safety focused governance, was absent and thus, this mechanism of the quality improvement approach was not triggered. For CPE to be effective, it needs to be applicable in the clinical area where it is to be applied. Thus, it will not work if the context it is designed for is not present.

A multi-disciplinary process in which nurses play a key role supports medication safety (Adhikari et al., 2014; Rohde and Domm, 2018). Open communication between disciplines, where the nurses advocate for their patients, ensures that patients received their medications in a timely manner and that correct medication is administered (Dickson and Flynn, 2012). A multidisciplinary approach to medication safety reflects a culture of medication safety in an organisation whereby all disciplines are involved in medication safety.

Receptivity to change was identified as a mechanism which involves the reasoning and responses of participants (Dalkin et al., 2015). Mechanisms have been described as being on a continuum and as rarely being activated via an on/off switch (Dalkin et al., 2015). Thus, the intensity of the mechanism would vary in line with the ever-evolving context. Previously, Clark et al. (2015) have reported that after CPE, some participants have aspired to be change agents but that organisational structures have prevented them from doing so and that they felt they had limited autonomy to initiate and sustain change. While participants in this study did show receptivity to change, the context responsible for igniting that change was not identified. Therefore, receptivity to change needs to be further explored and it should be explored in association with local leadership to determine if local leadership is a key context which can activate it.

It was anticipated that during testing of this CMO configuration that multidisciplinary collaboration would enable receptivity to change amongst staff. From Stage 1, it was identified that multi-disciplinary collaboration was a contextual factor which is an essential subset of the culture in the organisation in relation to medication safety. Receptivity to change was discussed by experts in Stage 2 in relation to contextual issues specifically in relation to the culture of the organisation and very emphasised that it is a mechanism that is activated or fires in the right context (Dalkin et al., 2015). While all participants' demonstrated receptivity to change, no link between receptivity to change and a multi-disciplinary context was found. In this study, the QC-Ms on Medication Administration were examined, and no association was found between the context, the mechanism and the achievement of QC-M scores. Further exploration is required to determine if any association can be made between the safe medication administration education programme and the medication administration QC-M scores.

6. Conclusion

This study found that the leadership styles (context) displayed by ward managers influenced how staff adopted reasoning skills in medication administration (mechanism) and thus reduce the number of reported medication errors. While a relationship between context, mechanism and outcome was not established in two of the proposed CMOs, the factors which can influence the application of knowledge developed in CPE into practice have been identified. If time constraints were not in place the iterative process of realist evaluation would indicate that data would again be reviewed through the early stages of this study to identify other possible mechanism. This study also identified the importance of the inclusion of stakeholders when evaluating CPE programmes. Clinical observation was highlighted as a key component in the verification of actual practice change and in

identifying contextual factors and mechanism which are activated in certain contexts. Not only can realist evaluation be beneficial in identifying the high-level outcomes of CPE such as its effect on patients, but it can also explore the process as to how these outcomes are achieved. Realist evaluation offers an excellent choice for evaluating continuing professional education.

This research also highlights the importance of contextual factors, which need to be considered when developing curriculum for CPE. In designing, developing and evaluating curriculum for CPE, educators need to include frameworks for translating and implementing new knowledge and skills into clinical practice. Given the complexity of CPE and its transfer into clinical practice frameworks such as those provided by Implementation Science (Rycroft-Malone and Bucknall, 2010) would assist in identifying and overcoming the barriers to transfer and thus optimise patient outcomes.

While some of the context and outcomes factors measured in this study are specific to CPE on medication safety, other findings from this study are transferable to other continuing professional education programmes. These include the key role of local leadership and ward culture facilitating transfer of learning.

Abbreviations

CPE	continuing professional education
cCMO	conjectured Context Mechanism Outcome
HIQA	Health Information and Quality Authority
QC-M	Quality Care Nursing Metrics

CRediT authorship contribution statement

FB: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Validation; Visualization; Writing - original draft; Writing - review & editing.
BH: Conceptualization; Methodology; Supervision; Validation; Visualization; Writing - review & editing. Final approval.
JH: Conceptualization; Methodology; Supervision; Validation; Visualization; Writing - review & editing; Final Approval.

Ethics approval and consent to participate

The Research and Ethics Committee from the study site granted approval for this research. (*Name withheld due to maintaining anonymity for the research site*).

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Funding

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research,
authorship, and/or publication of this article.

References

Abstoss, K.M., Shaw, B.E., Owens, T.A., Juno, J.L., Commiskey, E.L., Niedner, M.F., 2011. Increasing medication error reporting rates while reducing harm through simultaneous cultural and system-level interventions in an intensive care unit. BMJ Quality & Safety 20, 914–922.

Adhikari, R., Tocher, J., Smith, P., Corcoran, J., MacArthur, J., 2014. A multi-disciplinary approach to medication safety and the implication for nursing education and practice. Nurse Educ. Today 34, 185–190.

Astbury, B., Leeuw, F.L., 2010. Unpacking black boxes: mechanisms and theory building in evaluation. Am. J. Eval. 31, 363–381.

Atack, L., Luke, R., 2008. Impact of an online course on infection control and prevention competencies. J. Adv. Nurs. 63, 175–180.

Biron, A.D., Lavoie-Tremblay, M., Loiselle, C.G., 2009. Characteristics of work interruptions during medication administration. Journal of nursing scholarship 41, 330–336.

Bloomer, M.J., Cross, W., Endacott, R., O'Connor, M., Moss, C., 2012. Qualitative observation in a clinical setting: challenges at end of life: qualitative observation at end of life. Nursing & Health Sciences 14, 25–31.

Bowen, G., 2009. Document Analysis as a Qualitative Research Method Qualitative Research Journal 9.

Braun, V., Clarke, V., 2006. Using thematic analysis in psychology. Research in Psychology 3, 77–101.

Chiesa, M., Hobbs, S., 2008. Making sense of social research: how useful is the Hawthorne effect? Eur. J. Soc. Psychol. 38, 67–74.

Clark, E., Draper, J., Rogers, J., 2015. Illuminating the process: enhancing the impact of continuing professional education on practice. Nurse Educ. Today 35, 388–394.

Cottney, A., Innes, J., 2015. Medication-administration errors in an urban mental health hospital: a direct observation study: medication-administration errors. Int. J. Ment. Health Nurs. 24, 65–74.

Craig, J., Clanton, F., Demeter, M., 2014. Reducing interruptions during medication administration: the White Vest study. J. Res. Nurs. 19, 248–261.

Dalkin, S.M., Greenhalgh, J., Jones, D., Cunningham, B., Lhussier, M., 2015. What's in a mechanism? Development of a key concept in realist evaluation. Implementation science: IS 10, 49.

Department of Health and Children, 2008. The commission on patient safety. In: Report of the Commission on Patient Safety and Quality Assurance, Dublin.

Dickson, G.L., Flynn, L., 2012. Nurses' clinical reasoning: processes and practices of medication safety. Qual. Health Res. 22, 3–16.

Draper, J., Clark, L., 2016. Managers' role in maximising investment in continuing professional education. Nursing Management - UK 22, 30–36.

Ellis, L., Nolan, M., 2005. Illuminating continuing professional education: unpacking the black box. Int. J. Nurs. Stud. 42, 97–106.

Garafalo, L., 2016. Continuing nursing education and outcomes: making a difference in patient care. J. Contin. Educ. Nurs. 47, 103–105.

Halligan, M., Zecevic, A., 2011. Safety culture in healthcare: a review of concepts, dimensions, measures and progress. BMJ Quality & Safety 20, 338–343.

Hardwick, S., Jordan, S., 2002. The impact of part-time post-registration degrees on practice. J. Adv. Nurs. 38, 524–535.

Health Information and Quality Authority, HIQA, 2017. Report of the Announced Inspection of Medication Safety at XXXXX Hospital Dublin.

Hegney, D., Tuckett, A., Parker, D., Robert, E., 2010. Access to and support for continuing professional education amongst Queensland nurses: 2004 and 2007. Nurse Educ. Today 30, 142–149.

Hopkinson, S.G., Jennings, B.M., 2013. Interruptions during nurses' work: a state-of-the-science review. Research in Nursing & Health 36, 38–53.

Houghton, C.E., Casey, D., Shaw, D., Murphy, K., 2010. Ethical challenges in qualitative research: examples from practice. Nurse researcher 18, 15–25.

Hughes, E., 2005. Nurses' perceptions of continuing professional development. Nurs. Stand. 19.

Katsikitis, M., McAllister, M., Sharman, R., Raith, L., Faithfull-Byrne, A., Priaulx, R., 2013. Continuing professional development in nursing in Australia: current awareness, practice and future directions. Contemporary Nurse: Supporting a Strong and Resilient Contemporary Nursing Workforce 45, 33–45.

Lahti, M., Kontio, R., Pitkänen, A., Välimäki, M., 2014. Knowledge transfer from an e-learning course to clinical practice. Nurse Educ. Today 34, 842–847.

Lambert, N., 2012. Ban happy sheets!—understanding and using evaluation. Nurse Educ. Today 32, 1–4.

Lee, N.-J., 2011. An evaluation of CPD learning and impact upon positive practice change. Nurse Educ. Today 31, 390–395.

Manley, K., Jackson, C., McKenzie, C., Martin, A., Wright, T., 2017. Safety Culture, Quality Improvement, Realist Evaluation (SCQIRE): Evaluating the Impact of the Patient Safety Collaborative Initiative. England Centre for Practice Development.

Manley, K., Martin, A., Jackson, C., Wright, T., 2018. A realist synthesis of effective continuing professional development (CPD): a case study of healthcare practitioners' CPD. Nurse Educ. Today 69, 134–141.

Mann, K., Sargeant, J., Hill, T., 2009. Knowledge translation in interprofessional education: what difference does interprofessional education make to practice? Learn. Health Soc. Care 8, 154–164.

Manzano, A., 2016. The craft of interviewing in realist evaluation. Evaluation 1–19.

Mulhall, A., 2003. In the field: notes on observation in qualitative research. J. Adv. Nurs. 41, 306–313.

NMBI, 2014. Code of Professional Conduct and Ethics. NMBI Dublin.

Nursing and Midwifery Board of Ireland, 2007. Guidance to Nurses and Midwives on Medication Management. NMBI.

Nursing and Midwifery Board of Ireland, 2015. Scope of Nursing and Midwifery Practice Framework, Dublin.

Office of Nursing and Midwifery Services Director, -Health Services Executive, 2018. National Guideline for Nursing and Midwifery Quality Care- Metrics Data Measurement in Acute Care. Dublin.

Ogrinc, G., Batalden, P., 2009. Realist evaluation as a framework for the assessment of teaching about the improvement of care. J. Nurs. Educ. 48, 661–667.

Ogrinc, G., West, A., Eliassen, M.S., Liuw, S., Schiffman, J., Cochran, N., 2007. Integrating practice-based learning and improvement into medical student learning: evaluating complex curricular innovations. Teaching and Learning in Medicine 19, 221–229.

Owen, G.T., 2014. Qualitative methods in higher education policy analysis: using interviews and document analysis. Qual. Rep. 19, 1–19.

Patton, M., 2015. Qualitative Research and Evaluation Methods. Integrating Theory and Practice. Sage, Thousand Oaks, CA, USA.

Pawson, R., 1996. Theorizing the interview. Br. J. Sociol. 47, 295–314.

Pawson, R., 2006. Evidence-based Policy: A Realist Perspective. Sage, London.

Pawson, R., Tilley, N., 1997. Realistic Evaluation. SAGE, London.

Pawson, R., Tilley, N., 2006. Realist Evaluation, DPRN Thematic Meeting 2006 Report on Evaluation.

Pool, I.A., Poell, R.F., Berings, M.G., Ten Cate, O., 2016. Motives and activities for continuing professional development: an exploration of their relationships by integrating literature and interview data. Nurse Educ. Today 38, 22–28.

Potter, P., Wolf, L., Boxerman, S., Grayson, D., Sledge, J., Dunagan, C., Evanoff, B., 2005. Understanding the cognitive work of nursing in the acute care environment. J Nurs Adm 35, 327–335.

Relihan, E., O'Brien, V., O'Hara, S., Silke, B., 2010. The impact of a set of interventions to reduce interruptions and distractions to nurses during medication administration. Quality and Safety in Health Care 19, e52.

Rohde, E., Domm, E., 2018. Nurses' clinical reasoning practices that support safe medication administration: an integrative review of the literature. J. Clin. Nurs. 27, e402–e411.

Rycroft-Malone, J., Bucknall, T., 2010. Models and Frameworks for Implementing Evidence-based Practice: Linking Evidence to Action. Wiley-Blackwell, Oxford.

Rycroft-Malone, J., Fontenla, M., Bick, D., Seers, K., 2010. A realistic evaluation: the case of protocol-based care. Implementation Science 5, 38.

Stake, R.E., 1995. The Art of Case Study Research. Sage, Thousand Oaks, Calif, London.

Stolee, P., McAiney, C.A., Hillier, L.M., Harris, D., Hamilton, P., Kessler, L., Madsen, V., Le Clair, J.K., 2009. Sustained transfer of knowledge to practice in long-term care: facilitators and barriers of a mental health learning initiative. Gerontology & Geriatrics Education 30, 1–20.

Sulosaari, V., Suhonen, R., Leino-Kilpi, H., 2011. An integrative review of the literature on registered nurses' medication competence. J. Clin. Nurs. 20, 464–478.

Tame, S.P., 2009. Perioperative nurses' perceptions and experiences of continuing professional education. Journal of Perioperative Practice 19, 257–262.

Tolson, D., Schofield, I., 2012. Football reminiscence for men with dementia: lessons from a realistic evaluation. Nurs. Inq. 19, 63–70.

Vann, B.A., Coleman, A.N., Simpson, J.A., 2014. Development of the Vannsimpco leadership survey: a delineation of hybrid leadership styles. Swiss Business School Journal of Applied Business Research 3, 28–38.

Verweij, L., Smeulers, M., Maaskant, J.M., Vermeulen, H., 2014. Quiet please! Drug round tabards: are they effective and accepted? A mixed method study. J. Nurs. Scholarsh. 46, 340–348.

Walshe, C., Ewing, G., Griffiths, J., 2012. Using observation as a data collection method to help understand patient and professional roles and actions in palliative care settings. Palliat. Med. 26, 1048–1054.

Westbrook, J.I., Li, L., Hooper, T.D., Raban, M.Z., Middleton, S., Lehnbom, E.C., 2017. Effectiveness of a 'Do not interrupt' bundled intervention to reduce interruptions during medication administration: a cluster randomised controlled feasibility study. BMJ Quality & Safety 26, 734–742.

Westrum, R., 2004. A typology of organisational cultures. Quality and Safety in Health Care 13, ii22–ii27.

Wong, G., Greenhalgh, T., Pawson, R., 2010. Internet-based medical education: a realist review of what works, for whom and in what circumstances. BMC Medical Education 10, 12.

Wong, G., Greenhalgh, T., Westhorp, G., Pawson, R., 2012. Realist methods in medical education research: what are they and what can they contribute? Med. Educ. 46, 89–96.

Wong, G., Westhorp, G., Manzano, A., Greenhalgh, J., Jagosh, J., Greenhalgh, T., 2016. RAMESES II reporting standards for realist evaluations. BMC Med. 14, 96.

Yin, R.K., 2018. Case Study Research and Applications: Design and Methods, 6th ed. SAGE Publications, Inc, Thousand Oaks, CA.