

A Realist Evaluation of a Safe Medication Administration Education Programme in the Republic of Ireland

A thesis submitted in partial fulfilment of the requirements of
Cardiff University for the Degree of Professional Doctorate in
Nursing

2018

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Acknowledgements

I wish to thank my supervisors Dr Jane Harden and Professor Ben Hannigan who have been a constant support throughout this thesis conception, development and final production. Your constant enthusiastic encouragement and positivity has had an impact on me far greater than this study.

I also wish to acknowledge the advice and guidance provided by Professor Laserina O'Connor and Dr Dominic Roche who advised me at various stages during the research design, data collection and analysis.

This study would not have been possible without the many participants who gave their time. In particular I wish to thank the four staff nurses who willingly allowed me to observe them in clinical practice.

I would also like to express my appreciation to the Nursing Department in my organisation for their support throughout this process.

For my family, Alan, who started this journey with me and to Hannah and Maya, who joined us on the way, I am forever grateful for your understanding and patience. *Is grá liom.*

Finally to my mother, Joan, who taught me that through persistence, dedication and hard work I can achieve anything that I set my mind to. I dedicate this thesis to your memory.

Abstract

Background: Continuing professional education (CPE) for nurses is deemed an essential component 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. However, there is little empirical evidence of its effectiveness or factors which may influence its application into practice. This thesis 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 provides the framework for this research study. Realist evaluation stresses the need to evaluate programmes within "context," and to ask what "mechanisms" are acting to produce which "outcomes." The realist evaluation cycle for this study had four distinct stages. Firstly, I built initial theories as conjectured CMO configurations (Stage 1 and 2), then these CMO conjectures were tested (Stage 3) and then they were refined (Stage 4).

Methods: Data was collected and analysed separately for each of Stages 1, 2 and 3. However, as realist evaluation is iterative, I often returned to a previous stage to clarify meaning or understanding. Document analysis and interviews were used in Stage 1 to commence the process of building CMO conjectures. Realist interviews took place in Stage 2 to refine the conjectured CMO configurations. Stage 3 involved the testing of the conjectured CMO configurations through three embedded case studies which involved interview, clinical observation, analysis of further documents and analysis of data from reported critical incidents and nursing care metric measurements.

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

and their relationship allowed for further exploration of outcomes associated with the context and mechanism constructs.

Recommendations: The conjectured CMO configurations put forward at the end of the thesis should be further tested utilising a different CPE programme. These theoretical propositions could 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 providing CPE programmes is to maintain and improve patient care.

Contents

Operational Definitions	18
Chapter 1- Introduction to this Thesis.....	22
1.1 Introduction	22
1.2 Medication Safety	22
1.3 Medication Safety –The Nurse’s Role.....	23
1.4 Continuing Professional Education for Medication Administration.....	24
1.5 Patient Safety	24
1.6 The Research Study.....	25
1.6.1 Research question.....	25
1.6.2 Aims.....	26
1.6.3 Outcomes	26
1.7 Thesis Overview	26
Chapter 2- Literature Review of Continuing Professional Education.....	28
2.1 Introduction	28
2.2 Defining the Concept of Continuing Professional Education	28
2.3 Historical Context of Continuing Professional Education in Ireland.....	30
2.4 Scope of the Literature Review.....	31
2.5 Search Strategy	31
2.6 Organisation of this Review	35
2.7 Level 2a- Modification of Attitudes and Perceptions	38
2.7.1 Attitudes.....	38
2.7.2 Confidence	40
2.8 Level 2b - Acquisition of Knowledge and Skills	41
2.9 Level 3- Behavioural Change.....	45
2.9.1 Intentions to change	45
2.9.2 Self-reported changes to practice.....	47

2.9.3 Actual practice change	50
2.10 Level 4 a) Organisation Change	53
2.11 Level 4 b) Benefits to Patients and Families	54
2.12 Barriers to Transfer	56
2.13 Facilitators of Transfer	58
2.14 Limitations of Literature Review.....	59
2.15 Conclusion.....	60
Chapter 3- Methodology	62
3.1 Introduction	62
3.2 Evaluation Research.....	62
3.3 Challenges for Evaluation of Continuing Professional Education.....	63
3.4 Scientific Evaluation	64
3.5 Management/System Models of Evaluation	65
3.6 Realist Evaluation.....	66
3.7 Philosophical Underpinnings of Realist Evaluation	68
3.8 Nursing and Realist Evaluation	70
3.9 Why Realist Evaluation in my Research?	71
3.10 The Application of the Principles of Realist Evaluation in my Research	71
3.11 Ethical Approval	74
3.12 Conclusion.....	74
Chapter 4 – Stage 1 Theory Development	75
4.1 Introduction	75
4.2 The Safe Medication Administration Education Programme	76
4.3 Document Analysis.....	77
4.3.1 The organisation.....	78
4.3.2 Policy and guideline review.....	79
4.3.3 Data analysis.....	80

4.4 Interviews.....	83
4.4.1 Selection of interviewees	83
4.4.2 The interview.....	85
4.4.3 Analysis of interview data	86
4.5 Document and Interview Data Analysis.....	88
4.6 Formulation of Conjectured Context Mechanism Outcome Configurations	91
4.6.1 Conjectured CMO configurations.....	91
4.6.2 Context	92
4.6.3 Mechanism	93
4.6.4 Outcome.....	94
4.7 Preparing Conjectured CMO Configurations	94
4.7.1 An exemplar of grappling with context or mechanism allocation- Multi-disciplinary collaboration	96
4.7.2 The conjectured CMO configurations	97
4.8 Rigor	100
4.9 Conclusion.....	100
Chapter 5- Stage 2 Theory Refinement	102
5. 1 Introduction	102
5.2 Selection of Interviewees/ Experts	102
5.3 The Interview	103
5.3.1 The realist interview.....	103
5.3.2 Teacher learner cycle	104
5.4 Data Analysis.....	105
5.5 Findings and Discussion	106
5.5.1 Introduction.....	106
5.5.2 Conjectured CMO 1	106
5.5.3 Conjectured CMO 2.....	111

5.5.4 Conjectured CMO 3	113
5.6 Conclusion	116
Chapter 6- Stage 3 Testing the CMO Conjecturers	118
6.1 Introduction	118
6.2 Case Study	118
6.2.1 Introduction to case study	118
6.2.2 Case study in realist evaluation	118
6.2.3 The case	119
6.3 Sampling	120
6.3.1 Individual level participants	120
6.3.2 Selection of embedded cases	121
6.3.3 Embedded cases	122
6.4 Data Collection	125
6.4.1 Introduction to data collection	125
6.4.2 Observation	126
6.4.3 Semi-structured interviews	131
6.4.4 Documentation review	133
6.5 Rigor	136
6.5.1 Introduction to rigor	136
6.5.2 Observation and the Hawthorne Effect	136
6.5.3 Strategies used to aid rigor	136
6.6 Ethics	137
6.6.1 Ethics in observation	137
6.6.2 Respect for patients' privacy	139
6.6.3 Dual identity	139
6.6.4 Dress during observation	141
6.7 Data Analysis	141

6.7.1 Semi-structured observation tool	142
6.7.2 Field notes	143
6.7.3 Interview data	143
6.7.4 Inspection reports	144
6.7.5 Medication incident reports	144
6.7.6 Quality Care Nursing Metrics	144
6.8 Conclusion	144
Chapter 7-Stage 4- Testing Conjectured CMO 1	146
7. 1 Introduction	146
7.2 Ash Ward.....	146
7.2.1 Context- Patient safety culture	146
7.2.2 Mechanism- Reasoning skills	149
7.3 Hazel Ward.....	151
7.3.1 Context- Patient safety culture	152
7.3.2 Mechanism- Reasoning skills	154
7.4 Oak Ward	155
7.4.1 Context- Patient safety culture	155
7.4.2 Mechanism- Reasoning skills	158
7.5 Outcomes.....	159
7.5.1 Reporting medication incidents -Ash Ward	160
7.5.2 Reporting medication incidents-Hazel Ward	161
7.5.3 Reporting medication incidents-Oak Ward.....	163
7.6 Conclusion and Reconfigured CMO 1	165
Chapter 8 -Testing Conjectured CMO 2.....	166
8.1 Introduction	166
8.2 Context- Safety Focused Governance Structure in the Organisation.....	166
8.3 Ash Ward.....	167

8.3.1 Context- Safety focused governance structure	167
8.3.2 Mechanism- Quality improvement approach	170
8.4 Hazel Ward.....	171
8.4.1 Context - Safety focused governance structure.....	171
8.4.2 Mechanism- Quality improvement approach	175
8.5 Oak Ward	176
8.5.1 Context- Safety focused governance structure	176
8.5.2 Mechanism -Quality improvement approach	178
8.6 Conclusion and Reconfigured CMO 2	179
Chapter 9 -Testing Conjectured CMO 3.....	181
9.1 Introduction	181
9.2 Multi-disciplinary Collaboration at Organisational Level	181
9.3 Ash Ward.....	182
9.3.1 Context- Multi-disciplinary collaboration	182
9.3.2 Mechanism - Receptivity to change.....	184
9.4 Hazel Ward.....	186
9.4.1 Context- Multi-disciplinary collaboration	186
9.4.2 Mechanism- Receptivity to change.....	186
9.5 Oak Ward	187
9.5.1 Context- Multi-disciplinary collaboration	187
9.5.2 Mechanism- Receptivity to change.....	188
9.6 Exploration of a Potential Mechanism – Correct Patient Identification	189
9.6.1 Ash Ward	189
9.6.2 Hazel Ward	191
9.6.3 Oak Ward.....	191
9.7 Outcome	192
9.7.1 Quality Care Nursing Metrics (QC-M)	192

9.7.2 Ash Ward	193
9.7.3 Hazel Ward	194
9.7.4 Oak Ward.....	194
9.8 Conclusion and Reconfigured CMO 3	195
Chapter 10- Discussion	196
10.1 Introduction to Discussion	196
10.2 Patient Safety Culture	197
10.2.1 Leadership	197
10.2.2 Ward culture	198
10.3 Reasoning Skills	200
10.4 Reporting Medication Incidents	202
10.5 Safety Focused Governance Structure	205
10.5.1 Interruptions in medication administration	205
10.5.2 Wearing the red apron.....	208
10.5.3 Physical structure	210
10.6 Quality Improvement Approach	211
10.7 Multi-disciplinary Collaboration for Medication Safety	212
10.8 Receptivity to Change	213
10.9 Quality Care Nursing Metrics.....	214
10.10 Correct Patient Identification	215
10.11 Conclusion to Discussion	216
11.1 Introduction.....	219
11.2 Reflection on my Thesis Journey	219
11.2.1 Ethical approval and University Panel Reviews	219
11.2.2 Distance student	220
11.2.3 Learning from the community of realist researchers	220
11.2.4 Reflection on observation	222

11.3 Original Contribution to Knowledge	223
11.4 Study Limitations	224
11.5 Post Doctorate Plans.....	225
11.6 Conclusion.....	226
References	227
Appendices	257
Appendix 1: Critical Appraisal of Articles Included in the Literature Review	258
Appendix 2: Ethical Approval -Cardiff School of Nursing and Midwifery Studies, School Research Ethics Committee	279
Appendix 3: Ethical Approval - Organisation’s Research and Ethics Committee	281
Appendix 4: Approval- Organisation’s Nursing Research and Innovation Committee	282
Appendix 5: Approval- Organisation’s Chief Executive	283
Appendix 6: Approval -Director of Nursing for the use of Nursing Quality Care Metrics ..	284
Appendix 7: Stage 1- Participant Information Leaflet (PIL) and Consent.....	285
Appendix 8: Stage 1-Sample of Semi -Structured Interview Schedule.....	288
Appendix 9: Stage 2- Sample Semi Structured Interview Schedule - Expert Interview Quality Management -Local Organisation	290
Appendix 10: Stage 2- Code Book.....	292
Appendix 11: Stage 3- Participant Information Leaflet and Consent- Observation and Interview	293
Appendix 12: Stage 3- Participant Information Leaflet and Consent-Interview CNM’s.....	297
Appendix 13: Situations where I will intervene during observation	300
Appendix 14: Semi Structured Observation Tool	301
Appendix 15: Mapping Conjectured CMO Configurations to Data Collection	303
Appendix 16: Stage 3-Sample Interview Schedule –Following Observation.....	306
Appendix 17: Sample Interview Schedule Stage 3 Manager	308

Appendix 18: National Coordinating Council for Medication Error Reporting and Prevention- Categorisation of Medication Errors.....	310
Appendix 19: Poster Displayed During Observation	311

List of Figures

Figure 2.1 PRISMA adapted from Moher et al. (2009)	34
Figure 2.2 Extension of the Barr et al (1999) framework	36
Figure 3.1 Paradigm position of realist evaluation	68
Figure 4.1 Thematic Map: Code- Social System	82
Figure 4.2 Thematic Map- Interviews: Code-Interprofessional	87
Figure 4.3 Formulation of theme: multi-disciplinary collaboration	88 & 96
Figure 6.1 Stage 3 Embedded case study	120

List of Tables

Table 2.1 Search terms	32
Table 2.2 Inclusion and exclusion criteria	33
Table 2.3 Studies included in review according to the extended evaluation framework	36- 38
Table 3. 1 Kirkpatrick's levels of evaluation	65
Table 3.2 Theoretical assumptions underlying this realist evaluation- adapted from Pawson and Tilley (1997) and Westhorp et al. (2011)	70
Table 3.3 Realist evaluation study design	73
Table 4.1 Braun and Clarke (2006) Framework for Thematic Analysis	81
Table 4.2 Initial themes in analysis of documents	83
Table 4.3 Description of interviewees	84
Table 4.4 Initial themes from interviews	87
Table 4.5 New formulations of themes	89
Table 4.6 Definition of themes	90-91
Table 4.7 Further refinement and allocation to context, mechanism or outcome	98
Table 5.1 Expert details for interview: Stage 2	103
Table 6.1 Stage 3 - Inclusion criteria	121
Table 6.2 Final Stage 3 participants	122
Table 6.3 Stage 3 observation details	127
Table 6.4 Stage 3 interview details	131
Table 6.5 Score Card Quality Care Metrics	134
Table 6.6 Example of Stage 3 mapping document – Context- Patient Safety Culture	143
Table 6.7 Coding template	144
Table 7.1 Stage 3 participants	146
Table 7.2 NCC MERP Classification of MRI's for Ash Ward	161
Table 7.3 NCC MERP Classification of MRI's for Hazel Ward	163
Table 7.4 NCC MERP Classification of MIR's for Oak Ward	164

Table 9.1 QC-M level of compliance	192
Table 9.2 QC-M indicators for medication administration	193
Table 9.3 QC-M for Ash Ward 2017	193
Table 9.4 QC-M for Hazel Ward 2017	194
Table 9.5 QC-M for Oak Ward 2017	195
Table 10.1 Proposed context, mechanism and outcome's for CPE on medication safety	216

Operational Definitions

Clinical Nurse Manager II (CNM II): Senior nurse with a formal role of being in charge of a ward.

Continuing Professional Education: Is a lifelong learning process which takes place after the completion of the pre-registration education and training, and is a vital component of CPD. It consists of planned learning experiences which are designed to augment the knowledge, skills and attitudes of registered nurses and registered midwives for the enhancement of nursing and midwifery practice, education, leadership and research (NMBI 2015, p. 15).

Continuing Professional Development: Encompasses experiences, activities and processes that contribute towards the development of a nurse or midwife as a healthcare professional. CPD is, therefore, a lifelong process of both structured and informal learning (NMBI 2015, p. 19).

Correct Patient Identification: At the patient's bedside, the patient's identity should be verified by name and medical record number, using the medication record and the patient's identity band, and verbally with the patient where possible.

Conjectured Context Mechanism Outcome configurations (CMOs): Are the proposed hypotheses, which attempt to tease out specific causal pathways, as pre-specified mechanisms, acting in pre-specified contexts spill out into pre-specified and testable outcome patterns (Pawson and Manzano-Santaella 2012).

Context: The basic premise is that there will be a range of conditions, often sociocultural, that affect the outcomes of any programme. These are referred to as Contexts (C) (Jolly and Jolly 2014). Context is about having the right conditions to activate the mechanism (Pawson and Tilley 1997).

Mechanisms: Are the ways in which people respond – their reasoning about what they should do, and the resources they can bring to bear (Pawson and Tilley 1997, p.67). Mechanisms are the underlying entities, processes or structures, which operate in particular contexts to generate outcomes of interest (Astbury and Leeuw 2010).

Outcomes: Hypotheses about how the programme results in observed outcomes (O).

Do Not Disturb Signage: An A3-sized red sign inscribed in white with the words: Do Not Disturb Medicine Round in Progress, used during the medicine round, which helps reduce interruptions and distractions from Organisation Policy.

Interruption to medication administration: Interruptions have been defined as situations in which nurses stop preparing or administering medications so they can deal with an external stimulus (Westbrook et al. 2017).

Medication administration: The nurse is responsible for calculating, mixing, labelling and preparing the medication. They must always check for patient allergies before administering medications. They must observe the '5 Rights' (right patient, right drug, right dose, right route, and right time) (An Bord Altranais 2007).

Medication error: Defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is under the control of the healthcare professional, patient or consumer (National Coordinating Council for Medical Reporting and Prevention 2018).

Medication incident report (MIR): Reports made of actual or potential medication errors and adverse medication reactions. The healthcare organisation under study operates a paper reporting format. These reports are required to be reported nationally to the State Claims Agency.

MDA: MDA refers to the Misuse of Drugs Acts 1977, 1984, and the Misuse of Drugs Regulations, 1988, 1993, 2007 and 2017. The legal term for these drugs is Controlled Drugs (the abbreviation MDA is used in the organisation under study).

Near Miss: Event or situation where the error does not reach the patient / service user and no injury results (e.g. incorrect dosage is prescribed but it is recognised and adjusted before the medication is administered).

Organisational culture: The values, behaviours, goals, attitudes, practices and beliefs shared across an entire organisation (Scott et al. 2003).

Patient safety climate: The subset of organisational culture, relating specifically to the attitudes, values, norms and beliefs towards patient safety (Ausserhofer et al. 2013).

Programme theory: Programme theory encompasses the assumptions and perspectives of the programme designers and implementers and is assumed to underlie a particular intervention (Pawson and Tilley 1997). Realist evaluation develops a particular kind of programme theory, structured as Context- Mechanism Outcome configurations (CMOs) (Westthrop et al. 2011). Testing the programme theory entails identification of the CMO configurations which become the analytical instruments that help build the programme theory (Mukumbang et al. 2016).

Red alert apron: A red plastic disposable apron worn by the nurse administering medications.

Red alert apron practice: This is the practice of always wearing the red plastic disposable apron during drug administration, and preparation if necessary, to alert all staff, patients and visitors not to disturb that nurse during the medicine round. The red apron is supported by the use of 'Do Not Disturb' signage. One sign is hung from the lid of the medicine trolley, and a second hooked on the patient-room doorframe to alert all staff, patients and visitors that a medicine round is in progress.

Safety culture: The product of individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety programmes. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measure (Halligan and Zecevic 2011).

Single medication administration: A medication episode was defined as the administration of one or all medications prescribed for a single time point for one patient (Popescu et al. 2011).

Transfer of knowledge: The degree to which learners apply the knowledge, skills and attitudes gained in a training context into practice (Vasli et al. 2018).

Workplace culture: A specific type of subculture involving an identifiable grouping within an organisation. In healthcare, such a 'workplace' may be a unit, ward or department, or a professional group, e.g., medicine or nursing (Braithwaite et al. 2016).

Chapter 1- Introduction to this Thesis

1.1 Introduction

This thesis is about the development of nursing knowledge and skills on medication administration through the utilisation of continuing professional education on medication safety. The thesis will examine the factors that enable or constrain how nurses transfer this new knowledge into their clinical practice. Continuing professional education (CPE) for nurses is deemed an essential component 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. Currently in Ireland, there is no mandatory requirement to undertake CPE to renew nursing registration. While the benefits of nurses engaging in continuing professional education are well documented and will be explored further in Chapter 2, there is little empirical evidence of its effectiveness on healthcare outcomes, which can support the financial investment (Draper and Clarke 2007; Draper et al. 2016).

1.2 Medication Safety

'Patient Safety First' is a wide ranging initiative which was launched in 2010 in Ireland, and sets an agenda for change that aims to deliver services of consistently higher quality that are safer for patients, with errors reduced to as low a level as possible. One area which it focuses on is Medication Safety, and a National Medication Safety Forum has been established. One of the aims of the Medication Safety Forum is to develop initiatives to improve the safety of the medication process such as the prescribing, dispensing and administering of medicines. In 2017, the World Health Organisation (WHO 2017a) also identified medication safety as the theme of the third Global Patient Safety Challenge. This global safety initiative aims to address the weaknesses in health services which lead to medication error occurring and the harm from these errors. In Ireland in 2016, the Health Information and Quality Authority (HIQA) commenced a medication safety monitoring programme to examine and positively influence the adoption and implementation of evidence based practice in public acute hospitals around medication safety (HIQA 2016). HIQA is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland.

Medication errors have been shown to be a prevalent and on-going problem which results in varying degrees of preventable harm to patients. International literature suggests that one medication error occurs for every five doses given in US hospitals (Mansur 2016). In the Republic of Ireland in 2016, there were 5,505 medication related adverse events reported (State Claims Agency 2017). In a systematic review, Keers et al. (2014) examined the empirical evidence on the nature and prevalence medication administration errors in healthcare settings and reported that a median rate of error was 19.6% of total opportunities for error. Studies consistently reported wrong time, omission and wrong dose, which the most frequently reported administration errors. An Australian literature review of medication safety in acute care, identified the range of reported medication errors as varying between 14 to 26% of all incidents reported (Roughead and Semple 2009). However, it is important to remember that these are only the reported incidents and do not account for the unreported case. United Kingdom figures suggest that less than 1% of medication incidents are spontaneously reported, meaning that many learning opportunities, as a result of these errors, are lost (Cousins et al. 2012).

1.3 Medication Safety –The Nurse’s Role

Medication related errors can occur at many points in the medication cycle, from the prescription and dispensing to the administration (Wimpenny and Kirkpatrick 2010). Medication administration error represents one of the major concerns in patient safety (Kim and Bates 2013), and is the primary concern of nursing. The nurse administering the medication represents the last safety check and therefore the final opportunity to ensure that all aspects of this process have been appropriately adhered to (Leufer and Cleary-Holdforth 2013). Wimpenny and Kirkpatrick (2010), in a systematic review on roles and systems for routine medication administration to prevent medication errors in hospital based, acute care settings, found that levels of medication administration errors have been reported as accounting for 38% of all adverse drug events and have been calculated as occurring in 38% of all administrations. Routine medication administration is that which is normally carried out by nurses at specified time intervals in hospital wards and units. Wimpenny and Kirkpatrick (2010) have discussed a number of nursing factors which have been identified as contributing to errors, these include mathematical skills, knowledge of medications, the quality of the prescription, length of experience, shift patterns, workload

and staffing levels, medication delivery systems, single-nurse administration, policies and procedures and distractions and interruptions.

In an observational study by Keohane et al. (2008), it was found that 26.9% of nurses' time was spent on medication related activities. This is a significant proportion for the nursing workload through the shift. They also note that the activity of medication administration occurred throughout the day and in equal proportions on different types of units. As medication management makes up such a significant element of nursing workload, it is also a key component of nursing competence. This competency needs to be continually updated as the clinical environment is ever changing in relation to technology, patient caseload, work processes and pharmacological advances.

1.4 Continuing Professional Education for Medication Administration

The report 'Building a Culture of Patient Safety' (DoHC 2008) refers to the requirement for education and continuing professional development in order to enhance all aspects of patient safety. It recommends that education should span all levels of healthcare education from undergraduate teaching, to post graduate, continuing education and professional development. HIQA (2012) also recommend that healthcare organisations should plan and devise education programmes for their staff, based on strategic objectives and the needs of their patient population and all staff should be provided with the required ongoing education and training to maintain their competency, skill and knowledge (HIQA 2012).

Continuing professional education for nurses in healthcare organisations spans many topics. Safety in relation to medication administration is currently high on the international and national agenda, and education is an identified strategy to address this agenda. Education for medication safety forms a component of the larger medication safety programme within acute hospitals. Chapter 2 presents a narrative literature review on the evaluation of CPE for nurses and provides an in-depth critical discussion on the topic.

1.5 Patient Safety

A fundamental concept in the delivery of healthcare, both internationally and within Ireland, is the focus upon safe and effective care to all patients (Department of Health and Children (DoHC) 2008). Nevertheless, the World Health Organisation (WHO 2017b) report that each year, an inadmissible number of patients suffer injuries or die because of unsafe and poor

quality healthcare. Most of these injuries are avoidable. It is commonly reported that around 1 in 10 hospitalised patients experience harm, with at least 50% of these are preventable. The European Union Commission (2014) have further estimated that 8% to 12% of patients admitted to hospital suffer from adverse events. Specifically in the Irish context, the Eurobarometer survey (European Union Commission 2014) reported that 25% of respondents stated that either they, or a family member, had experienced an adverse event when receiving healthcare. In addition 54% of respondents feared harm from the healthcare system.

The Institute of Medicine in the USA, in their seminar report from 2000 entitled 'To Err is Human', identified many issues and areas of concern and outlined a strategy for improvement for building a safer healthcare system. In Ireland in 2008, the Commission on Patient Safety and Quality Assurance (DoHC 2008) published their report "Building a Culture of Patient Safety". This document provides for the Irish strategic focus on patient safety, and is based around changing practices within the health services to improve quality and safety. The patient safety initiative incorporates all aspects of patient safety.

In order to set the scene for medication safety education and provide a rationale for this study it was necessary to provide a brief overview of the national and global patient safety agenda. However, the literature and policy background on patient safety is extensive and exploration and discussion of it is beyond the scope of this thesis. The focus of this thesis is on continuing profession education and in particular a continuing professional education programme on medication safety.

1.6 The Research Study

1.6.1 Research question

The research question which guided this study is: *How are knowledge and skills obtained through a continuing professional education programme for safe medication administration transferred to the clinical care environment?*

Through the use of realist evaluation this study aimed to achieve the following aims and outcomes.

1.6.2 Aims

This study aimed to:

- identify factors (in the clinical area or in the course itself) that enable or constrain the application of knowledge and skills gained through the safe medication administration education programme into practice
- explore the underlying mechanisms that influence the success or failure of the safe medication administration education programme
- describe the impact on clinical practice which can be associated with the safe medication administration education programme
- describe how the mechanisms of application of the safe medication administration education programme and the characteristics of context combine to enable or constrain the education programme in achieving its desired outcomes

1.6.3 Outcomes

The identified outcomes for this study were to:

- inform the development and implementation of nursing continuing professional education programmes
- guide policy development in relation to continuing professional education for nursing at local and national level in Ireland
- generate theory on continuing professional development programmes for nursing, which can be further refined and tested at national and international level
- disseminate generated theories at a national and international level through publication and conference presentations

1.7 Thesis Overview

This thesis is divided into numerous parts to reflect the stages of my realist evaluation design. The introduction section is comprised of three chapters. Chapter 1 provides an introduction to international problem of medication safety within the patient safety agenda. It also introduces continuing professional education as a method of assisting in meeting the competency requirements of nurses in achievement of medication safety. It then goes on to introduce the study and provide the aims and objectives of the study. Chapter 2 defines the

concept of CPE and provides a narrative review of the empirical literature. It concludes by identifying the existing gaps in knowledge on the application of CPE into clinical practice. Chapter 3 provides an overview of evaluation methods and frameworks used when evaluating nurse education and introduce realist evaluation. The chapter then presents realist evaluation as an underpinning methodology which guides this research thesis and provides the design framework for the study. Following setting out the design, the study is made up of four stages.

Stage 1 is detailed in Chapter 4. Chapter 4 outlines the data collection, analysis and findings in order to develop the conjectured context, mechanism, outcome configuration (CMOc). Initial conjectured CMOcs are proposed at the end of this chapter.

Stage 2 is detailed in Chapter 5. Chapter 5 describes the refinement of the conjectured CMOcs. Refinement was undertaken through expert interviews, data analysis and further data comparison and analysis between findings from Stage 1 and this stage. On completion of Stage 2, three conjectured CMO configurations are put forward for testing in Stage 3.

Stage 3 is detailed in Chapter 6. Testing of the three conjectured CMOcs was conducted through case study. The case study contained three embedded units of analysis. Chapter 6 provides details in relation to observation and interview in the embedded case study sites.

Stage 4 of the study considers the findings from the previous Stage 3. Stage 4 consists of four chapters. Chapter 7 presents the findings related to the first conjectured CMOc. Chapter 8 presents the findings related to the second conjectured CMOc, and Chapter 9 presents the findings related to the third conjectured CMOc. Finally, Chapter 10 discusses the findings from Stage 3 in light of the broader empirical evidence. Chapter 10 concludes by putting forward the accepted programme theory and other findings from the study.

The thesis concludes with Chapter 11. Chapter 11 identifies the unique contribution to knowledge provided by this thesis and identifies the limitations of the study. It also provides a reflection on my thesis journey and identifies my research plans post completion.

Chapter 2- Literature Review of Continuing Professional Education

2.1 Introduction

This chapter begins by providing a definition of continuing professional education, and then briefly describes its history in the Irish context. The chapter then presents a narrative review of the literature on continuing professional education for nurses. A narrative review provides interpretation and critique with its key purpose to deepen understanding of the topic under review (Greenhalgh et al. 2018). During this narrative review, I aim to document my search strategy, and provide scholarly critique of the underpinning evidence and draw this evidence together.

2.2 Defining the Concept of Continuing Professional Education

There is a lack of consensus in the literature concerning the definition of the term continuing professional education (CPE) (Hegney et al. 2010; Gould et al. 2004). Continuing professional education and continuous professional development (CPD) are often used interchangeably in the nursing and healthcare literature, and include both formal and informal learning (Ryan 2003; Hegney et al. 2010; Vasli et al 2018). Not only are the terms ‘continuing professional education’, and ‘continuing professional development’ used interchangeably, their meaning also varies (Gijbels et al. 2010), and thus this requires clarification.

The definition offered by An Bord Altranais agus Cnáimhseachais na hÉireann (Nursing and Midwifery Board of Ireland (NMBI)) (2015) is the definition which is utilised for the purpose of this thesis. NMBI (2015, p. 15) defines continuing professional education as:

‘continuing education is a lifelong learning process which takes place after the completion of the pre-registration education and training, and is a vital component of CPD. It consists of planned learning experiences which are designed to augment the knowledge, skills and attitudes of registered nurses and registered midwives for the enhancement of nursing and midwifery practice, education, leadership and research.’

Continuing professional education is an integral component of Continuous Professional Development which encompasses more than structured learning activities. The NMBI definition of CPD is utilised in this thesis:

“CPD encompasses experiences, activities and processes that contribute towards the development of a nurse or midwife as a healthcare professional. CPD is, therefore, a lifelong process of both structured and informal learning.” (NMBI 2015, p. 19)

CPE and CPD gained prominence in nursing in the last decade, as healthcare organisations demanded an adaptable workforce. Continuing professional education as part of ongoing CPD is widely acknowledged as an important and effective part of maintaining on-going professional competency for qualified nursing staff (Atack and Luke 2008). A competent workforce is critical to the provision of quality nursing care (Pool et al. 2016). It 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 also 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, currently there is limited empirical evidence of the effectiveness of continuing professional education in both Ireland and internationally. There is also an absence of reported evaluations on the clinical and patient outcomes related to CPE (Hardwick and Jordon 2002; Clark et al. 2015).

Internationally, CPE contributes to act as evidence of competence for renewal of registration. In the United States of America, nurses are required to complete a certain number of hours of CPE to renew registration (Hegney et al. 2010). Since 2012, Australian nurses and midwives are now expected to maintain which is used as evidence of CPD, for yearly renewal of registration (Katsikitis et al. 2013). In the UK, nurses must have undertaken 35 hours of continuing professional development (CPD), relevant to their scope of practice as a nurse or midwife in the three year period since registration. Of those 35 hours of CPD, at least 20 hours must have included participatory learning (Nursing and Midwifery Council, 2017).

In Ireland, at the present time, An Bord Altranais agus Cnáimhseachais na hÉireann (Nursing and Midwifery Board of Ireland) does not require the provision of evidence of CPE for continuing registration, although it is considered essential in order for nurses to acquire new knowledge and competence that will enable them to practise (NMBI 2014). Currently, the responsibility for CPE as outlined in the Scope of Practice for Nursing and Midwifery Framework (NMBI 2015) lies with the nurse. New legislation to regulate the profession of

nursing in Ireland was enacted in November 2011. The Nursing and Midwives Act (2011) states that there is a duty for registered nurses to demonstrate competence to the satisfaction of the Regulatory Board. The Act provides that the Board may require a nurse or midwife, who fails to demonstrate competence, to attend a course of further education or training (Nurse and Midwives Act 2011). However, this legislation has yet to be operationalised by NMBI.

2.3 Historical Context of Continuing Professional Education in Ireland

To enable a better understanding of the structures for delivery of CPE for nurses, it is necessary to provide a background on nurse education in Ireland.

In the last twenty years, nurse education in Ireland has undergone significant change. Historically, nursing education was conducted by hospital training programmes under an apprenticeship model. Students had a dual role as learner and employee, and service demands superseded their educational needs (Carroll 1998). The traditional apprenticeship training had its curriculum based on behaviourism. In reply to much criticism of the apprenticeship based model of undergraduate and post graduate nurse education, these programmes moved to Higher Education Institutes (HEIs). From 1994 to 1998, a transfer of all nurse preparation programmes into HEIs took place, commencing with a three year diploma level course (Begley 2008). The Report of the Commission of Nursing (Carroll 1998) marked a significant change in the position of nursing education and the future of nursing, whereby on its recommendations, undergraduate nurse education commenced at degree level in 2002. Post-graduate education programmes are delivered at the National Framework of Qualifications (NFQ) Level 9, and aim to further develop these reflective and critical abilities within specialist areas. NFQ Level 9 is equivalent to Level 7 in the framework for higher education in England, Wales and Northern Ireland (Quality Assurance Agency for Higher Education 2014).

The radical transformation in nurse education means that graduate and post graduate academic awards are now provided by the HEIs. Education for continuing professional development is delivered in the Centres of Nurse and Midwifery Education and the Nursing Practice Development Departments, which are attached to the acute teaching hospitals. The Centres of Nurse and Midwifery Education and Nursing Practice Development work closely

with the hospital service to meet the needs for education and training, and remain responsible for continuing professional education and development.

2.4 Scope of the Literature Review

For this study, the review is focused on examining continuing professional education focusing on outcomes, and how outcomes are achieved. A clear review question was developed in order to guide me in conducting the review (Stern et al. 2014).

The question for the review was: *How are knowledge and skills which are gained through continuing professional education programme transferred to clinical practice?*

An initial scoping search and review was completed prior to ethical application and repeated prior to commencement of Stage 1 of this study. The original searches and reviews were of an ad hoc nature, and did not utilise a defined structured search strategy. The review contained in this chapter was completed in late spring 2018 and updated in June 2018.

2.5 Search Strategy

The purpose of a search strategy is to translate the research question into a format that the search engine can understand (Kable et al. 2012). While this literature review is a narrative review, the search strategy which was conducted held some systematic properties. This section will clearly articulate the search strategy utilised. From an initial scoping review, there was a large amount of literature found on continuing professional education and development, and thus in order to focus of the review, a precise inclusion criteria was determined (Stern et al. 2014).

In this review, the structure for documenting the search strategy is the 12 step systematic approach described by Kable et al. (2012). The SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) mnemonic (Cooke et al. 2012) was utilised in the development of the search strategy. SPIDER has been found to be suitable for searching for qualitative and mixed methods research (Cooke et al. 2012). This search strategy entailed searching for research based papers which addressed the transfer of CPE into practice.

The bibliographic databases, CINAHL Plus (Cumulated Index of Nursing and Allied Health Literature), Pubmed and PsycINFO, were all systematically searched based on the search terms outline in Table 2.1. Furthermore, the reference lists in all identified studies were inspected to identify further relevant studies. The use of Boolean operators (AND/OR)

narrowed down the parameters of the search (Kable et al. 2012). Synonyms and alternative spellings for terms were explored to improve the scope of the search.

Search Terms	and/or
Continuous professional development	Transfer Outcome Change
Continuing professional development	Transfer Outcome Change
CPD	Transfer Outcome Change
Continuous professional education	Transfer Outcome Change
Continuing professional education	Transfer Outcome Change
CPE	Transfer Outcome Change

Table 2.1 Search terms

Retrieved articles were assessed for relevance based on the inclusion and exclusion criteria (Kable et al. 2012). The review process of potential articles for inclusion was undertaken in several stages. The search terms used were quite broad and the terms such as the abbreviation, CPE, can be used in multiple circumstances. Thus, there were a large number of initial hits on all three databases searched. First, all potential articles were reviewed based on their title. Then all duplicates were removed across all databases. Initial searching included all health professionals. This produced an excessive number of articles and following review of a number of these, the limitations of their applicability to nursing was reviewed and they were then excluded from further review. The next stage of screening involved the reviewing of abstracts. The search process was recorded throughout in order to ensure that replication and omission of references was avoided (Kable et al. 2012).

	Inclusion Criteria	Exclusion
Sample	Healthcare professionals, *At the later stage of abstract review only nursing and studies including nursing were included	Non healthcare professions for example teachers
Phenomenon of interest	Continuing professional education/development which involves a structured education programme	Major award made by a third level institution
Design	All design types, quantitative and qualitative	
Evaluation	No quality review due to nature of evaluations reported	
Research type	Primary research studies, systematic reviews	Literature reviews Discussion papers/ editorials

Table 2.2 Inclusion and exclusion criteria

Within the database search, only English language papers were included as no translation service was available and the time range was selected from 1998 to 2018. The 20 year period reflected the time since the publication of the Commission on Nursing (Carroll 1998), which is pivotal in the design and delivery of nurse education in Ireland.

For the final step of article selection, I proposed to use the JBI Critical Appraisal checklist. The intended purpose of the quality appraisal was to exclude papers that report poorly designed/executed/ inadequately described studies, where results are biased, or affected by study limitations (Kable et al. 2012). However, when examining retrieved articles using the Critical Appraisal checklist, it was found that numerous papers presented evaluations which would not meet the appraisal requirements. I felt that it was important that these should not be excluded from the review, as the purpose of the review is to establish the gap that currently exists and to determine the purpose of my study which is presented in the following chapters. A total of 41 papers are included in this narrative review. In one case the same study was presented in four different publications (Tame 2009; Tame 2011; Tame 2012 and Tame 2013). Just one of these studies (Tame 2009) was utilised in the review. Records

from the search can be seen in Figure 2.1, displayed in a PRISMA adapted from Moher et al. (2009). Papers included come from an international perspective, with papers from countries such as: Lithuania, Finland, the Netherlands, Canada, Australia, United States of America, Jordan, the UK and a single paper from Ireland. Publications have been sourced from across highly rated journals, such as the Journal of Advanced Nursing and Nurse Education Today, to the topic specialised journals, for example the Journal of the Association of Nurses in AIDS Care, Intensive Critical Care Nursing, Oncology Nursing Forum, Community Wound Care and Accident and Emergency Nursing.

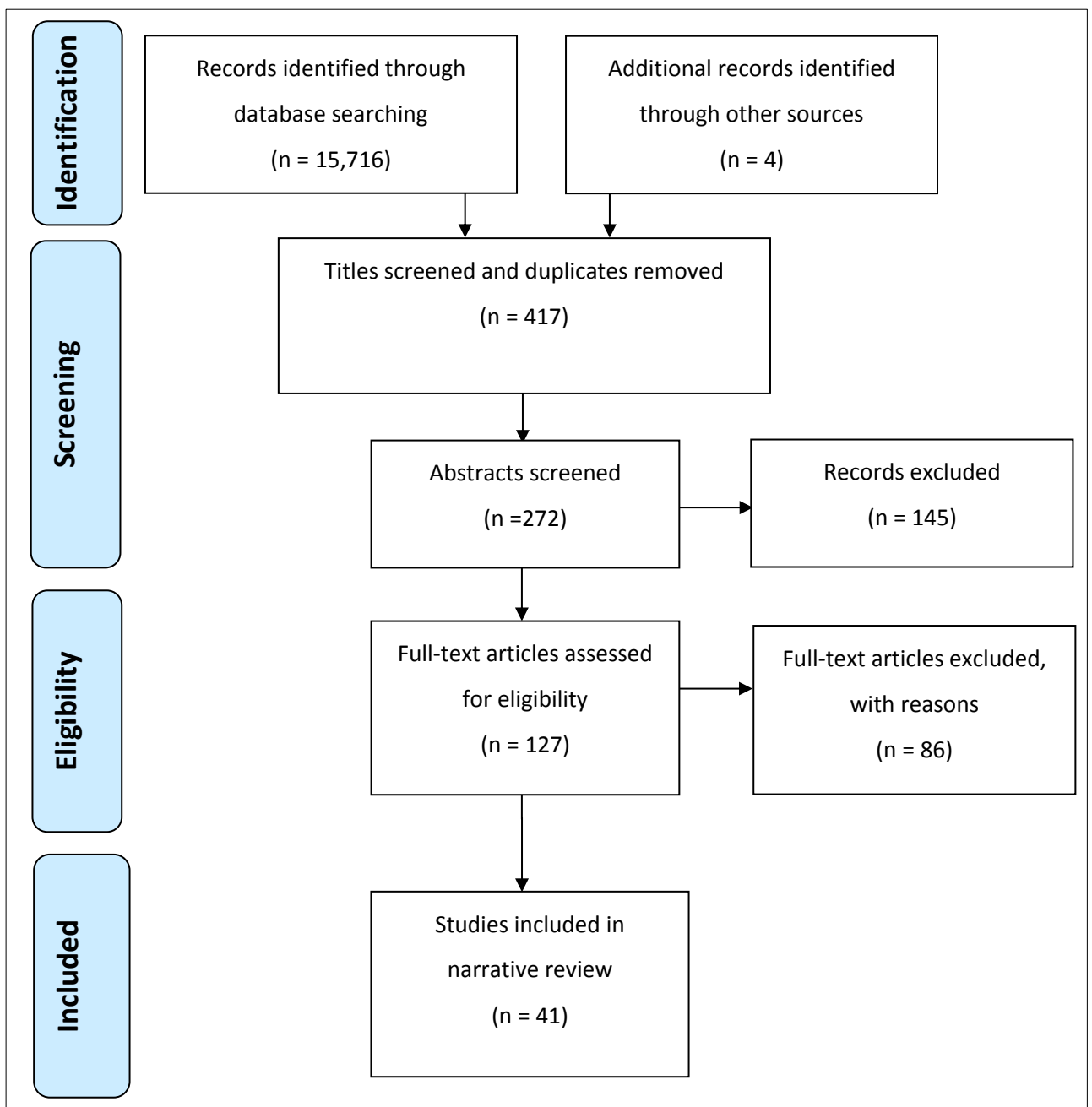


Figure 2. 1 PRISMA adapted from Moher et al. (2009)

2.6 Organisation of this Review

The original intention for this review was to undertake a realist review of the literature. However, when I commenced the critical appraisal of the literature it became apparent that I would be unable to perform a realist review as the studies included provided little if any details in relation to contextual or other external factors which may influence the transfer of learning. Thus a comprehensive picture of the best available published evidence is presented in this narrative literature review utilising an extended version of the Barr et al. (1999) evaluative framework.

This evaluative framework was originally put forward by Kirkpatrick (1959) and later extended by Barr et al. (1999) and focuses on the evaluation of outcomes which can be related to education. In this literature review the framework by Barr et al. (1999) has provided a useful structure to present and critique the literature. However, the framework suggests a simple, cause and effect relationship which does not take account of the multitude of variables such as the individual, team, organisational or system factors that influence the process of translating knowledge into healthcare practice (Lee 2011; Ilott et al. 2014). Thus in order to provide a comprehensive review and critique of the existing research evidence and to address the review question, it was necessary to include additional components on the factors which effect transfer of CPE. Therefore, this literature review extends the framework to include the examination of the barriers and facilitators of transfer of learning from CPE into practice. The utilisation of the extended framework acknowledges that transfer of learning is not a simple process and multiple factors can affect it and act as either a barrier or a facilitator. The extended framework is illustrated in Figure 2.2.



Figure 2.2 Extension of the Barr et al. (1999) evaluation framework

Where studies evaluated more than one level of this framework, the highest level evaluated is reported. Table 2.3 identifies the publications which are reported in this narrative review and the associated level.

Evaluation Framework	Description of level	Publications included
Level 1	Learner's reactions	None reported
Level 2 a	Modification to attitudes and perceptions	Yoshioka et al. (2014) Lin et al. (2014) Philp et al. (2017) Smith et al. (2017)
Level 2 b	Acquisition of knowledge and skills	Fleet et al. (2011) Smith and Topping (2001) Mockiene et al. (2011)

Evaluation Framework	Description of level	Publications included
Level 2 b (contd)		<p>Yacoub et al. (2015)</p> <p>Wetta-Hall et al. (2007)</p> <p>Tippett (2004)</p> <p>Burhenn et al. (2016)</p> <p>Schubert (2012)</p>
Level 3	<p>Behavioural change</p> <p>Intentions to change</p> <p>Self -reported change</p> <p>Actual change</p>	<p>Wellings et al. 2017</p> <p>Lahti et al. (2014)</p> <p>Moore and Allan (2012)</p> <p>Steginga et al. (2005)</p> <p>Ostrom and van Mierlo (2008)</p> <p>Bull et al. (2017)</p> <p>Tarnow et al.(2013)</p> <p>Huba et al. (2000)</p> <p>Cohen et al. (2016)</p> <p>Mann et al. (2009)</p> <p>Mitchell (2017)</p> <p>Pullen (2006)</p> <p>Tennant and Field (2004)</p> <p>Ryder et al. (2018)</p> <p>Ilott et al. (2014)</p> <p>Dennison (2007)</p> <p>Hickin et al. (2017)</p> <p>Lyons and Kasker (2012)</p>

Barr et al. (1999) Evaluation Level's	Description of level	Publications included
Level 4 a	Change in Organisation	Liaw et al. (2016)
Level 4 b	Benefits to patients, families and communities	Stolee et al 2009 Steven et al. (2018) Bernaix et al. (2008)
Extended framework	Factors affecting transfer to practice	Ellis and Nolan (2005) Hughes (2005) Tame (2009) Gould et al. 2007 Nayeri and Khosravi (2013) Clark et al. (2015) Lee (2011)

Table 2.3 Studies included in review according to the extended evaluation framework

2.7 Level 2a- Modification of Attitudes and Perceptions

All the studies which reported learners experience at Level 1, also reported findings at a higher level of the Barr et al. (1999) evaluation framework. This section critically reviews the literature available that reports on findings equivalent to Level 2a modification of attitudes and perceptions following education. In this section, self-reported confidence is utilised as a measure of perception.

2.7.1 Attitudes

In a before and after trial (non-randomised) in Japan, Yoshioka et al. (2014) evaluated an end-of-life nursing care continuing education programme for general ward nurses. The objective of this study was to compare the evaluation indicators before and after the intervention in order to assess its educational effectiveness. The education was delivered using mixed methods with lecture, discussion and simulated case scenarios providing application of new theory to practice. The evaluation was completed before, immediately after and two months after the education intervention. Knowledge about end-of-life nursing care significantly increased immediately after the end of the education programme, and this

level was maintained for two months after the programme. Similar results were obtained for nurses' self-reported confidence concerning end-of-life nursing care. Attitudes toward end-of-life nursing care were significantly improved immediately after the programme but the positive attitude toward caring for dying persons decreased to pre-intervention levels by two months after the end of the programme. This was a small study with just twenty five nurses participating.

A study in Taiwan by Lin et al. (2014), explored the effects of an education programme based on the theory of planned behaviour on Intensive Care Unit (ICU) nurses' attitudes and behavioural intentions to advocate for deceased organ donation. It was an experimental study with randomisation of a control group. Participants, who came from across three ICUs in three different medical centres, were randomly allocated into the experimental group (n=61) or the control group (n=60). The control group were given an information brochure about organ donation and the experimental group received the brochure and an education programme. The educational programme was multifaceted with didactic lectures, workshops and the use of videos. Before the education programme, there were no differences in attitude and behavioural intentions of organ advocacy between the control and experimental groups. After the education programme, the nurses in the experimental group significantly changed their attitude and behavioural intentions on organ advocacy, both immediately and two months later. By utilising multivariate analysis, the authors found that the most important factor influencing attitude and behavioural intention was the experience of receiving the educational programme. The authors concluded that the education programme was the only predicting factor to enhance the attitude and behavioural intentions of organ advocacy.

Neither of these studies provided a rationale as to why they were measuring attitudes. A positive attitude in one's ability to apply new knowledge and skills into practice is a significant indicator for transfer of learning. Attitude is one of the three constructs of Ajzens' (1991) theory of planned behaviour. Godin et al. (2008) identified that the theory of planned behaviour is very useful to explain healthcare professional's behaviours and intentions. An identified function of CPE is the development of nurses attitudes, and this is acknowledged in the NMBI (2015, p 19) definition of CPE which *'consists of planned learning experiences which are designed to augment the knowledge, skills and attitudes of registered nurses and registered midwives for the enhancement of nursing and midwifery practice, education,*

leadership and research'. While positive attitudes are an indicator for change of practice, they must be seen as just an indicator and not as a guarantee for transfer into practice.

2.7.2 Confidence

Confidence in one's own knowledge and ability has been identified as a key facilitator in the transfer of new knowledge into practice (Nayeri and Khosravi 2013). Like attitude, confidence is a perception construct, which is argued assists in uptake of knowledge and skills (Philp et al. 2017). Bull et al. (2017) also identify that confidence and intentions are key psychological determinants of behaviour.

Following a tertiary-based education programme for gynaecological oncology, Philp et al. (2017) reported on their evaluation of content and nurse confidence. The evaluation was designed as pre-post education questionnaire. Participants indicated improved confidence immediately after participating in the course, whilst confidence subsequently declined at three months and stabilised up to 12 months post-course, it still remained significantly higher than before the course. There was a large attrition rate during the study period, 62 RN's completed the first evaluation, with only 24 RN's completing the final evaluation at 12 months. No specific details of the education intervention were provided other than it was of one week duration.

Smith et al. (2017) evaluated the success of a multimodal educational strategy (i.e. online learning module coupled with standardised patient simulation experience) on critical care nurses' knowledge and confidence to assess and manage delirium using a specified ICU delirium assessment tool. A convenience sample of 34 critical care nurses working in an adult medical-surgical ICU was recruited from a large community medical centre. The study consisted of a pre-test, the online learning module, and a post-test. A second post-test was completed six weeks after the online learning module to evaluate the retention of knowledge. A simulation experience was also provided to supplement the online learning. Although there was no significant change from pre to post-test scores on the Knowledge of Delirium tool, the Educational Methodology Satisfaction tool revealed that the simulation helped participants feel educated about delirium. Nurses in this study reported significantly increased confidence levels. The majority of nurses felt confident in their correct use of the ICU assessment tool post-simulation, reinforcing that simulation in nursing education is an

effective teaching strategy. The simulation provided nurses with the ability to practice assessment skills using the instrument, thereby acquiring expertise and confidence.

These studies presented in this section describe changes to attitudes, perceptions and confidence following CPE. There appears to be an assumption that positive attitudes and confidence will lead to improved patient care (Tame 2009; Nolan et al 2000). However, this may be too simplistic an assumption as many variables exist which prevent knowledge and skills being implemented into practice (Cervero 1985; Tame 2009).

2.8 Level 2b - Acquisition of Knowledge and Skills

A vast amount of the publications included in this review had knowledge gained from continuing professional education as an outcome of their study. This extended section will present these studies.

The attainment of knowledge for nurses has been reported in many evaluations of inter-professional education interventions. Fleet et al. (2011) reported their evaluation of an online CPD course for health professionals on asthma and their findings from a pre and post knowledge assessment. The e-learning course was self-directed based around the principles of case learning, and had received accreditation from Royal College of Physicians and Surgeons of Canada. A total of 125 course participants completed both pre- and post-knowledge assessments. Although, statistically significant increases were found in post intervention knowledge scores for the whole group, no statistical significance was achieved for registered nurses. Limited details in relation to the e-learning education course were provided in this paper and thus, there is a failing in establishing any factors which may have influenced nurse's poor knowledge attainment.

Smith and Topping (2001) reported nurse participants self-rated knowledge (n=14) that was developed over the duration of a children's neuro-science course. The course ran over six months and involved 12 contact days. The greatest improvement in self-reported knowledge scores was between the evaluations completed on the induction day prior to the taught element of the course and the evaluation completed on the final taught day. This was a once off education offering with the evaluation taking place with a small sample size of just fourteen. The study was of self-reported knowledge and not verified tested knowledge gain. There was no evaluation of self-reported knowledge gain at other times following the course, and thus no evidence was provided of retention of knowledge over time.

One of two randomised control trials (RCT) included in this review examined the impact of an education intervention on the acquisition of HIV-related knowledge and attitudes in nurses in Lithuania. In this RCT, Mockiene et al. (2011) established three groups of nurses from three separate hospitals, which formed the two intervention groups and the control group. Each group consisted of 80 registered nurses. The education intervention process was implemented in two hospitals using different interventions: a two-day workshop (13 hours) and distribution of written material in one hospital, and distribution of only written materials in the other hospital. Another hospital was chosen for control purposes. Teaching elements included lectures, group discussions, conversations with people living with HIV, a film about HIV, lecture hand-outs and distribution of written materials. The intervention provided to the second intervention group consisted of the same academic journal articles that were provided to the first intervention group. Additionally, lecture hand-outs from the first intervention group were provided to intervention group two.

Pre-intervention and post-intervention knowledge and attitude scores were taken and Mockiene et al. (2011) found that after the intervention, there was a statistically significant difference in nurses' knowledge levels between the groups: the knowledge level of first intervention group nurses was higher than that in the second group and in the control group and likewise, the knowledge level in the second intervention group was higher than that in the control group. There were no statistically significant improvements in the knowledge level and attitudes in the second intervention group because of the intervention. The positive attitude changes, post interventions, in the first and second intervention groups were only minor and not of statistical significance. This RCT showed that it was not merely receiving information which improved knowledge, but the methods and ways in which this information is delivered hold significance. Knowledge gain was evident but without a significant change to attitude it is uncertain if this new knowledge will be transferred into practice and how long the new knowledge will be maintained if it is not used. The authors described this study as an RCT, however, nurses were placed into groups depending on their location of work, and this does not constitute randomisation. Also, it is difficult to determine if, or how, much control the authors were able to exert in this study. The three groups were based in different hospitals, but no further information has been provided in relation to the participants or their exposure, or perhaps lack of exposure, to patients with HIV and/or AIDS.

This may be a significant contributing to attitudes towards HIV/AIDS and also knowledge acquisition.

A quasi-experimental, one-group, pre-test/post-test design by Yacoub et al. (2015) examined outcomes of a diabetes education programme for registered nurses (n=129) caring for individuals with diabetes. The post-test questionnaire was administered immediately following the education session to examine knowledge in the participants. The education session was one day and was presented via PowerPoint™. No further details of teaching methods were provided. The education programme was found to have a positive effect on nurses' actual and perceived diabetes knowledge. Knowledge was tested immediately after the intervention and thus, we are unable to determine if this new knowledge was retained over time. It appears from the publication that education was provided utilising a didactic format, and no details of the underpinning pedagogical education principles were provided. The didactic lecture format as a means for knowledge retention is not supported in the literature. Evidence suggests that passive lectures provide the lowest knowledge retention rate of any method of learning and that educators need to move towards student-centred learning (DiPiro 2009).

An interdisciplinary study on the outcomes of a one day conference as a CPE intervention for the management of burns was reported by Wetta-Hall et al. (2007). While they did not report on nursing independently, they did find a significant improvement in self-rated ability, and confidence and a positive improvement in post-test knowledge in healthcare professionals. This study involved a large sample size of 383 participants. The educational style or methods of the conference delivery were not detailed, so this cannot be taken into consideration when examining the positive results. Similar to Yacoub et al. (2015), knowledge was tested immediately following the education, and no measures of retention of knowledge over time were taken.

A five day advanced trauma nursing course was developed and delivered by Tippet (2004). In order to determine its effectiveness, knowledge was assessed at four time-points during the study; a) before the candidates received their information manuals b) at the commencement of the course c) on completion of the second course day and d) three months after the completion of the course. Statistical analysis of the small sample of 14 demonstrated a highly significant change in the knowledge levels of participants following

attendance on the course. However, three months after the course, participants' knowledge levels were not statistically significantly different from pre-course levels, which suggested that retention of knowledge over time was poor. This study did not report on participants had exposure to advanced trauma following the course and they also provided no details of the advanced trauma course.

Utilising a survey design, Burhenn et al. (2016) also demonstrated a statistically significant increases in nurses' knowledge of geriatric care following the implementation of an educational programme targeted at oncology nurses. Nevertheless, nurses' attitudes remained the same pre- versus post-education. Knowledge of geriatric conditions was shown to be retained over time, and improved significantly from year 1 to year 2 in each area studied. However, if attitudes are unchanged it would seem unlikely that knowledge would be applied and thus, behaviour change would not occur as a result of the education intervention.

Schubert (2012) examined the effect of simulation as a CPE strategy on nursing knowledge and critical thinking in failure to rescue with 58 participants. No details of the simulation were provided. A knowledge test on failure to rescue events was developed to measure knowledge at all cognitive levels. It was administered before, immediately after and then two weeks after the simulation. Mean scores on the tools that measured nursing knowledge and critical thinking increased as a result of the failure to rescue simulation. Knowledge growth after the simulation showed sustainability over time. However, there was a low return rate (21%) for the two week post knowledge assessment. Again, this study just reports knowledge attainment and not application of the new knowledge to practice.

In the studies presented in this section, I have not been able to directly compare and contrast findings as few studies reported details of the education intervention, and in those which did so, there are multiple variations in the duration and methods of delivery. None of the studies have provided evidence of the learning outcomes for the intervention or the academic level to which the education intervention has been prepared. Also, many of the studies have provided very limited details of the educational methods and underlying pedagogical philosophies of the education. It must be remembered that the most effective delivery method depends on the intended outcome of the education programme, and that *'one size does not fit all'* (Gould et al. 2007, p 604).

While many of the studies did report positive knowledge gains immediately after the education was completed, this does not demonstrate value or long term benefit from the education. The studies which do report knowledge retained over time have not examined the application of this knowledge into clinical practice. Many education programmes as reviewed in this section set out to improve clinical performance; however, they have implicitly assumed that performance is mainly shaped by knowledge, which is actually only one small part of the personal dimension, which in turn is only one part of the performance equation (Roberston et al. 2003). Thus, as continuing professional education is aimed at ensuring the maintenance and improvement of the competencies already gained (Nsemo et al. 2013), then surely a report of knowledge gain is not an adequate measure of effectiveness of CPE.

2.9 Level 3- Behavioural Change

While also improving knowledge and skills (which has been reported in the previous section), it is essential that this new knowledge and skills are transferred to patient care. Transfer of learning is the major goal of professional education (Lauder et al. 1999; Draper and Clark 2007) and as the purpose of CPE is to maintain or enhance competence, nurses are expected to integrate what they learn into clinical practice (Nayeri and Khasiauvi 2013). Knowledge transfer is defined as the degree to which learners apply the knowledge, skills and attitudes gained in a training context into practice (Vasli et al. 2018). However, knowledge transfer is a complex, non-linear process which involves multiple different factors and interactions (Rycroft-Malone et al. 2009). For the purpose of this review, publications which reported on transfer of new knowledge and skills into clinical practice are presented in the following categories 1) intentions to change 2) self-reported changes and 3) actual practice changes supported through data collection specific to the topic under investigation.

2.9.1 Intentions to change

Many studies have reported positive intentions to change as a measure of CPE effectiveness. Intention is identified as a predictor of change behaviour (Wellings et al. 2017) but not of change behaviour itself. In this review, I have placed intentions to change on Level 3- Behaviour Change of the Barr et al. (1999) evaluation framework. Nonetheless, as is pointed out by Wellings et al. (2017, p. 281), statements of intention can be a reliable “*but not a perfect*” link to behaviour in the real world, and therefore could offer a close measure for behaviour change.

Utilising Kirkpatrick's evaluation model as a framework, Wellings et al. (2017) set out to evaluate learner's intentions to change their practice resulting from their learning and their perceived barriers to implementing practice changes. Results revealed the multiple, interconnected challenges involved in translating new learning into practice. Data was obtained from 61 (n=1003) continuing education seminars that were conducted in Australia. No further details of the seminars were provided such as topics, delivery methods, duration etc. Data was reported quantitatively, with qualitative analysis performed on open ended questions. The most common changes that programme participants indicated they would make were linked to improved patient care. The concepts assessment, outcomes, and understanding were also closely linked to this theme suggesting that the educational seminars had a perceived positive benefit to patients.

A qualitative study by Lahti et al. (2014) described the transfer of knowledge gained from an e-learning course to daily clinical practice. The e-learning course focused on ethically appropriate and therapeutically effective daily practice to enable nurses to manage distressed and disturbed patients in psychiatric hospitals and inpatient units. A sample of 35 nurses completed the questionnaire and also completed reflective accounts on which this publication was based. Respondents reported that knowledge gained during the course could be transferred to daily practice and also that the course gave useful ideas to develop their daily work. This study also reported nurse's perceptions of how the learning could be transferred into practice but did not report how they actually did transfer it into practice.

A one day conference which focused on changing the current practice in the administration of intramuscular (IM) vaccine injection was evaluated by Moores and Allan (2012). Through the use of pre and post conference questionnaires, they set out to determine whether the education was effective in eliciting a change in knowledge and behaviour among the 140 respondents. The pre and post questionnaire illustrated an improvement in knowledge in relation to IM injection technique for vaccines and furthermore, some respondents indicated that they would change their practice. Self-reported change of practice statements were qualitative statements and were not quantified.

2.9.2 Self-reported changes to practice

An Australian study by Steginga et al. (2005), evaluated the impact of an intensive nursing education course on nurses' knowledge, confidence, attitudes and perceived skills in the care of patients with cancer. The intervention group completed one of two cancer related education programmes. The multi-faceted cancer education programmes were delivered via direct contact hours. The research design was a quasi-experimental, longitudinal, pre-test/post-test design, with a follow-up assessment six weeks after completion of the education course. Nurses in the intervention group rated the education course as highly effective in improving their knowledge about cancer and cancer support services, their confidence in their ability to work effectively with patients with cancer, and their ability to network effectively with other nurses working in cancer care. This was a self-reported increase in confidence and gain of knowledge. This study also examined the application of new knowledge to practice. Upon completion of the course, participants reported being more willing to discuss psychosocial concerns with patients and family members. Some participants reported that their actual communication with physicians had improved since attending the course, and others already had provided in-service education to other staff members to share their new knowledge. The sample size was small with just 53 participants completing the study. Participants took one of two programmes, but the results were not reported based on the programme which was undertaken. Therefore, from the findings one is unable to determine which factors of the CPE programme may have led to the self-reported changes in practice.

Oostrom and van Mierlo (2008) reported an evaluation of an education programme for homecare workers in the Netherlands on aggression management to help them to cope with workplace violence. The training programme was evidence based and delivered via direct contact, which involved three, four-hour sessions, two to three weeks apart. Data was collected from 42 participants via a questionnaire administered at three time-points a) before the education b) immediately after and c) five weeks after the education intervention. Results from the study showed a considerable and significant improvement on the experimental variables of insight into assertiveness, aggression and the ability to cope with adverse working situations. These improvements persisted after the training, indicating that the training resulted in enduring changes in knowledge and behaviour. Participants' scores on ability to cope showed a further increase after the training. After the training

programme, participants may have had the opportunity to apply the knowledge and behaviour they learned in the training in their everyday work situation. These findings are based on self-reported measures in participants' beliefs in their ability to cope and may not reflect the true reality.

Qualitative data from a study by Bull et al. (2017) on medication safety training in Mozambique, described how participants reported that the training on medication safety was acceptable, enjoyable and led to practice changes, through improved capability, opportunity and motivation. The brief description of the intervention included two days of direct contact which included PowerPoint presentations, action planning and feedback. Nearly all participants reported that the drug calculation training had already impacted positively on their medication safety practices (behaviours), including calculating drug doses with more precision, using a calculator and informing colleagues on wards of information gained from the training. Similar to other evaluations reported here there was a small sample size of just 36 participants and it was a self-reported behavioural change. With self-reports there is a potential for social desirability bias (Bull et al. 2017). Interestingly in this study, while participants self-reported practice changes, knowledge was found to be poor in some aspects.

Tarnow et al. (2013) provided a day and a half CPE programme on mindfulness which was attended by 157 people (90 nurses, 7 physicians, and 60 participants from other disciplines). The goal was to teach mindfulness practices to enable attendees to anticipate problems and intervene quickly with small problems and near misses. The delivery methods included storytelling and case studies to actively engage small groups in creative problem solving and specific communication tools useful in the practice setting. Participants developed action plans to implement at least one mindfulness practice in their work settings. Most participants reported that they were very successful or somewhat successful in implementing their action plan. Bull et al. (2017) also utilised action plans in their course delivery and likewise identified self-reported behavioural change.

An evaluation of a HIV/AIDS education programme on providers practise and patient care was reported by Huba et al. (2000). This study reports the findings from telephone interviews with healthcare professionals (n=218) approximately eight months after they had taken part in the training. Huba et al (2000) found increased knowledge at the patient and

system level, and also respondents gave concrete and specific examples of how the training helped them change their practice, which they attributed to what they learned or clarified during training. They also reported that learning from the course enabled them to provide more compassionate care and more appropriate care because of a change of attitude. They also reported that it increased their awareness, and nurses reported how it allowed for changing policy and procedures at the system level for caring for patients with HIV.

Following an inter-professional education (IPE) programme in the United States on Parkinson's disease, Cohen et al. (2016) examined knowledge, attitude and practice changes before and after the training course. Trainee results were compared to results of a control group. A very large sample of 1,468 across a 10 year period from 2003-2013 took part in the programme. Cohen et al. (2016) reported that there was a statistically significant post-test improvement in all major outcomes. For the outcome, 'self-perceived knowledge', there was some decline found at six months post training but significant improvements remained. Qualitative analyses also confirmed post-training practice changes. Similar to other studies reported in this section these were self-reported practice changes. Retention of knowledge or practice changes specific to the nursing discipline was not reported. This finding of retention of knowledge over time is in contrary to Tippet (2004), who found that knowledge was not retained over time. The Cohen et al. (2016) study was of a much larger scale, with a sample size of 1,468 compared to 14 in the Tippet (2004) study. Cohen et al. (2016) have provided limited details as to the education intervention other than it were evidence based, involved multi-day training and was inter-professional. The Tippet (2004) study was a five day study with practical hands-on case based skills. What is most significant in Cohen et al. (2016) is that at six months post education, 97% of respondents reported that they had made practice changes.

Another inter-professional CPE intervention was evaluated by Mann et al. (2009), who explored knowledge translation following a CPE course delivered by Cancer Care Nova Scotia. In self-report questionnaires (n=336), high percentages of participants reported changes in both clinical practice and inter-professional interactions three months after the sessions. Participants identified time and work-load as major barriers to change as well as lack of micro- and macro-system level support. The most common reported enabler of change was having attended the educational session. Participants agreed that the modules led to the acquisition and/or enhancement of knowledge and skills. Overall, participants

reported more changes at an individual level (e.g. 'questioning patients more thoroughly') than on a system-wide level (e.g. 'Development of paediatric support team').

Mitchell (2017) conducted a before and after evaluation to assess the value of an accredited CPD module on practice in the assessment and management of leg ulcers. This module was accredited at a London university. It was a small evaluation (n=8) with all the nurses interviewed commenting that the module had changed and influenced their practice in some way and provided some examples of changes to their practice, including improved confidence with certain skills. Mitchell (2017) described this work as an evaluation audit and thus did not claim it to be empirical research.

An evaluation of 42 courses with over 300 participants offered by a large Australian CPE provider was completed by Pullen (2006). The effectiveness of the pedagogical and instructional design (e-pedagogy) of online continuing professional education was examined. The questionnaires investigated knowledge gained, and self-reported behavioural change. The majority agreed that knowledge of the course material increased, and that material was useful and applicable to their professional practice. It was also found that courses, which incorporated a clinical or diagnostic tool as a part of the course material, were found to increase practice behaviour change more so than those courses that did not use such tools.

2.9.3 Actual practice change

The studies reported in the previous section all involved self-reported changes to behaviour. Research suggests that healthcare professionals tend to over-estimate their perceived capability when performance is independently measured (Davis et al. 2006). This section reviews a number of studies which reported findings of actual changes to practice. These were reported by stakeholders or observed or verified by the research team.

In a before and after quasi-experimental study design, Tennant and Field (2004) compared the practice of nurses working in Intensive Care Units. An intervention and comparison group were established. There were an equal number of five in each group. The first group undertook the ICU course while the second group, who also worked in the same ICU, did not undertake the course. This publication reports on the evaluation of an education intervention but has failed to provide details of the intervention such as educational pedagogy, the duration or the delivery methods. A comparison of the pre- and post-course self-assessed knowledge scores across both groups suggest that all the participants

developed in terms of their practice in the ICU. Managers also scored the participants in relation to their practice. The intervention group finished with a higher overall score, whilst the greatest change was noted in the control group who did not take the course. This finding suggests that nurses learn and develop expertise regardless of taking a CPE course. The authors did acknowledge the study limitations and identified the study as a pilot study. No details in relation to the duration, level of the course or teaching methodologies were provided. It was also of poor methodological quality.

Ryder et al. (2018), in an evaluation of specialist CPD courses, gathered responses from course participants and key course stakeholders (n=24). Respondents reported that course participants had attained new specialist knowledge and skills for their relevant area. Respondents also reported that course participants incorporated new skills into practice, and an increase in knowledge, competency and confidence in practice was reported across all courses. While this study utilises stakeholders to report changes in practice, it fails to attribute the reports to course participants or stakeholders.

In a single group mixed method, pre and post-test study, Ilott et al. (2014) evaluated the learning effect of workplace-based, blended e-learning on dysphagia for stroke rehabilitation nurses. The sessions were facilitated by an experienced nurse lecturer and comprised a needs analysis, e-learning programmes, practical skills about modifying fluids, and action planning to transfer learning into practice. Ward manager participation was ensured by having the manager co-sign the attendance certificate confirming the expectation that the learning would be put into practice. The sample studied consisted of 22 nurses and 10 healthcare assistants. Data was collected via questionnaires, administered at four time points, and via direct observation (34 hours). The observations provided an insight into the practice context, and the questionnaires were used to investigate the learning effect. All participants achieved a nationally recognised level of competence. The learning effect was evident on the post and follow-up knowledge measures, with some items of knowledge and attitude achieving significance. There were also self-reported changes in practice. While some changes in practice were observed or reported during the post-intervention observations, the authors were unable to establish the effect of the education on clinical practice.

Similarly, Dennison (2007) failed to observe a change in practice following a medication safety education programme which aimed to reduce the harm caused to patients by medication errors; specifically errors related to the intravenous infusion of high-alert medications. Participants were required to complete two 30-minute computer modules focusing on medication safety. Changes in the climate of safety, nurses' knowledge and behaviour, the number of infusion pump alerts and reported medication errors were evaluated both before and after completion of the education programme. A statistically significant change in knowledge regarding medication errors occurred, but there was no change in the climate of safety scores, the use of behaviours advocated in the medication safety education programme to improve medication infusion safety, the number of infusion pump alerts or the number of reported errors. The author concluded that strong support and follow up is required for participants in order to foster changes in medication safety behaviour.

A change in practice was verified by Hickin et al. (2017) when evaluating an education intervention. They examined the impact of education on nurses' knowledge of delirium, knowledge and perception of a validated screening tool and use of the delirium screening in a 16 bedded ICU in Canada. Nursing knowledge and perception were measured at baseline, 3-month and 18-month periods. Delirium screening was then assessed over 24-months. The education intervention consisted of PowerPoint presentations incorporating information on delirium, patient testimonial, the delirium screening tool and procedures for using the screening tool. Similar information was also emailed to participants and posted on a SharePoint site. To reinforce the teachings, unit level and individualised bedside follow up was provided. The formal educational intervention phase lasted approximately one month and informal education and reminders were maintained for the duration of the study period. They found a significant difference in knowledge scores at three months post intervention and knowledge scores at the 18-month follow-up were significantly lower than the three month period and not statistically different from those at baseline. While short-term impacts of education were positive, the level of knowledge over the longer term, the eighteen month period, was not demonstrated. Hickin et al. (2017) did, however, find that the use of the delirium screen tools did increase with a significant difference in use post intervention. The time of post intervention was not reported and this may have to do with the initial gain in knowledge.

A CPE one day course on intravenous catheter insertion, maintenance and infection prevention for 33 nurses was evaluated by Lyons and Kasker (2012). The findings showed that the continuing education course improved the knowledge and skills of experienced nurses. Improvement in knowledge was shown immediately after the course and 8 to 12 weeks later. Significant skills improvement with regard to infection prevention and policy adherence were also found. No contextual details were provided in this study which may have facilitated the retention of knowledge or the observed maintenance of skills. However, it is important to note that this evaluation was conducted in a Magnet® facility. A Magnet® facility has achieved a quality status through external approval.

While multiple studies reported intentions to change practice and self-reported practice changes, a limited number of studies actually attempted to verify these practice changes. Along with self-reported changes, Tennant and Field (2004) and Ryder et al. (2018) also included stakeholders in reporting practice changes. However, in Tennant and Field (2004), there was no difference reported between the intervention and non-intervention group. Only four publications in this review completed actual observation or data collection to verify a change in practice. Of these, Ilott et al. (2014) and Dennison (2007) reported no observed practice change. The remaining two studies, Hickin et al. (2017) and Lyons and Kasker (2012) did report observed and verified practice changes.

2.10 Level 4 a) Organisation Change

At the highest level of evaluation on the Barr et al. (1999) evaluation framework, there were limited reports found during the literature search. For this level, Organisational Change, only a single study was found which addressed this level of evaluation.

Liaw et al. (2016) evaluated the impact of a CPE web-based simulation on nurses' recognition of and response to deteriorating patients in clinical settings utilising a pre- and post-intervention methodology. The study took place in two general wards in an acute tertiary hospital and had 99 participants. They measured outcomes across all four levels of Kirkpatrick's evaluation model. Nurses completed a questionnaire and clinical areas were reviewed for cases which were triggered by ward nurses for six months prior to and following the intervention. The nurses showed positive attitudes towards the transfer of learning and reported positively on the transfer of learning from the web-based simulation to clinical practice. At Level 4a, Organisation Change, a significant increase in the number of

cases being triggered by nurses in the medical ward was reported, but no changes were reported in the surgical ward. The authors identified that this may have been due to the characteristics of patients admitted to the medical ward who were more likely to deteriorate from their underlying medical diagnosis and comorbidities than the surgical patients. Nevertheless, the improved outcome from the triggering data of the medical ward provided some evidence to support the effectiveness of education intervention. While evaluation has been reported at a high level, this study fails to identify any contextual characteristics of the medical ward which may have favoured the transfer of knowledge and skills or characteristics of the surgical ward which impeded the transfer of education.

2.11 Level 4 b) Benefits to Patients and Families

Only three studies included in this review related CPE to positive outcomes for patients or families which equates to Level 4b on the Barr et al. (1999) framework.

Stolee et al. (2009) reported direct benefits to patients as a result of CPE education. This CPE intervention also involved the introduction of new patient assessment materials and aimed at developing the knowledge and skills of health professionals who care for older persons with complex physical and mental health needs and associated behaviours. The education intervention consisted of an 18 hour programme, followed by local training supporting application of skills and a follow up of a 12 hour programme. Training support included items such as teleconference, local networking support group and website support. In total 439 nursing homes in Ontario, Canada undertook the education. A sample of eight high achievers and four nursing homes with limited success undertook follow up telephone interview. Most of the successful homes had several trained staff members, many of whom had been given designated time to work as in-house trainers. These homes were involved in a number of key related activities: assessment (data collection), case conferencing, care planning, staff education, provision of care, linkages and partnerships with external resources. Participants from homes that were identified as having limited success were often unsure of who and how many staff within their facility had been trained and generally reported minimal activity related to the learning initiative. All of these homes did not currently have a trained staff member who was serving in a facilitative role and were not actively engaged in any related activities in a meaningful way. Several participants indicated that activity was limited to staff participation in training and that transfer of training to clinical practice had not occurred. Interview participants across homes identified increased staff knowledge, improved patient

assessment and diagnoses, and enhanced resident care and quality of life as positive impacts derived from the intervention.

Following a workshop for health visitors (HV) focusing on the care needs of children with complex needs in the community, Steven et al. (2018) completed a realist evaluation. Participants were asked about professional activity following the workshop, including if they had instigated any actions they considered as a result of their attendance. HVs suggested the knowledge gained regarding roles and services, together with links formed, enhanced their confidence to contact other services. Examples of practice enhancements attributed to workshop attendance included confidence building, improved team working, facilitation of early referral and accessing additional support for families. The use of a realist evaluation methodology, allowed Steven et al. (2018) to pay attention to the contexts and mechanisms, which facilitated them to promote attendance, engagement and subsequent practice application. This is the only realist evaluation included in the review and it offers potential for the use of this methodology in further evaluations of CPE.

In a quasi-experimental time-series pre-test/post-test design, Bernaix et al. (2008) explored the effectiveness of a lactation education programme for nurses in a Neonatal Intensive Care Unit (NICU) in an American Midwestern tertiary-care children's hospital. Data was collected from nurses and from mothers. The 4-hour educational intervention was provided using a lecture and discussion format, and included specific content related to breast anatomy and lactation physiology, lacto-engineering, the nutritional needs of the high-risk infant, and the mechanics of pumping and storing breast milk. In this study, the educational programme was found to be effective in improving the sampled NICU nurses' lactation knowledge, and intentions, attitudes, and beliefs toward providing lactation support to mothers of high-risk infants. This study suggests that this intervention had a short-term effect on knowledge, and that an additional reinforcement or intervention booster offered no later than 3 months may be required for continued retention of facts. An effect was noted on mothers in NICU as well who reported that perceptions of the supportive atmosphere for lactation in the NICU also significantly improved following the education.

2.12 Barriers to Transfer

The following section explores the barriers identified during the literature review which have been reported to impact on the transfer of learning into practice.

Ellis and Nolan (2005) reported a longitudinal evaluation of a short educational programme utilising a case study approach. Data was gathered from three groups of stakeholders over an eighteen month period in order to explore the context within which CPE operates, and to highlight those factors which appear to influence the outcomes of CPE. Data was collected using documentary analysis and in-depth semi-structured interviews with educators, students on the programme and their managers. The latter two groups were interviewed at four points in time (prior to the course, immediately post course, 6 and 12 months post course). One of the themes identified by students was the perceived continued indifference of their managers and thus, staff reporting feeling thwarted or discouraged from taking their ideas further. Conversely, in the small number of cases where staff received positive and proactive managerial support, enthusiasm remained high. The nature of the clinical environment to which staff returned following completion of their course was the main source of discontent, with the emphasis firmly placed on the lack of managerial support for initiating and sustaining change.

Similar to Ellis and Nolan (2005), a lack of manager support was a common barrier identified in the literature. Respondents in the publication by Hughes (2005) reported a lack of support from managers as well as identifying how managers' leadership styles played a part in the 'no change' culture of nursing. Respondents reported how the inability to alter practices caused frustration, disillusionment and feelings of being disempowered. Tame (2009) also uncovered that managers' attitudes pervaded all aspects of CPE where managers appeared to drive the culture in the clinical area. The role of managers in facilitating CPE transfer was explored by Gould et al. (2007) when examining nurses' experiences of CPE. The potential positive effects of CPE were seen by respondents (n=451) to be curtailed by the ability and willingness of managers to 'allow' CPD to be implemented and cascaded.

A study undertaken in Iran by Nayeri and Khosravi (2013) aimed to identify nurses' experience with applying knowledge obtained from CPE programmes. The study used

interviews with CPE participants and their managers until data saturation was achieved (n=34). They did not explore if participants had transferred knowledge, but rather factors which influenced their transfer. The five main categories which influenced the transfer in either a positive or negative manner were: (1) personal interest and self-confidence; (2) organisational structure and atmosphere; (3) professional nature; (4) opportunity to put education into practice; and (5) design of educational programmes.

Resistance to the use of new knowledge and change from other team members was also identified across a number of studies. This was reported to come from medical colleagues (Steginga et al 2005; Hughes 2005) and nursing peers (Tarnow et al. 2013). In Tarnow et al. (2013), respondents also reported the ability to “sell” team members on the need to make the change as a barrier. Ellis and Nolan (2005) also found that, if education was ad hoc in nature and it was combined with low management motivation, little change was likely to occur. Nayeri and Khosravi (2013) found that the routine oriented approach in hospitals proved a barrier when participants attempted to introduce innovative change which they had come to know through CPE.

In Wellings et al. (2017), respondents reported lack of time, work related issues and hospital procedure and policy were identified as the greatest barriers to transfer of learning. Hospital policy and procedures as a barrier were not explored any further. Policies and procedures are required to be written using the best available evidence and CPE should also use the best available evidence to guide its content; therefore, it is unclear as to how these could work as a barrier. Respondents identified the barriers as all external to them and did not identify any methods to overcome these barriers. Similar barriers reported were also reported by Steginga et al. (2005) in relation to not having sufficient time in the workplace. Ryder et al. (2018) also found that their respondents reported time management issues due to the busy clinical environment, staffing levels and availability of the support of a Clinical Facilitator as barriers to transfer. Likewise, Mann et al. (2009) in their study of multi-professional healthcare workers, identified time and work-load as the most common barrier to change, in both clinical practice and inter-professional interactions. Bull et al. (2017) reported on perceived barriers which were identified as time shortages on the perceived opportunity for application of training.

Again, Tarnow et al. (2013) identified similar barriers; with the number one barrier identified was lack of time to meet as a group, followed by the number of current change projects and lack of a useful measure of the problem. Clark et al. (2015) identified the inhibitors to transfer of new skills, as the clinical workload which limits involvement in developing, delivering and evaluating CPE and service providers with different cultures, agendas and timescales and the lack of organisational processes to systematically support CPE in the workplace. Limited autonomy for students to initiate and sustain change juggling work and study alongside clinical role demands.

2.13 Facilitators of Transfer

Empirical evidence of factors which facilitate the transfer of education into practice is limited. While studies such as those by Liaw et al. (2013) and Ilott et al. (2014) demonstrate the positive transfer of new knowledge into practice, they do not identify or explore what factors facilitated this transfer.

Mann et al. (2009) found that the most frequently identified enablers to change were attendance at the specified CPD course, increased knowledge and a team approach. Likewise, Stolee et al. (2009) found that successful implementation of the learning initiative was dependent on factors such as management support, available time for activities, availability of trained staff, peer and physician support, learning strategies and supportive resources used in training.

Lee (2011) found that professional peer attitude both helped and hindered learning transfer for CPE participants. Peer attitudes were identified as peer interest, willingness to support and help, motivation and enthusiasm for development and change. In Lee's (2011) education intervention, the managers were involved as key stakeholders. Some managers reported that they did not know how learning was transferred into practice and none of the line managers identified or explored their role as facilitators of learning. This could be a factor hindering positive practice change, although there was acknowledgement from the managers that local support was essential for change. Lee (2011) did conclude that following discussion, the line managers' prioritisation and focus was upon the organisation of resources for effective care delivery.

The work of Clark et al. (2015) has not already been discussed as it was not regarded as an evaluation of a CPE course, but rather focuses on the processes that key stakeholders

perceive to be most important in facilitating a positive impact of CPE on practice. All stakeholders highlighted the importance of a positive, supportive organisational culture in maximising the impact of CPE. A strategic commitment to CPE at institutional level in healthcare organisations was recognised by managers and students as crucial in establishing an ethos where both organisational and individual needs come together. All stakeholders highlighted the importance of partnership working. Partnerships were seen as particularly important between educators, who were essential to developing and delivering relevant CPE, and managers who played a key role in sponsoring and supporting their staff. Managers identified their greatest difficulty was providing support in the context of the demands of a busy workplace setting. Due to their busy clinical responsibilities, students identified a lack of time to share their knowledge and thus change practice. Several students highlighted that there was little organisational expectation, and hence personal motivation, that they should apply their new learning to practice. They also identified a lack of infrastructure to support shared learning.

Stolee et al. (2009) and Nayeri and Khosravi (2013) were the only studies reviewed which identified characteristics about the education programme itself which may influence transfer of learning. The education programme includes the process, the quality and applicability of education and the design of education programmes.

2.14 Limitations of Literature Review

Continuing professional education and continuing professional development are used interchangeably and have multiple meanings. Due to the multiple meanings the literature search was extensive and protracted. Many articles found were subjected to full review in order to identify their suitability. The abbreviations CPE and CPD also have multiple meanings and thus this also led to extensive 'hits' when undertaking the search. Due to the large number of hits and an extensive reviewing process, there is a possibility that some articles may have been missed. Other terms such as training are, on occasion, used to describe CPE. The term training was not searched and this may have also led to the exclusion of some relevant evidence. There is a proliferation of CPE course with no uniformity in the delivery of CPE course and there is diversity in nursing and midwifery education systems across countries (Gijbels et al. 2010). Not all CPE is equal in terms of academic level, duration, delivery methods and underlying pedagogical assumptions. Also many reported evaluations provide very little detail on the education intervention itself. Thus, it was not

possible to compare and contrast findings, and the interpretation and understandings of the findings is limited.

2.15 Conclusion

As well as developing and delivering CPE for nurses, it is essential that educators develop an understanding of its impact on practice and patient care delivery. Therefore, evaluation studies should focus not just on the lower levels of evaluation such as knowledge and skills acquisition, but on evaluative research which illustrates that learning from CPE benefits clinical practice (Lauder et al. 1999). However, evaluating CPE based only on its capacity to directly influence practice, reflects an impoverished understanding of how change in clinical practice actually occurs (Olson and Tooman 2012). Therefore, the context of the CPE initiative and the agency of the learners also need to be taken into account (Steven et al. 2018). By extending the Barr et al. (1999) evaluation framework I have successfully appraised the existing literature, albeit limited literature on the factors which affect transfer of CPE into practice.

Educators who are conducting an evaluation of CPE need to identify key stakeholders who are pivotal to the CPE process. The context of service delivery also needs to be examined as it is complex, multi-faceted and dynamic (Rycroft-Malone et al. 2012). Taking both into account recognises the importance of stakeholders and context in the development and implementation of the education intervention, and acknowledges that the delivery CPE independently will not lead to a change in practice and improvements in patient care. The majority of studies included in this review have completed the evaluations from the sole view of the participants, with only three studies involving key stakeholder and a single study reporting family/patient experiences. In order to develop a greater understanding of transfer and context and produce robust evaluations at level 3 and level 4 key stakeholders need to become involved.

In this review the majority of studies which reported evaluation at the higher levels of behaviour change and impact on the organisation or patient and family did so from participants' self-reports. Only three studies included in the review involved observation or collection of data by the research team. Of those, Dennison (2007) reported no significant and Ilott et al. (2014) found no visible change in staff practice. Liaw et al. (2016) was the only

study to verify a change in practice by examining the number of triggers for the deteriorating patients before and after their education intervention.

While many evaluations on CPE have been published, there still remains a dearth of empirical evidence of the direct impact on the organisation and the benefits to patients and carers. As illustrated by this narrative literature review, there are numerous methodological challenges in undertaking an evaluation of a CPE programme. Thus, the effectiveness of CPE needs to be fully explored through a systematic and methodologically sound programme evaluation approach which explores the context, involves multiple data collection methods and involves key stakeholders. Realist evaluation provides a methodologically robust framework which can address many of these issues. Chapter 3 further describes realist evaluation and its application in this thesis.

Chapter 3- Methodology

3.1 Introduction

This chapter sets the scene for the use of realist evaluation in my study. It begins by providing an introduction to evaluation and determines the meaning of evaluation research. It then sets out to examine the challenges of undertaking evaluation of CPE programmes. Next, it briefly describes the management and scientific models of evaluation. Realist evaluation is then introduced and its philosophical underpinnings are discussed. The place of realist evaluation in nursing and the justification for the selection of realist evaluation for this study is given. Finally, this chapter concludes by outlining the principles of realist evaluation which are applied in this study and outlines the design of the study.

3.2 Evaluation Research

There is currently an impetus for healthcare organisations to provide continuing professional education for nurses on medication safety. Nonetheless, in the age of accountability and finite resources, organisations must ensure that they can obtain a return on their investment (Draper et al. 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). Research evidence of the effectiveness of CPE is also needed, as is the clarification of how best to provide this education in order to achieve educational outcomes that will lead to improved patient care (Mann et al. 2009).

Evaluation research is an approach used widely in education and healthcare and is a process intrinsic to academia and nursing programmes (Raines 2009). Evaluation research involves the systematic assessment of information in order to provide useful feedback about a particular programme or project (Patton 2015). The aim of evaluation research is to learn how well a programme, practice, or policy is working or not working (Polit and Beck 2017). Evaluation research can be undertaken to evaluate the process being used, the impact of the programme or the cost of the programme (Polit and Beck 2014). While evaluation of education interventions is common practice for educators, it is essential that an evaluation research approach is utilised. An evaluation research approach ensures quality assurance, and also enhances knowledge and understanding of the intervention under investigation. Evaluation research will evaluate a programme or practice that is embedded in an existing

organisational context and thus it may confront problems that are organisational or interpersonal (Polit and Beck 2017).

Various typologies of evaluation theories, approaches or models exist (Attree 2006; Mark and Henry 2013), and the terms are often used interchangeably (Hansen et al. 2013). Similar to all nursing research, a triad of paradigms are possible: positivist (quantitative), constructivist (essentially qualitative) and realist (Wainwright 1997; Attree 2006). The positivist approach uses the scientific principles of hypothesis testing and quantitative data, while the constructivist approach utilises constructivist methods exploring how people make sense of their experience by the use of qualitative data to generate theory (Attree 2006). The third, more recent addition is the realist approach (Pawson and Tilley 1997). This approach integrates other theories to design an evaluation using mixed methods and data sources. It is based on the assumption that the evaluator already has a theory about what works, how and under what conditions. The selection of the methods and approaches to be used for a research evaluation depend on the aim and the purpose of the evaluation, the researcher's orientation, the research question which need to be answered and the problems which need to be resolved.

3.3 Challenges for Evaluation of Continuing Professional Education

There are several methodological and conceptual challenges for the evaluation of CPE education programmes (Hegney et al. 2010; Lee 2011). Educational systems and healthcare organisations are not simple systems, they are complex and each educational programme exists in a context in the 'real' world of clinical practice (Ogrinc et al. 2007; Ellis and Nolan 2005; Ogrinc and Batalden 2009). 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).

As demonstrated in the literature review in Chapter 2, evaluations have tended to report student perceptions or students outcomes of education programmes. While students may report benefits in terms of changes in attitudes and enhanced knowledge and skills, there is little reference made to developments in practice, organisational change or improved patient care (Gijbels et al. 2010; Hegney et al. 2010). Evaluations which attempt to provide an estimate of a programme's effectiveness through the assessment of one or more

outcomes often provide no explanation or understanding with regard to how recorded outcomes might have been produced (Salter and Kothori 2014). 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.

3.4 Scientific Evaluation

Many evaluation studies on nursing education programmes have reported the use of interventional designs. Such scientific-experimental models of evaluation follow the positivist paradigm (Attree 2006). Reported interventional designs include a randomised cluster controlled study (Wang et al. 2017) and pre and post-test knowledge and confidence reports (Redmond et al. 2018). Published evaluations of medication safety education also report intervention studies such as Sneck et al. (2016), who examined medication competency using a descriptive correlation design, Van Lancker et al. (2016), who examined the effectiveness of an e-learning course on medication safety using a clustered quasi-experimental study, and Lu et al. (2013) who examined nurses' knowledge of high-alert medications by utilising a randomised controlled trial.

In interventional designs, extraneous variables are difficult to control and often experimental research is unable to attribute a clear distinct relationship between an education intervention and practice (Clark et al. 2015). Experimental evaluations only produce descriptions of outcomes and do not provide explanations of why programmes work (Pawson and Tilley 1997). Dennison (2007) reported that when completing an evaluation of an education intervention on safety of medication administration there was difficulty in relating changes in practice to the education programme as many different extraneous variables were present that may have affected the results of the evaluation. While interventional designs have a central position in application of evidence to practice their ability to investigate complex interventions meaningfully has been questioned (Greenhalgh et al. 2004; Seers 2007; Mackenzie et al. 2009). Thus, it was necessary to adopt a research methodology for evaluation which is both contextual and responsive (Ellis 2003).

3.5 Management/System Models of Evaluation

Management or systems models of evaluation were developed in business and adopt a business theory or operational research approach (Attree 2006). They tend to be based on the constructivist paradigm. Multiple frameworks have been developed to guide educators, managers, evaluators and policy makers on how to evaluate the complex and highly variable phenomenon commonly called ‘training’ (O’Malley et al. 2013). A framework helps to provide the evaluator with a method of determining the most appropriate evaluation level for the activity and inform their data collection.

A commonly used management or system model for evaluation is that of the Kirkpatrick model first presented in 1959. It was designed primarily for use in business and industry (O’Malley et al. 2013) as a model for evaluating training, but is now applied across healthcare settings to evaluate training and education and is outcomes based (Dubrowski and Morin 2011). The Kirkpatrick model includes four levels: 1) reaction (i.e. student satisfaction), 2) learning (i.e. knowledge increase), 3) performance (i.e. behaviour change in practice), and 4) impact (i.e. results as final outcomes) (Kirkpatrick and Kirkpatrick 2006). The Barr et al. (1999) evaluation framework (modified version of Kirkpatrick’s typology) was utilised in the literature review in Chapter 2 in order provide structure to the literature presented. In order to address some of the criticism of an outcome based model of evaluation the literature review extended the Barr et al. (1999) evaluation framework.

Level	Description of level	Data collected
1	Reaction	Assessment of learners’ views
2	Learning	2a: Change in learners’ views or attitudes 2b: Change in learners’ knowledge or skills level
3	Performance	Change in learners’ behaviour
4	Impact	4a: Change in organisational practice level 4b: Change patient care

Table 3. 1 Kirkpatrick’s levels of evaluation

Some evaluations on nursing education programmes have utilised the Kirkpatrick framework such as Lahti et al. (2014) and Dorri et al. (2016). Lahti et al. (2014) reported using

Kirkpatrick's (1998) model of learning outcome evaluation to evaluate an e-learning course, while Dorri et al. (2016) also utilised it in the evaluation of in-service training in cardiopulmonary resuscitation.

Another evaluation model frequently utilised is Stufflebeam's Context, Input, Process and Product (CIPP) model. First described in print in 1971, Stufflebeam intended CIPP Model evaluations to be process orientated and focus on programme improvement instead of proving something about the programme (Frye and Hemmer 2012; Dubrowski and Morin 2011). The CIPP model consists of four complementary sets of evaluation studies that allow evaluators to consider important but easily overlooked programme dimensions (Frye and Hemmer 2012). The CIPP model requires the consideration of multiple aspects of a programme including input from representative stakeholders (Lippe and Carter 2018). These aspects are assessed via four main evaluations (context, input, process, and product), which when placed together, provide data to assess the overall programme. While the CIPP model does examine context, it does not examine the interplay between knowledge application, knowledge transfer and its context and it is also unable to answer some significant questions or issues (Hakan and Seval 2011). An example of the use of the CIPP model in evaluation of education can be seen in Lippe and Carter (2018), who utilised it to evaluate an end of life education programme for nurses.

These system models tend to underplay the complexity of the social world (Coldwell and Simkins 2011), with the emphasis on the programme itself rather than the stakeholders. There is also a focus on learning outcomes and the success or failures, rather than on the why, without proper emphasis on integration of the programme's content with the setting (Dubrowski and Morin 2011). While these models offer tools and instruments for research, it is essential that a model of evaluation is utilised which allows for the understanding of the contextual conditions.

3.6 Realist Evaluation

Realist Evaluation provides the research framework for this study. Realist evaluation was developed by Pawson and Tilley (1997) and was initially utilised to evaluate crime prevention measures. Realist evaluation is primary research that adopts a theory driven approach to the

evaluation of social programmes (Doi et al. 2017) and provides an understanding of how and why interventions work in the real world (Byng et al. 2008). The evaluator's role is to understand what works, for whom and in what circumstances (Pawson and Tilley 1997; Contandriopoulos and Brousselle 2012). Other evaluation methodologies, as discussed previously, have tended to focus primarily on the outcome of an intervention to the detriment of the mechanism and contextual aspects. The realist evaluation approach considers the social processes as an important factor in understanding why a programme does or does not work in particular circumstances (Pawson and Tilley 1997).

Realist evaluation is not a method or a technical procedure (Salter and Kothari 2014); rather it is logic of enquiry (Pawson and Tilley 1997). Realist evaluation stresses the need to evaluate programmes within "context," and to ask what "mechanisms" are acting to produce which "outcomes." This is referred to as a context (C) mechanism (M) outcome (O) configuration. This CMO configuration is formulated as a middle-range theory (MRT).

To understand how an intervention might generate different outcomes in different circumstances, a realist evaluation examines how different programme mechanisms are triggered in particular contexts (Wong et al. 2016). A mechanism is not a variable or intervention, it is the changes in the reasoning and the behaviour of participants brought about in a particular context (Pawson and Tilley 1997; Wong et al. 2016). Mechanisms are the underlying entities, processes or structures which operate in particular contexts to generate outcomes of interest (Astbury and Leeuw 2010). These relationships are context bound, they are not fixed; and thus particular interventions/programmes/innovations might work differently in different situations and circumstances (Rycroft-Malone et al. 2010). Context is about having the right conditions to activate the mechanism (Pawson and Tilley 1997). Rather than identifying simple cause and effect relationships as provided by other evaluations, realist evaluation is concerned with finding out about what mechanisms work, in what conditions, why, and to produce which outcomes (Salter and Kothari 2014).

Realist evaluation is method-neutral and both quantitative and qualitative data are routinely collected (Marchal et al. 2012). Realist's explicit philosophical foundations and its methodology set realist evaluation apart from other theory-driven approaches (Marchal et al. 2012).

3.7 Philosophical Underpinnings of Realist Evaluation

Realist Evaluation is underpinned by the philosophy of critical realism (Williams et al. 2017). Critical Realism is a philosophical approach in which its proponents combine a realist ontological perspective (theory of being) with a relativist epistemology (theory of knowledge) (McEvoy and Richards 2003). Realism is often considered a 'third way' (Wainwright and Forbes 2000; Danermark et al. 2002), which stands between positivism and constructivism (Befani et al. 2007) and acknowledges that the world is an open system, with structures and layers that interact to form mechanisms and contexts (Rycroft-Malone et al. 2010). Figure 3.1 from the RAMESES project depicts the paradigm position of realist evaluation.

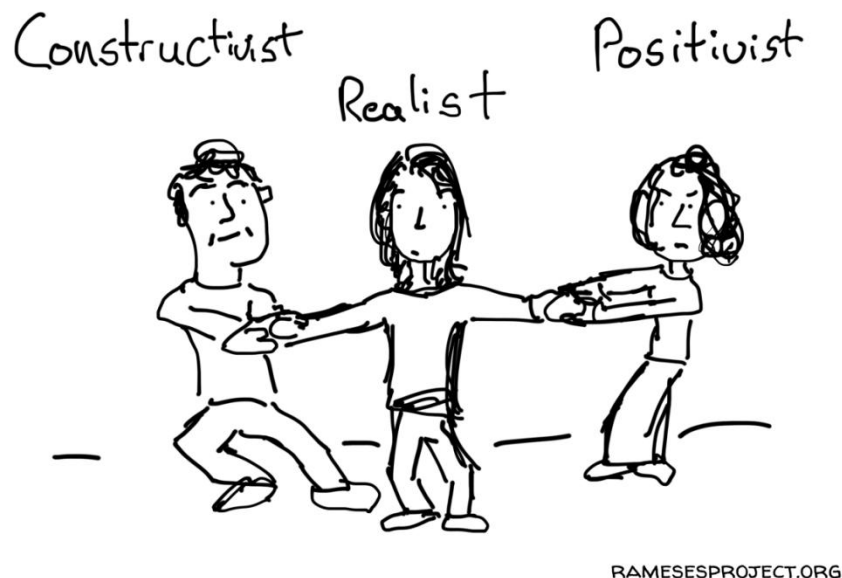


Figure 3.1 Paradigm position of realist evaluation

Critical realism offers a philosophy of science that addresses difficulties that have been encountered in theorising and researching the social world (Angus et al. 2006). Critical realism confronts complexity (Clark et al. 2008) and can enlighten the different influences on patient and professional activities during care episodes (Angus et al. 2006).

The theory of critical realism proposes that social structure operates at many sites and levels and that events experienced at the individual level may be the culmination of numerous,

perhaps even countervailing, extra local influences (Scambler 2001). Thus, complex phenomena cannot be understood fully based on direct sensory experiences alone, as they exist independent of people's knowledge of them. Consequently, critical realism is based on the ontology that the world is deep, differentiated and stratified (Bergene 2007) and consists not only of events, but objects, including structures, which have powers and liabilities capable of generating events (Sayer 1992).

Reality is seen as a stratified ontology, where what we experience is only the tip of the iceberg. Bhaskar (1978) proposes that in order to view a world that ontologically goes further and thus to be in a position to investigate society, it is necessary to include three layers of reality which are distinct: the empirical layer, the actual layer, and the real layer. The empirical layer is the domain of experience and can be observed by humans (Mearns 2011; Angus et al. 2006). Next is the actual layer which encompasses events that exist or actually happen in time and space. Finally, there is the real layer, which is whatever naturally or socially exists, including, but going beyond facts, perceptions and experiences (Mearns 2011; Angus et al. 2006). Bhaskar (1978) suggests that the real layer includes structures, powers and liabilities and allows observable events to emerge (Mearns 2011; Angus et al. 2006).

From the critical realist perspective, understanding the real domain is the proper role of science. To develop theory from this perspective is to explain why, but from a transcendental perspective. That is, the focus is not usually on the specific event observed, but on what that event tells us about enduring underlying causal relationships (generative mechanisms) that lie beyond common experience (the empirical domain). In essence, critical realism concerns itself with uncovering the domain of the real, that is, those underlying generative mechanisms that give rise to the demi-regularities we observe and experience daily (DeForge and Shaw 2012). The real is whatever naturally or socially exists, including, but going beyond experiences and events (Angus et al. 2006). It is argued that such generative mechanisms are nothing other than the ways of acting of things. The concept of generative mechanism is clearly described by DeForge and Shaw (2012) when they describe the critical realist worldview as being characterised not by successionist causation (wherein doing A to B leads to C), but rather by generative causation wherein the interplay of conditions from the domain of the real give rise to the events we observe in the domain of the actual. The real basis of causal laws is provided by the generative mechanisms of nature.

The underlying theoretical assumptions of realist evaluation which are applied in my research evaluation study are provided in Table 3.2.

Type of assumption	Assumption	Application
Ontology–the nature of reality	The material and social worlds are real, reality is stratified	I needed to penetrate beneath the surface of observable inputs and outputs of the programme
Epistemology- how we come to understand reality	No final truth or knowledge, but improvement in knowledge is possible	Each person (stakeholder) perceives their own construction of that world, which is influenced by their own social and historical experiences. Outcomes are dependent on the context
How causality works	Generative causation	Mechanisms operating differently in different contexts generate patterns of outcomes. Therefore, I had to attend to how and why the education programme had the potential to cause change

Table 3.2 – Theoretical assumptions underlying this realist evaluation- adapted from Pawson and Tilley (1997) and Westhorp et al. (2011)

3.8 Nursing and Realist Evaluation

In the 20 years since the movement began, there has been a gradual increase in published papers that apply realist evaluation in health systems research (Wong et al. 2016; Marchal et al. 2012). The use of realist evaluation has been applied to numerous healthcare and clinically focused studies (Doi et al. 2017; McGaughey et al. 2017; Williams et al. 2103; Tolson and Schofield 2012; Rycroft-Malone et al. 2010; Tolson et al. 2007; Byng et al. 2005). In a special edition on realist evaluation, in *Nursing Inquiry*, Pawson (2012) discussed the great potential of realist evaluation for nursing, as within nursing there is huge variation across what it does and what it is.

In recent years, there has been a small number of realist evaluations reported on nursing and medical education interventions and nursing education. Stavropoulou and Stroubouki (2014) reported the use of the principles of realist evaluation in the evaluation of a post-graduate quality assurance module. Machin and Pearson (2014) also utilised realist evaluation to explore action learning sets in a nursing and midwifery practice learning. Most recently, Steven et al. (2018) reported on the realist evaluation of a multi-disciplinary workshop for health visitors dealing with children with complex needs. While reports in

nurse education are few, Wong et al. (2012) advocated the suitability of realist research to provide evidence of the effectiveness of medical education.

3.9 Why Realist Evaluation in my Research?

The complexity of evaluating the effectiveness of CPE has been discussed previously and is a common theme in the literature (Lahti et al. 2014). My research question called for an understanding of the barriers and facilitators to the application into practice of the principles of safe medication administration education programme. Realist evaluation provides a framework for understanding 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 the framework for me to ask 'how' and 'for whom' and following Stage 4 will enable me to influence policymakers to tailor educational interventions and policy to particular purposes, target groups and sets of circumstances (Wong et al. 2012). 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). 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.

3.10 The Application of the Principles of Realist Evaluation in my Research

The methodological rules of realist evaluation are recognised to be emergent (Tolson et al. 2007), this research evaluation followed the general principles for realist evaluation advocated by Pawson and Tilley (1997, p. 215-219) as a guide. These eight principles were:

1. Generative causation- I 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- I uncovered what is contained below the surface of inputs and outputs. It was not just what I observed that was important to gather information on but also on the cultural and social processes.

3. Mechanisms- one of the focuses of my realist evaluation was to understand why an education programmes 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 realist evaluation worked 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- these 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, I engaged in a teacher-learner relationship with policy makers, practitioners and participants (Stage 2 and Stage 3). It was essential to elicit stakeholder involvement and engagement.
8. Open systems- realist evaluation 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, I could not provide control mechanism to maintain the equilibrium.

Underpinned by the principles outlined above, following an iterative explanation building process, this study proceeded in four key stages depicted in Table 3.3. Realist evaluation seeks to build initial programme theories as conjectured CMO configurations (Stage 1 and 2), test (Stage 3) and then refine them (Stage 4) (Doi et al. 2017). The initial programme theories were based on propositions which are related to the context, mechanism and

outcome. These initial programme theories were developed as conjectured CMO configurations through document analysis and interviews with policy makers and key stakeholders (Stage 1). They were then refined by experts (Stage 2). The conjectured CMO configurations then drove the remaining aspects of the evaluation (Pawson and Tilley 1997; Rycroft-Malone et al. 2010; Wand et al. 2010). Stage 3 involved the testing of the conjectured CMO configurations by a case study which involved observation, interviews, further document analysis and gathering of quantitative data. The final stage, Stage 4, involved reviewing the findings from Stage 3 to confirm, modify, or reject the conjectured CMO configurations put forward in Stage 2. The stages were undertaken sequentially such that the findings from each stage informed the next stage. Although presented as a linear process in Table 3.3 this research study was a realist evaluation cycle.

The RAMESES II reporting standards for realist evaluations (Wong et al. 2016) were also considered for the final writing up of this realist evaluation.

Stage	Description of stage	Sources of data and activity
Stage 1	Identification of initial programme theories as conjectured Context Mechanism Outcome configurations	Six Interview—key stakeholders- education developers, education and medication safety experts
Stage 2	CMO refinement (programme theory refinement)	Three expert interviews- (patient safety, medication safety and education)
Stage 3	Testing the conjectured CMO configurations (programme theories)	Single Case study site – three embedded units Observation of practice (Four participants) Interviews with four participants and three managers Quality Care Nursing Metrics for three embedded sites Reported Medication incidents for three embedded sites
Stage 4	Refining the CMO configurations and thus the programme theory	Analysis and interpretation Refined CMO configurations

Table 3. 3 Realist evaluation study design

3.11 Ethical Approval

Ethical approval to undertake the study was obtained from Cardiff University, School of Nursing and Midwifery Studies, School Research Ethics Committee (Appendix 2) and the organisation's Research and Ethics Committee (Appendix 3). Approval was also obtained from the organisation's Nursing Research and Innovation Committee (Appendix 4) and the organisation's Chief Executive (Appendix 5). Further permission to access data for Stage 3 was granted by the Director of Nursing in the site of the case study (Appendix 6). All data is reported in a way which provides anonymity for all participants. On occasion, the gender of participants throughout the study may have been altered in order to protect the identity of participants. All data collected including observation field notes, digital recordings and interview transcripts is stored in accordance with the Data Protection Amendment Act 2003 (Government of Ireland 2003). All data is stored in a locked cabinet and all electronic files are password protected on a secured drive. The application of specific ethical principles is addressed in the chapters related to the data collection methods. For example, in Chapter 6 there is a large section detailing the ethical principles applied during observation.

3.12 Conclusion

This chapter has provided an overview of evaluation as a research method. It has provided a rationale for the selection of realist evaluation in this study. This chapter has also introduced the principles of realist evaluation which are further developed and applied throughout this thesis. The design of this study utilising the principles of realist evaluation is also outlined, and the chapter has concluded by providing details of the ethical approval and other permissions obtained in order to conduct the study.

Chapter 4 – Stage 1 Theory Development

4.1 Introduction

The first stage of the research is presented in this chapter and completion of Stage 1 will provide the conjectured CMO configurations which will be refined in Stage 2 (Chapter 5) and later tested in Stage 3 (Chapter 6). Stage 4 involved the reporting of the findings and the analysis of the conjectured CMO configurations (Chapters 7, 8 and 9). Stage 4 then confirms, modifies, or rejects the conjectured CMO configurations generated in Stage 2. Thus the 'findings' in this realist evaluation did not occur until Stage 4 which aimed to pinpoint the CMO configuration of features needed to sustain a programme (Pawson and Tilley 2004).

Stage 1 is the launching pad for any realist evaluation, and according to Pawson and Tilley (2004), it is the most distinctive phase. The purpose of Stage 1 was for theory gleaning and began by eliciting and formalising the programme theories which formed the conjectured CMO configurations which were refined in Stage 2 and later tested in Stage 3. Theory gleaning is the realist term which is used to describe the development of theory which forms the conjectured CMO configurations. To elicit the programme theory, researchers unearth the models that the actors are implicitly using to describe, and understand the intervention this is referred to by Pawson and Tilley (1997) as 'folk theories'. Programme theories can be gathered from various sources such as documents, interviews and observation. Pawson and Tilley (1997) and Pawson and Manzano-Santaella (2012) advocate a pluralist and pragmatic approach to the collection of realist data advocating the use of a selection of methods in order to ensure the appropriate data is gathered to support the generation of conjectured CMO configurations. Indeed, Manzano (2016) advocates that realist enquiries should aim to collect large amounts of data in order to move from constructions to explanations of causal mechanism. In this study the conjectured CMO configurations were developed based on a document analysis of local and national policy, course documentation and policy maker interviews. According to Pawson and Tilley (2004), documentary analysis and interviews with programme architects can help to articulate the formal programme theory in CMO configurations.

The development of conjectured CMO configuration(s) is the starting point for the evaluation. The conjectured CMO configuration is a proposition stating what it is about an initiative which works for whom in what circumstances. This conjectured CMO configuration is further developed, refined and tested in the latter stages of the evaluation.

4.2 The Safe Medication Administration Education Programme

The safe medication administration education programme is an asynchronous e-learning programme. The content was developed by nurse educators and nurse practice development facilitators. The e-learning programme was designed on *Articulate* e-learning software by a learning technologist. The curriculum design was based on the education theory of constructivism. Learner engagement was required throughout the programme. The stated aim of the programme was to enable nurses in the organisation to update their skills and understanding of evidence-based principles and practice in the safe administration of medications and apply these to everyday practice. Three learning outcomes were provided. These were:

- 1) Describe the principles of safe medication administration utilising the 5 rights of medication administration and apply them to practice
- 2) Evaluate medication incidents and recommend solutions
- 3) Demonstrate accuracy in drug calculations

The programme contained four learning modules. The first learning module reviewed the safety aspects of medication administration and the significance of the '5 rights of medication administration'. The second learning module described the importance of reporting medication incidents, and provided real examples of reported medication incidents in the organisation. The learner works through these medication error reports while critically reviewing them. The third learning module was scenario based. These scenarios provided real patient cases and their medication management issues. The learner worked through the medications and responded to the interactive sections, which highlight the importance of medication knowledge and where further information could be obtained. The fourth and final learning module was on medication calculations required for practice. The learner again worked through multiple case scenarios.

The e-learning programme was estimated to take the learner approximately three hours to complete. However, based on the principles of student centred learning it was a self-paced programme. The learner could leave it at any time and return to where they have left off. They could also revisit any part of the programme at any time. The e-learning programme was available to all nursing staff 24 hours a day on the organisation's learning management system. All nursing staff new to the organisation were required to undertake the programme as part of their induction to medication safety.

4.3 Document Analysis

Document analysis is a systematic procedure for reviewing and evaluating documents. Like other analytical methods in qualitative research, document analysis requires that data be examined and interpreted in order to elicit meaning, gain understanding and develop empirical knowledge (Bowen 2009). Document analysis is a common method which has been reported on multiple occasions in realist evaluations. Published papers by Tolson et al. (2007), Rycroft-Malone et al. (2010) and Rycroft-Malone et al. (2011) all utilised document analysis in order to develop their programme theories and conjectured CMO configurations, which were later tested.

When conducting document analysis, Bryman (2016) cautions that care needs to be taken in relation as to how organisation's documents are viewed. In Stage 1 of this study, documents were viewed as what they were, namely texts written with a distinctive purpose in mind (Bryman 2016). In accordance with the underpinning philosophy of realist evaluation, the documents were viewed as a distinct level of reality (Atkinson and Coffey 2011) and used in identifying the context. The documents used in this analysis were used to establish the first two layers of Pawson (2006) four layers of context. The two layers which these documents helped to uncover were: (1) the broader infrastructural system, the outermost layer and (2) the institutional setting, encompassing the cultural aspects of a given contextual domain (Pawson 2006).

The use of document analysis in Stage 1 had numerous advantages. As there is limited research evidence on the effectiveness of continuing professional education for nurses and as there is a dearth of studies in the Irish setting, the formulation of testable conjectured CMO configurations from a realist review and synthesis of the literature would not have been possible. The documents helped to determine the characteristics of the organisation

which give it its identity (Owen 2014). They also aided in providing data on the context in which the case study was to take place (Bowen 2009). The documents also *'help the researcher uncover meaning, develop understanding, and discover insights relevant to the research problem'* Merriam (1998, p. 118). Bowen (2009) contends that the use of this documentary data also serves to ground the research in its context and related phenomena being investigated. Thus document analysis is a useful method to aid in the development of conjectured CMO configurations.

As recommended by Bryman (2016) document analysis was used to develop an understanding of aspects of the organisation and its operations but was also supported with other sources of data. Interviews were also utilised at this stage to collect data. The document analysis was performed prior to the interviews in Stage 1. This allowed for initial analysis of the documents which was then used and integrated into the development of the semi-structured interview template. Bowen (2009) proposes that information contained in documents can suggest some questions that need to be asked at interview and situations that need to be observed as part of the research. The interviews further aided the analyses and thus provided a contextual understanding of the documents and their significance

The document analysis in this research also provided information and details of events or situations that need to be observed and contributed strongly to the design of the observation tool which is used in Stage 3 of the study.

4.3.1 The organisation

The organisation in which this study took place was a large academic teaching hospital in the Republic of Ireland with an excess of 500 beds. It is a Model 4 or tertiary hospital and a national referral centre for many specialties. It is affiliated to a large university and contributes to the education and placement of many clinical professionals such as nurses, medicine laboratory technicians, research scientists, physiotherapists, occupational therapists, radiographers, medical social workers, dieticians and speech therapists. The hospital currently holds international accreditation which is considered a gold standard for patient safety and quality in healthcare. Similar to all acute hospitals in the Republic of Ireland, the organisation is also subject to review and inspection by Health Information and Quality Authority (HIQA) and other agencies such as National Cancer Control Programme. The hospital approves and utilises a large number of local policies, procedures and

guidelines. These policies, procedures and guidelines are developed and approved in a systematic manner. All clinical guidelines, policies and procedures are underpinned by evidence based practice and national and international guidelines.

4.3.2 Policy and guideline review

Healthcare is a complex process that involves a multitude of actions by many different people. It is widely acknowledged in the literature that policies, guidelines and protocols aid in improving the quality of healthcare provision by articulating consistent approaches for best practice (An Bord Altranais 2000). The role of the organisation's policy, procedure and guidelines are to provide general guidance about the organisation's mission, provide specific guidance toward implementing strategies to achieve the organisation's mission and provide a mechanism to control the behaviour of the organisation. In other words policies, procedures and guidelines are a direct link between an organisation's 'vision' and their day-to-day operations. Thus the analysis of organisational policies will provide a snapshot view of the culture and build the context of the organisation.

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; medication, error reporting, patient safety, education and 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 were on medication management. Two documents on medication management were excluded as they were based exclusively on the transplantation services, and also pharmacy specific policies were excluded. An example for pharmacy specific policies was any policy relating to the aseptic compounding service. All identified policies, procedures and guidelines were entered into NVivo™ (10).

National and professional standards from the Nursing and Midwifery Board of Ireland were searched and documents in relation to medication management, scope of practice, code of conduct and professional standards were also downloaded. A total of five documents

related to professional standards were entered into NVivo™ (10) for analysis. Course documentation including curriculum documents was also entered into NVivo™ (10).

4.3.3 Data analysis

While Stage 1 data analysis is reported separately from the other stages, it is essential to highlight that as Pawson (2006) has argued realist analysis is not a defined separate stage of the research process; but it is an ongoing iterative process of placing segments of information within a wider CMO explanation. There is an abundance of literature reporting the analysis of data in realist evaluations (Dalkin et al. 2015; Pawson 2013; Pawson and Tilley 1997; Westhorp 2013). However, these studies report analysis of data when CMO configurations have been proposed and data collection and analysis involved their refinement and or further testing. In these reported studies a realist lens to analysis was applied, where the researchers were analysing data focusing on refining or confirming CMO configurations. In Stage 1 of this study, no conjectured CMO configurations had been identified and the purpose of Stage 1 data collection and analysis was to build these propositions.

NVivo™ (10) was used as a tool to assist with the process of qualitative data analysis. Documents were imported into NVivo™. The analysis of all documents was conducted using thematic analysis. Thematic analysis is an independent and a reliable qualitative approach to data analysis (Vaismoradi et al. 2013) which systematically identifies, organises and offers insight into patterns of meaning across a data set (Braun and Clarke 2012). The framework provided by Braun and Clarke (2006) was used as the guiding framework for data analysis. The Braun and Clarke (2006) framework provides a robust, systematic method for coding qualitative data, and for then using that coding to identify patterns across the dataset in relation to the research question. While the Braun and Clarke (2006) framework is presented as a linear process of analysis, whereby when one phase is completed the next phase is moved to, the process actually was recursive where I moved back and forth through the phases as analysis took place.

Phase	Description of the process
1	Familiarising yourself with your data: transcribing data (if necessary), reading and rereading the data, noting down initial ideas.
2	Generating initial codes: Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3	Searching for themes: Collating codes into potential themes, gathering all data relevant to each potential them
4	Reviewing themes: Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic “map” of the analysis.
5	Defining and naming themes: Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells; generating clear definitions and names for each theme.
6	Producing the report: The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

Table 4.1 Braun and Clarke (2006) Framework for Thematic Analysis

All policies, guidelines, professional standards and course documentation were firstly read and then re-read. This allowed me to get a ‘feel’ for the organisation. Following this each item was reviewed again and I began to generate initial codes in a systematic fashion. Codes were generated from the documents using an inductive approach. Inductive coding occurs when the researcher does not have any pre-existing codes but looks to the data to generate these codes (Fletcher et al. 2015); it is a ‘bottom up approach’. Different to other methods of data analysis in thematic analysis, the development of a code is not dependent on the frequency of occurrence, but on how it may capture something important in relation to the research question (Vaismoradi et al. 2013).

All data relevant to each code was grouped together by using NVivo™ (10). At this point, it was essential that all codes were identified, as they may not be of significance in the document analysis to form themes, but in the later stages of analysis, when themes are being reviewed across the document analysis and interviews they may hold greater significance and move towards the formation of themes at that point. What was important was that all codes identified were relevant to answering the research question (Braun and

Clarke 2012). The research question was *'How are knowledge and skills obtained through a continuing professional education programme for safe medication administration transferred to the clinical care environment?'*

Codes were then collated and grouped together and themes began to emerge. Thematic maps were produced of themes, codes and their relationships. Figure 4.1 illustrates a thematic map for the initial theme of 'Social System'.

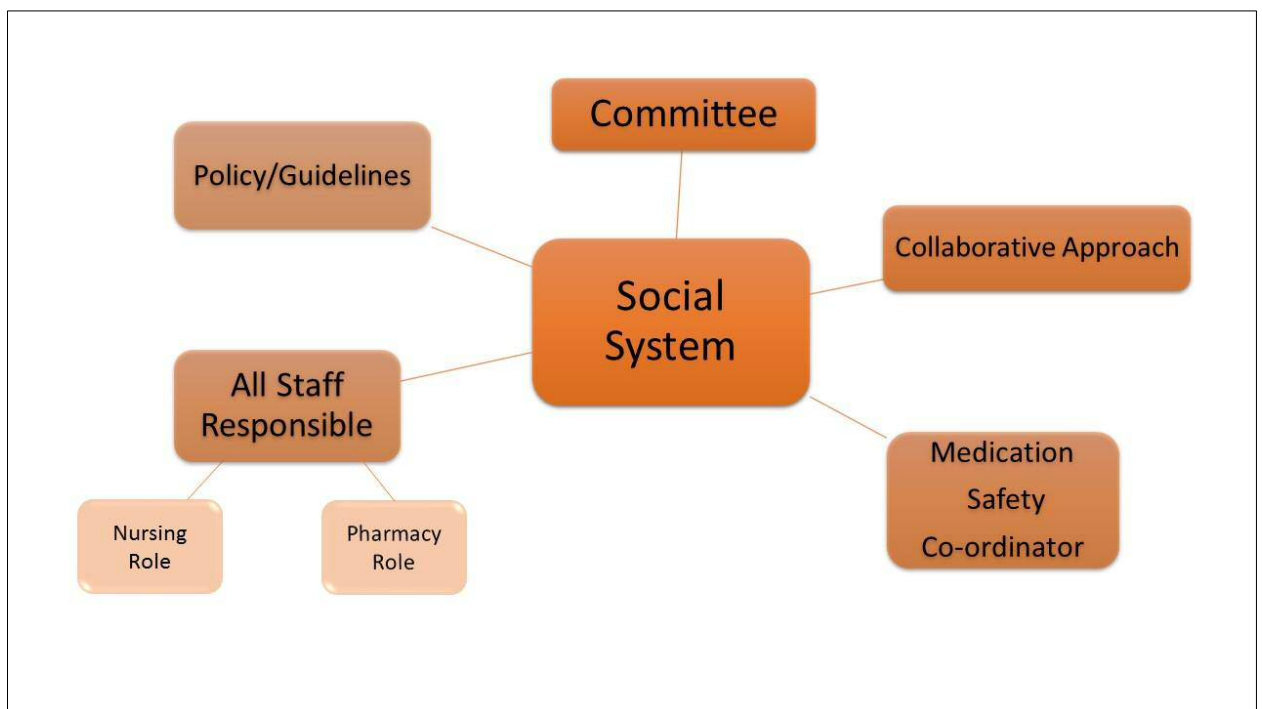


Figure 4.1 Thematic Map: Theme- Social System

As recommended by Braun and Clarke (2012) themes were developed to capture the most important and relevant elements of the data, and the overall tone of the data, in relation to the research question. In thematic analysis, themes are usually quite abstract, and therefore difficult to identify (DeSantis and Ugarriza 2000). Themes were reviewed across the organisation's policies and guidelines, the national standards and guidelines and the course documentation, and themes were then searched for and reviewed in relation to the coded extracts. The themes identified during document analysis can be seen in Table 4.2.

Themes identified in document analysis	
Work setting	Enabling behaviours
Leadership and peer support	Opportunity to apply learning
Organisational culture	Attitude
Organisational goals	Incident reporting
Social system	Patient safety

Table 4.2 Initial themes in analysis of documents

Braun and Clarke (2012) recommend that during this phase that exploration of the relationship between themes should be undertaken, and consideration should be given as to how themes will work together in an overall story about the data. This assisted when reviewing themes (Braun and Clarke 2006), and also when themes were being allocated into context, mechanism or outcomes. It also provides an audit trail. Bryman (2016) advises that the provision of evidence of key decisions relating to coding, theme identification and conceptualisations, as well as evidence base for these decisions, will assist in the justification of how themes were identified. At this point, analysis of documents paused until the interview data was analysed and brought to the same level.

4.4 Interviews

In order to support the document analysis and to assist in the development of conjectured CMO configurations, semi-structured interviews took place. Tracy (2013) proposes that qualitative interviews provide opportunities for mutual discovery, understanding, reflection, and explanation via a path that is organic, adaptive, and oftentimes energising. In realist evaluation interviews with practitioners are deemed especially important as discussions of apparent programme successes and failures can lead to refinement of conjectured context mechanism outcome configurations (Pawson and Tilley 2004).

4.4.1 Selection of interviewees

Pawson and Tilley (1997) recommend the selection of interviewees based on their CMO investigation potential. Each component to be developed, context, mechanism or outcome, require the need for a different kind of respondent. Manzano (2016) furthers this by suggesting that it is imperative that a broad range of programme stakeholders must be purposefully selected. Thus, a purposefully sample of six key policy makers from local and

national level were interviewed. Each informant was selected based on the significance of their expertise at a local and or national level. The numbers of interviews which is considered as an acceptable standard for qualitative methodologies is not applicable in realist evaluation. What is applicable in the selection of interviewees is of relevance and rigor is established through the conduction of a mixed method strategy (Pawson 2013). A description of the interviewees for Stage 1 can be found in Table 4. 3.

Role title	Local or National Level	Description -Expertise
Director of Nursing	Local	Professional lead for nursing within the organisation
Medication Safety Officer	Local	Pharmacist (Chief II) – Subject to the direction and supervision of Chief 1 Pharmacist. The Medication Safety Co-Ordinator is responsible for co-ordinating efforts to minimise risk to patient safety arising from the use of medication within the hospital
Curriculum Developer- safe medication administration education programme	Local	Registered Nurse Tutor- Nurse Education Centre
Professional Officer - Education	Nursing and Midwifery Board of Ireland– nursing registration body	Maintaining professional standards- led on update of professional guidelines on medication management for nurses and midwives
Clinical Lead- National Medication Safety Programme	Department of Health/ Health Service Executive	Pharmacist – Quality improvement Diversion
Director of Nursing and Midwifery - Office of the Nursing and Midwifery Services Directorate (ONMSD)	Department of Health/ Health Service Executive	Primary focus in the strategic development of Nursing and Midwifery to provide optimum patient centred care, leadership, supporting excellence and innovation and building capacity in nursing and midwifery to enhance patient care and service delivery

Table 4.3 Description of interviewees

All interviews took place in a venue of the interviewees choosing. Participants selected for interview were contacted via e-mail with a Participant Information Leaflet (Appendix 7) in relation to the study. All participants were asked to sign a Consent Form and interviews were audio recorded. Measures taken to safeguard confidentiality and anonymity were discussed in Chapter 3- 3.11.

4.4.2 The interview

In realist evaluation publications, little detail has been provided on the interview process. However, Manzano (2016) reported the interview process to be unproblematic. Interviews in Stage 1 of this research 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. In this stage the respondent's role is to help the researcher articulate first order theories (Manzano 2016). These theories identified how the contextual circumstances of the safe medication administration education programme may impact the behaviour and effectiveness (Manzano 2016). A semi-structured interview guide was drawn up based on the literature review and the document analysis. A structured interview guide was not utilised as set questions and a pre-determined response of a structured interview would provide little opportunity to question, or even understand, the chosen theoretical framework (Pawson 1996). Unlike other forms of qualitative interview, the objective of realist interview is not to elicit participant's narrative; rather it involves the use of exploratory questions to draw out the propositions of general enquiry (Manzano 2016). Questions posed and explanatory cues offered were done so in order to put the subject in a position which would allow them to think about the directions the interview was exploring.

Based on the recommendations of Manzano (2016), the topics covered reflected the objectives of the research as a whole and were related to the further development of the conjectured CMO configurations. 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). For example, the interview guide for the Medication Safety Officer in the organisation focused on the structure and local context of their role and on medication incident reporting. While the interview with the Clinical Lead of the National Medication Safety Programme took a more national approach discussing national quality improvement plans (Appendix 8 - Sample Semi-Structured Interview Schedule).

In realist interviews the evaluator needs to control the direction of the conversation while asking about the programme and also about the theories that the programme adopts (Manzano 2016). This relationship is contextually different from other qualitative interviews as it takes place in the context of evaluation, and evaluation for realist is about '*assisted sense making*' (Mark et al. 1999, p 179).

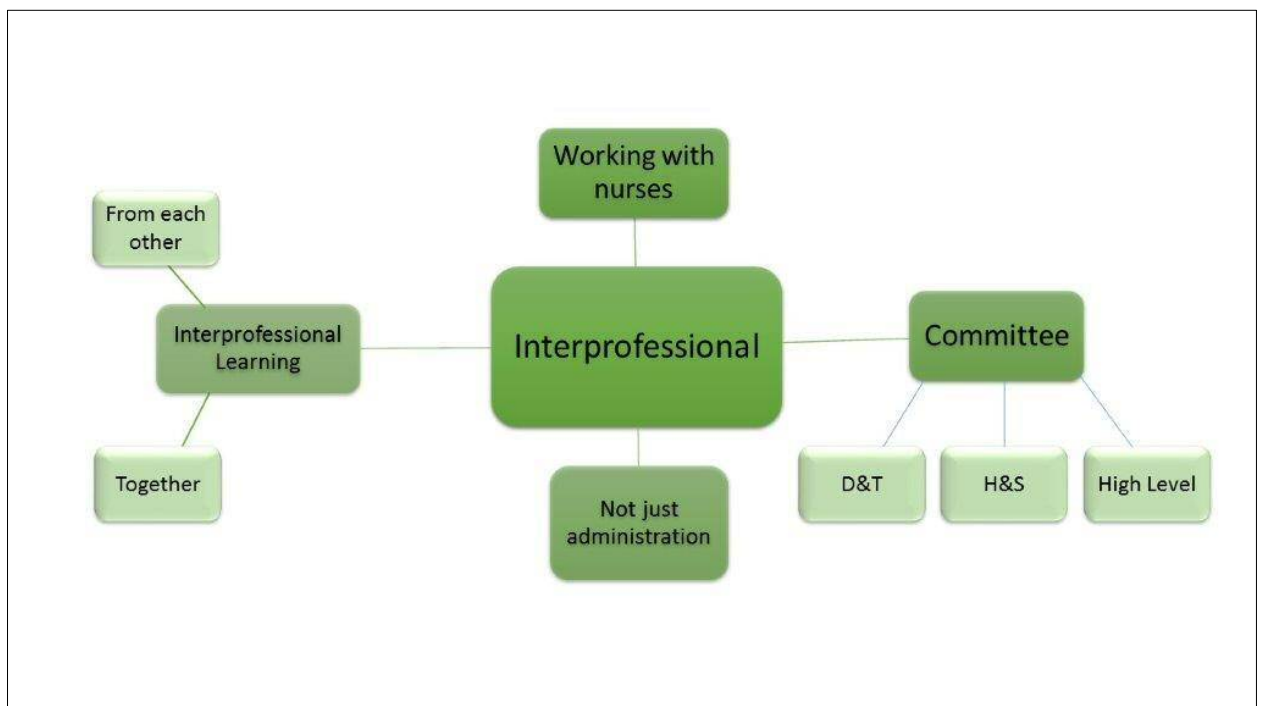
4.4.3 Analysis of interview data

Interviews lasted between twenty-one and forty-one minutes and were transcribed verbatim. The audio and text were uploaded to NVivoTM (10). The first phase of analysis began with listening to the interview audio and reading the transcripts. This also allowed for me to review the data, situate it and check the quality of transcription (Bryman 2016). Following this, each interview was individually read and re-read and then I began to generate initial codes in a systematic fashion. Similar to the document analysis, thematic analysis utilising the Braun and Clarke (2006) framework was used for the analysis of interview data (see Table 4.1).

Codes were generated inductively and independently of the codes produced in the document analysis. All data relevant to each code was grouped together via NVivoTM (10). Codes generated from all interviews were collated and grouped together and themes began to emerge. Similar to the document analysis, thematic maps were produced of themes, codes and their relationships. Initial themes from the interviews are detailed in Table 4.4. An example of a thematic map is given in Figure 4.2. This figure illustrates the thematic map for the theme Interprofessional.

Themes identified in interview analysis	
Legislation	Interprofessional
Professional standards	Education and resources
Organisational structure	Change Management/Quality Improvement
National Initiatives	Individual motivation
National structures	Philosophy of education
Leadership	Error Reporting
Organisation Values and Goals	Patient harm
Physical environment	Professional practice
Measuring impact	

Table 4.4 Initial themes from interviews



D&T- Drugs and Therapeutics Committee/ H&S- Health and Safety Committee

Figure 4.2 Thematic Map- Interviews: Theme-Interprofessional

4.5 Document and Interview Data Analysis

The next phase involved the deep analytic work of thematic analysis which was crucial to the shaping of the analysis into its fine-grained detail. During this phase, analysis was conducted with data sets from the document analysis and the interview analysis. Themes from both the document analysis and interview analysis were reviewed, compared and collapsed with new formations emerging. Prior to merging or collapsing themes across the data sets, all data in relation to an identified theme was reviewed. As this process was undertaken, thematic maps were developed to assist in the process. The thematic map for the theme Multi-disciplinary Collaboration can be seen in Figure 4.3.

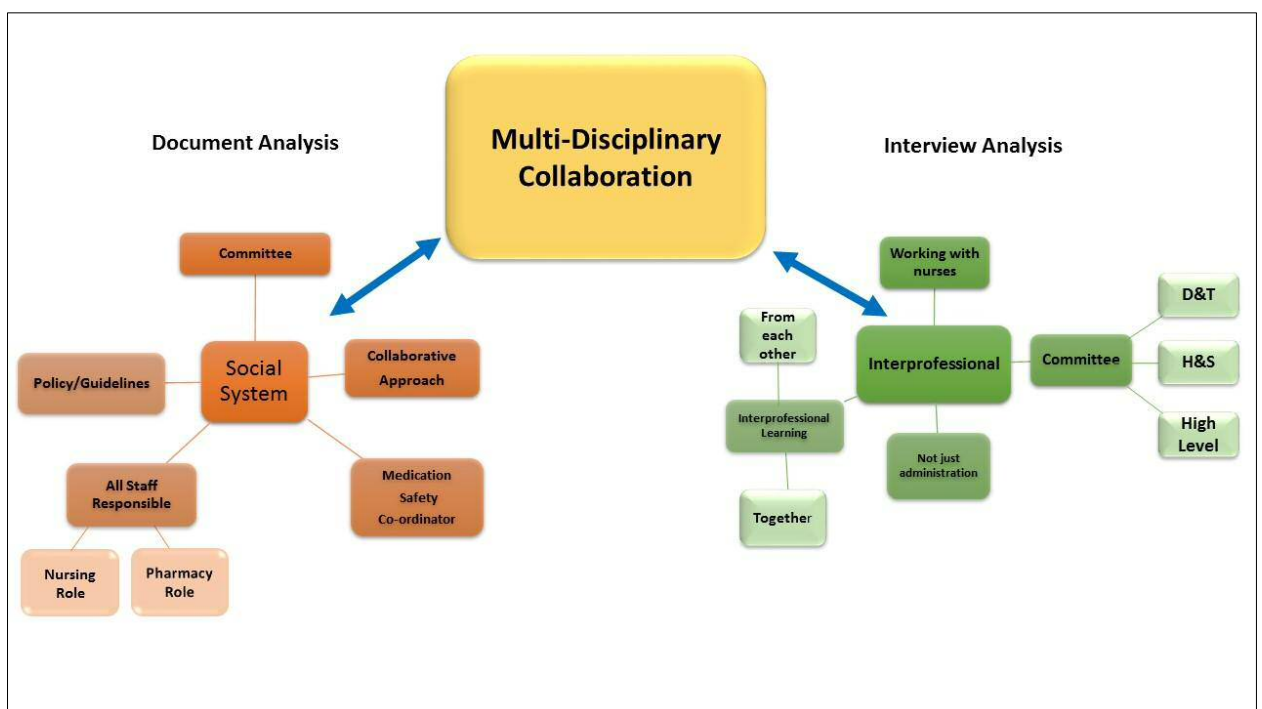


Figure 4.3 Formulation of theme: multi-disciplinary collaboration

This process was repeated for each theme as they were collapsed and merged. Final themes and their origin from the document analysis and or interview analysis are illustrated in Table 4.5. Ongoing analysis provided an opportunity for themes to be refined and allowed for the overall story of the analysis to be told. This provided for the generation of names and clear definitions for each theme (Braun and Clarke 2006), which was deemed essential when allocating themes according to context mechanism outcome configurations. The definition of themes is identified in Table 4.6.

Document Analysis	Interview Analysis	New Theme
Social system	Inter-professional Organisational structure	Multi-disciplinary collaboration
Incident reporting	Error Reporting Patient harm	Incident/near miss reporting
Leadership and peer support	Leadership	Leadership
Organisational goals Work setting	Organisation Values and Goals Physical environment	Safety focused organisation
Organisational culture Patient safety		Patient safety culture
	Professional standards Legislation Professional practice	Professional standards
	National Initiatives National Structures	National initiatives and structure
Opportunity to apply learning	Change Management -Quality Improvement	Change management/quality improvement
	Enabling behaviours Individual motivation	Receptivity to change
	Education and resources Philosophy of education	Critical thinking
	Measuring impact	Measuring impact/nursing metrics

Table 4.5 New formulations of themes

New Theme	Description of Theme
Multi-disciplinary collaboration	Working within and between disciplines and teams to maintain medication safety and to create a culture for medication safety. The culture of the organisation already exists and will not be changed by the safe medication administration education programme.
Safety focused organisation	Incorporates the organisations goals and values. It also incorporates the physical environment and it is the role of the organisation to ensure the physical environment supports medication safety. Individuals have to modify behaviour and medication administration practices based on the physical characteristics of the organisation's environment.
Patient safety culture	Overall hospital vision and goal- can be measured to some degree by the reported numbers of serious incidents.
Leadership	The role of the Clinical Nurse Manager (CNM) in facilitating change of practice and influencing change as well colleagues.
Professional standards	Setting out the legal responsibilities and accountable of the registered general nurse- this cannot be changed or manipulated by any programme therefore is classified as a context. Developed by the NMBI (registration body).
National initiative and structures	National policy and quality improvement plans and governance which influence both organisational changes and developments in structure and process of patient safety).Set standards of professional practice that cannot be influenced by the education programme.
Change management/ quality improvement	Involvement of participants who have undertaken the safe medication administration education programme in the management of change and improvement in the practice of administration of medication.

Table 4.6 Definition of themes

New Theme	Description of Theme
Receptivity to change	Education and resources other than those provided by the safe medication administration education programme-allow the application of the programme in practice and establish the culture of the organisation.
Critical thinking	From the philosophy of education and the knowledge to think about the practice of administration of medication.
Measuring impact/nursing metrics	Difficult to measure. National project on nursing metrics to measure documented care received.
Incident/near miss reporting	Reported errors or near misses with medication administration- can be quantified figure. However, not all incidents are reported. Also, reporting is not seen as a negative outcome but as a positive outcome, as if incidents and near misses are reported it allows management an opportunity to address flaws in the system.

Table 4.6 Definition of themes (contd)

4.6 Formulation of Conjectured Context Mechanism Outcome Configurations

4.6.1 Conjectured CMO configurations

In realist evaluation, explanation is the primary role and this takes precedence over description (Wilson and McCormack 2006). Realist evaluation considers programmes as theories and suggests that the evaluator's role is to understand what works, for whom, and in which circumstances (Pawson and Tilley 1997, 2005; Contandriopoulos and Brousselle 2012). Realist evaluation stresses the need to evaluate programmes within "context," and to ask what "mechanisms" are acting to produce which "outcomes." The realist evaluation approach considers the social processes as an important factor in understanding why a programme does or does not work in particular circumstances (Pawson and Tilley 1997). Thus, propositions combine to form a trio of explanatory components which are context-mechanism-outcome (CMO) configurations. Evaluators construct their explanations around these three crucial ingredients of any initiative: context (C), mechanism (M) and outcome (O) (Pawson and Tilley 1997). A conjectured CMO configuration is the starting point for the evaluation, this is a proposition stating what it is about an initiative which works for whom in what circumstances. This conjectured CMO configurations is further developed, refined and tested in the latter stages of the evaluation.

Realist evaluation aims to define generative causation (Pawson and Tilley 1997). However, this is dependent upon the ability of the study to test sets of propositions about CMO configurations (Tolson et al. 2007). Thus, the overall purpose of Stage 1 was to develop conjectured context mechanism outcome configurations as propositions or hypotheses which I was to test in the later stages of the research. In order to do so it was necessary to ensure that the conjectured CMO configurations were developed from the data in Stage 1 and written in a manner so as to ensure that these conjectured CMO configurations could be tested in the further stages of the study.

Following the identification of themes and in order to progress to Stage 2, it was necessary to allocate the themes into the designated categories of context, mechanism or outcome. The purpose of this was to render the programme theory or safe medication administration education programme into its constituent and interconnected elements. Thus, verifying if the right processes operate in the right conditions then the programme will prevail (Pawson and Manzano-Santaella 2012). Prior to the allocation it was first necessary to examine the realist interpretation of context, mechanism and outcome.

4.6.2 Context

In this research, Pawson and Tilley's (1997) understanding of context as referring to interpersonal and social relationships connected to situations and localities, was utilised as the 'backdrop' of interventions (Lacouture et al. 2015). In realist inquiry, four concentric layers of context are typically defined: (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). Context is seen to be about the capabilities and resources which people derive from belonging to a particular layer of stratified reality (Befani et al. 2007). These capacities and resources constrain actors' choices and modify their reasoning. However, Salter and Kothari (2014) warn that context should not be merely equated to location or setting but needs to include examination of roles and relationships, demographics, economic conditions and technology.

Pawson and Tilley (1997) provide an example of realist evaluation with reference to crime prevention and found that the installation of closed circuit television cameras (CCTV) alone

does not reduce crime. Rather, the cameras work by instigating a chain of reasoning and reactions in potential criminals. Realist evaluation is therefore about developing theory of the mechanisms through which the potential criminal thinks about CCTV, and the contexts needed to trigger such thinking. Nevertheless, context does not stand independently, by interacting with mechanisms through its constraining and enabling factors, context determines the direction of outcomes and change (Lacouture et al. 2015).

4.6.3 Mechanism

Identifying themes which address the mechanism in the formation of conjectured CMO configurations provided the greatest challenge. Astbury and Leeuw (2010) put forward that while mechanism is part of the evaluation language, they are less confident that it is applied correctly in practice. Therefore, it is essential that there was no confusion between programme measures and programme mechanisms (Astbury and Leeuw 2010) and this was crucial for me when I was constructing conjectured CMO configurations. In this realist evaluation, a mechanism was seen as focusing on developing an explanation of how the safe medication administration education programme may work through changing the reasoning and responses of participants in order to bring about a set of intended outcomes (Dalkin et al. 2015).

Programme mechanisms capture the many different ways in which the resources on offer may impinge on the stakeholders' reasoning (Pawson and Tilley 1997). In the philosophy of realism, mechanisms penetrate to the layer beneath, attempting to explain how particular measures work. Astbury and Leeuw (2010) identify three fundamental aspects of the concept of mechanism which is in line with 'realist' principles: mechanisms (1) are usually hidden, (2) are sensitive to variations in context, and (3) generate outcomes.

In order to avoid confusion between mechanisms and variables, a clear understanding of the term 'mechanism' and how it operates is required (Astbury and Leeuw 2010). Although variables and mechanisms can perform complementary functions in evaluation research, it is important to avoid conflating the two as to do so would risk losing the explanatory power of mechanisms. From a methodological point of view, mechanisms should reside at a level of abstracting above that of variables (Astbury and Leeuw 2010). Consequently during this

phase of analysis I needed to be clear that the mechanisms are not interventions or activities but they are what make an intervention or activity work.

Mechanisms are about how participants interpret and act on an intervention and are not directly observable (Pawson and Tilley 1997). This understanding of mechanism was also relevant in Stage 3 of the research, when observation and follow up interview were used to test the conjectured CMO configurations. Mechanisms can be 'constraining' when an intervention fails and/or 'enabling' when an intervention is successful in a particular context (Pawson and Tilley 1997). An example of the process of identifying a mechanism in this study is detailed in section 4.7.1.

4.6.4 Outcome

The final component of the CMO configuration is the outcome. The outcome of the configuration can be identified most easily (Dalkin et al. 2015). In this research, the outcome components were clearly identified and themes emerged of incident/ near miss reporting and measuring impact.

4.7 Preparing Conjectured CMO Configurations

Upon completion of analysis of the relevant documents and the interview transcripts, the themes were then used to identify conjectured context mechanism outcome configurations. These were then brought forward for further refinement in Stage 2.

The allocation of themes to context, mechanism or outcome was a challenging process. Pawson and Manzano-Santaella (2012) identify this as a methodological problem, as it is the same body of data or qualitative evidence which is available to be categorised as a context, a mechanism or an outcome. I was not alone in experiencing difficulty at this junction. Dalkin et al. (2015) acknowledge that deciding whether aspects within an intervention implementation process in a realist project contribute contextually or mechanistically to the overall explanatory endeavour, has become the realist researcher's quandary. Indeed, Tolson and Schofield (2012) identified that this process in theory is fine, but in practice they found that differentiation between context and mechanism was problematic as programmes do not come in pre-ordained chunks called contexts, mechanisms and outcomes. Rather these terms take their meaning from their function in explanation and their role in testing those explanations (Pawson and Manzano-Santaella 2012).

Currently, there are no standardised, methodological guidelines available for application of realist evaluation and thus, how CMO configurations are to be developed. Salter and Kothari (2014), in a systematic review of realist evaluations of knowledge translation, found that details as to how CMO configurations were constructed varied and also that relatively few completed evaluation studies described how they undertook this process.

In order to combat this difficulty, the recommendations of Pawson and Manzano-Santaella (2012) were adopted and I began by defining the explanatory role of each theme. Tolson and Schofield (2012) also recommend this approach, as the elements of contexts and mechanisms are not always 'clear cut' and go on to suggest the need for tight operational definitions of each term. The definitions for each theme have previously been identified in Table 4.6.

Prior to a theme being allocated, to context mechanism or outcome, each theme was reviewed in terms of context based on Pawson's (2006) 4 layers. 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 box, 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 identification was self-evident.

If a theme appeared to fit into context and mechanism, the theme was revisited and teased out. Revisiting the theme involved reviewing the supporting data in NVivo™ (10) and also the thematic map which formed it. This involved revisiting Phase 4 and 5 of the Braun and Clarke (2006) thematic analysis framework.

4.7.1 An exemplar of grappling with context or mechanism allocation- Multi-disciplinary collaboration

The allocation of the theme multi-disciplinary collaboration proved a challenge. On reviewing the data analysis that had been conducted in NVivo™ (10), the code and theme mind maps were reviewed again as in Figure 4.3.

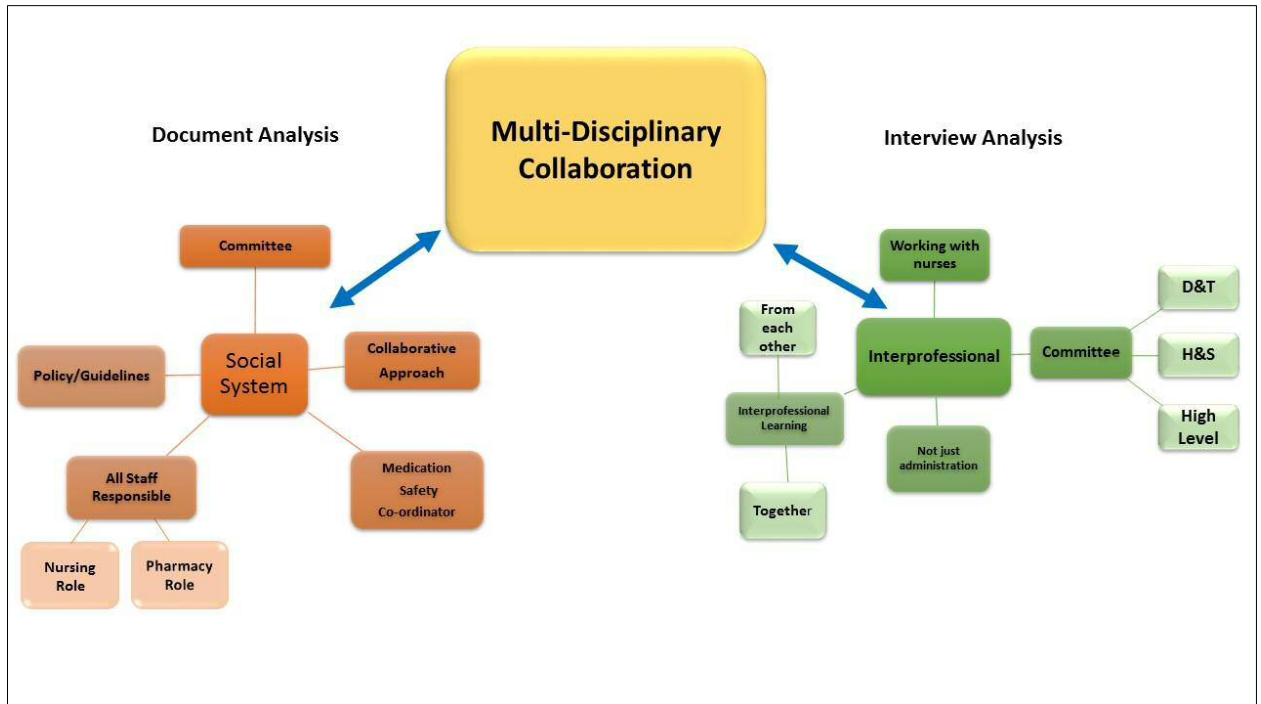


Figure 4.3 Formulation of theme- Multi-Disciplinary Collaboration

Several codes contributed to the overall theme of multi-disciplinary collaboration. In the document analysis, reporting systems for near misses and incidents were coded as social systems. The reporting relationship of the Medication Safety Officer to the Chief Pharmacist was also seen as part of the social system. This coding provided more information about the organisation, in that medication safety was under the remit of the pharmacy department and not under the direct remit of the CEO as a major patient safety issue.

In the analysis of interview data, two codes contributed to the theme, they were inter-professional and multi-professional working and its significance in medication safety. In interview 3 the respondent reported that:

“So nurses have huge responsibilities, but I also think that it's probably shared responsibilities that that message needs to get out so there can be more inter-professional learning which I don't know how much of that is-- I think some of that is happening.”

"..an inter-professional activity and it starts with the point of assessing the patient whether that would be the doctor in terms of saying, "We're going to give you X for this condition." To the pharmacist who's saying, "Hmm, well, maybe that drug in relation to the other drugs that you're on might not be the best choice." And so that the nurse has these resources available, can gather that information, inform their decisions"

The respondent in interview 3 clearly addressed the need for inter-professional collaboration, to ensure that the right medication reaches the right patient and all aspects of safe medication administration are adhered to. The respondent also identified the need for inter-professional learning from practice. The respondent in interview 1 also identified the involvement of all multiple disciplines in the administration of medications:

"a lot of the issues with the same high risk meds, administration might be a part of it. Administration maybe and monitoring might be a part of it, but there would be multiple disciplines involved in improving that process then"

While the safe medication administration education programme is targeted at nursing staff, the context in which it takes place is essential to its success or failure. Multi-disciplinary working is an essential subset of the culture in the organisation in relation to medication safety. Medication management is a complex multi-stage and multi-disciplinary process, involving doctors, pharmacists, nurses and patients (Adhikari et al. 2014). Errors can occur at any stage in the medication management process from prescribing, dispensing and administering, to recording and reporting.

From the review of the data it can be seen that multi-disciplinary collaboration is positioned as part of the institutional setting encompassing both the infrastructural system in how roles such as the Medication Safety Officer is operationalised and also in relation to the cultural aspect of the organisation. Thus multi-disciplinary collaboration was allocated to context.

4.7.2 The conjectured CMO configurations

Following data analysis, the themes were allocated to context, mechanism or outcomes as seen in Table 4.7. Before each theme was allocated, it was teased out and examined in line with the context and mechanism principles as discussed. Further refinement of themes occurred at this point also. While it is possible that more than one mechanism may be at

work at any one time to effect the change associated with the outcome, the activation of that mechanism depends upon the context in which the participants work.

Theme	Context mechanism or outcome	Allocation to CMO
Multi-disciplinary collaboration	The institutional setting, encompassing the cultural aspects of a given contextual domain	Context
Safety focused organisation	The broader infrastructural system, the outermost layer (incorporated into application of national initiative and patient safety culture- not tested as a specific context)	Context
Patient safety culture	The institutional setting, encompassing the cultural aspects of a given contextual domain	Context
Leadership	The institutional setting, encompassing the cultural aspects of a given contextual domain- (contributes to patient safety culture)	Context
Professional standards	The broader infrastructural system, the outermost layer (not tested in CMO configurations, as all testing was undertaken with registered nurses and thus, this is inherent to registration)	Context
National initiatives and structures	The broader infrastructural system, the outermost layer	Context
Change management-quality improvement	Is sensitive to variations in context	Mechanism
Receptivity to change	Changing the reasoning and responses of participants	Mechanism
Critical thinking	Is sensitive to variations in context	Mechanism
Incident/near miss Reporting	Measurable end point	Outcome
Patient harm	Overall end point	Outcome
Measuring impact/Nursing metrics	Endpoint	Outcome

Table 4.7 Further refinement and allocation to context, mechanism or outcome

Some themes were further merged in order to develop the conjectured CMO configurations.

Stage 1 conjectured CMO configuration 1 is: ***Registered nurses, who undertake a safe medication administration education programme in an acute hospital with a positive patient safety culture, may adopt critical thinking skills in medication administration which may led to reduced patient harm.***

Registered nurse in this configuration includes the theme professional standards as professional standards need to be applied for continuing registration with the nursing board. For the context, positive patient safety culture was considered to incorporate the safety focused organisation, organisational structure, leadership and organisation values and beliefs. For the mechanism, critical thinking was seen to include the philosophy of the education programme. For the outcome patient harm it was also seen to include incident and error reporting. `

Stage 1 conjectured CMO configuration 2 is: ***Registered nurses, who undertake a safe medication administration education programme in an acute hospital which adopts national policy on medication safety, may adopt a quality improvement approach to medication administration, which may lead to reduced patient harm.***

Registered nurse in this configuration includes the theme professional standards as professional standards need to be applied for continuing registration with the nursing board. Adopting national policy on medication safety was allocated as context in this configuration and a quality improvement approach was seen as a mechanism factor. Again for the outcome patient harm was also seen to include incident and error reporting.

Stage 1 conjectured CMO configuration 3 is: ***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.***

Registered nurse in this configuration includes the theme professional standards as professional standards need to be applied for continuing registration with the nursing board. Multi-disciplinary collaboration towards medication safety was allocated as a context construct. The mechanism factor identified for this configuration is receptivity to change. Receptivity to change incorporates the themes of individual motivation, enabling behaviours

and attitudes. Again for the outcome patient harm was also seen to include incident and error reporting.

4.8 Rigor

The use of multi data sources and methods of data collection allows theories to be built with relevance and rigor (Pawson 2013). The use of multiple sources and methods employed in this realist evaluation allowed the researcher to understand how each fragment of evidence contributes to the explanation and interpretations and how the safe medication administration education programme works and how these ideas are tested and refined within and between those fragments (Emmel 2013).

The semi-structured interview template was designed based on the document analysis and reviewed by my supervisor prior to conducting the preliminary interview. Following the completion of the first interview, some modifications were made to the structure of the tool. I also maintained a reflective diary to assist with recall of the interview process and to assist in the development of my interview skills.

Thematic maps were maintained to support decision making, and to assist in writing up the data analysis process and to provide an audit trail. Throughout the process of data analysis, regular supervision was undertaken and the discussion was based on this process. This was particularly important when allocating themes to context, mechanism or outcome. Extensive reviewing and debating took place between us in relation to which theme belonged to which category.

In order to clarify the quality of the conjectured CMO configurations, Stage 2 involved the presentation of these conjectured CMO configurations to three experts in order to further refine them.

4.9 Conclusion

This chapter has provided the details of the collection and analysis of data in order to develop three conjectured CMO configurations. In order to determine these provisional CMO configurations, an extensive document analysis and six key stakeholder interviews were undertaken. Thematic analysis of data took place using the Braun and Clarke (2006) framework. This thematic analysis framework is used throughout Stages 2 and 3 of this realist evaluation. The formulation of three conjectured CMO configurations brought this

stage to an end but as realist evaluation is an iterative process, the analysis of data obtained from this stage continues through the next stages. Stage 2 is reported in the Chapter 5, which describes how I went about refining the conjectured CMO configurations.

Chapter 5- Stage 2 Theory Refinement

5. 1 Introduction

This chapter presents Stage 2 of the realist evaluation process. Stage 2 involved refining the programme theory and the conjectured context mechanism outcome configurations put forward at the end of Stage 1. This chapter also discusses the selection of experts for interview, the realist interview, data management, analysis and findings. The chapter concludes with a discussion and reformulation of the conjectured context mechanism outcome configurations to be tested in Stage 3.

5.2 Selection of Interviewees/ Experts

Interviews were conducted as part of the programme theory refinement process. Manzano (2016) iterates the importance of purposefully selecting interview candidates based on the evaluator's hypotheses. Each component of the conjectured CMO configuration; contexts, mechanisms and outcomes, triggers the need for a different kind of respondent therefore as in Stage 1, respondent selection was based on their CMO investigation potential (Pawson and Tilley 1997). In Stage 2, interviews for refinement of the conjectured CMO configurations were undertaken with three purposefully selected experts. Interview respondents from the field of continuing professional education, patient safety and medication safety were invited to participate. Table 5.1 contains the details of the experts who took part in the interviews in Stage 2. In line with realist principles, these experts were not seen as research subjects but as key informants with the power and knowledge about how the safe medication administration education programme might be working (Manzano 2016).

Respondents were contacted by e-mail with the Participant Information Leaflet and Consent attached (as Stage 1, Participant Information Leaflet and Consent). All respondents who were approached to take part in Stage 2 consented to do so.

Interviewee	Description	Internal or External
Expert 1	Expertise in professional development for nursing and in national and international professional nursing issues	External to organisation
Expert 2	Head of Quality and Patient Safety – National expertise on patient safety and quality	Internal to the organisation
Expert 3	Head of Pharmacy Services/ expertise also at a national level on medication safety	Internal to the organisation

Table 5.1 Expert details for interview: Stage 2

5.3 The Interview

5.3.1 The realist interview

The principles of realist interviewing were applied when undertaking the interviews with experts in Stage 2. Pawson (1996) postulates that in realist interviews the researcher's programme theory (conjectured CMO configurations) is the subject matter of the interview, and the interviewee is there to confirm or falsify that theory, but above all to refine the programme theory. Likewise, Manzano (2016) describes how at this time theories are put in front of the interviewee for them to comment on, with the view to providing refinement of the conjectured CMO configurations. This guidance appears clear; nevertheless, I struggled with how I could apply this principle. Multiple questions arose for me. 'Do I write out my conjectured CMO configurations and show them to the interviewee?' 'Do I send it to them before hand?' 'Do I read it for them and ask what do you think of that'? At this point I sought guidance and posted a question on the discussion board for JISCMail for the RAMESES community. Ana Manzano, who is the author, of the 'The craft of interviewing in realist evaluation' responded advising to ask board questions in relation to my context, mechanism and outcome. This is further discussed in Chapter 11 (11.4.3). Based on this advice, the conjectured CMO configurations were 'presented' to the experts during the interview. The presentation of the conjectured CMO configuration was done through the interview questions. Interview guides were constructed based on the conjectured CMO configurations. An example of such questions is offered in 5.3.2 teacher learner cycle.

The design of my interview guides reflected the dynamic principles of realist interviewing and the interview contexts (Pawson 1996). Questions on the interview guide were constructed in order to refine the conjectured CMO configurations or to discard them

(Manzano 2016). The interview guides were semi-structured, containing exploratory questions based on the conjectured CMO configurations, and acting as instruments to draw out the propositions of the general inquiry (Manzano 2016). In this stage, the refinement of programme theory, 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 conjectured CMO configurations (Manzano 2016). This was necessary as the process of elucidating and refining the conjectured CMO configurations is iterative, and therefore the context in which each of the realist interviews occurred was dissimilar (Manzano 2016). Thus, interviews were undertaken using a semi structured interview schedule which was specific to each interviewee. Each of the three interview schedules was varied depending on the refinement stage and the stakeholders' awareness and experiences of the programme, including their reasoning (Dalkin et al. 2015) about specific propositions. The schedule acted only as a prompt for the researcher in order to ensure all subject areas were covered. A sample of Stage 2 semi structured interview can be found in Appendix 9.

5.3.2 Teacher learner cycle

Even though the same instruments are used in the realist interview as any qualitative interview, Manzano (2016) cautions that it is important to remember that the objective of the interview is not to gain the respondent's narrative but to confirm or deny the developed propositions. Pawson (1996) describes the process for realist interviews as a 'teacher-learner' cycle. This style of interviewing is where the evaluator 'teaches' the interviewee about the programme theory under review, and the interviewee is able to teach the evaluator about the components under review from their expert viewpoint (Pawson and Tilley 2004). Manzano (2006) describes this as asking questions like a realist. I adhered to this principle during the Stage 2 expert interviews. An extract from the interview with Expert 3 follows. This is extracted from the segment of the interview where conjectured CMO 2 is being discussed.

Interviewer: talking about governance and reporting as well, what I've come across and a lot of people have spoken about it, is the importance of the multi-disciplinary approach within an organisation or within a culture. Do you think that needs to be there in order to get this change in people's actions and people's thinking? Do we need a good strong multi-disciplinary approach and team to do that? Or does each discipline need to work in their own area?

Expert 3: *Oh, it has to be multi-disciplinary, yeah. There are elements within each discipline that are specific to them, so if you take even something like the medication process, so the medication process even though it starts in a lot of cases with the prescribing, and we talk of the triangle between, or even probably the fourth element in terms of the monitoring, but you've got the prescribing, the dispensing, the administration and the monitoring. But it really starts before then, which is actually the selection and the supply of the product in terms of when we receive the product into the pharmacy - and this is the multi-disciplinary element to it - we should really be purchasing for safety. So we should be purchasing products that if there's a risk that product could be... so it links into the safe... things like SALADs*... if there's a risk that it could be confused with another product, we should be identifying that at the earliest stage where we can. And then the same with administration issues. So any product that comes into the hospital when it's new, not only should be assessed on cost, but also should be assessed on, "Is it introducing a potential risk?" The multi-disciplinary element then is really, I think, very important, and that's why I suppose at a committee like D and T*, you have strong representation from nursing, pharmacy and consultants and NCHDs*, that it's across all three, and now with a director of quality in patient safety on D and T as well. So, yes. In short, the answer is yes, I do believe that it's better to have it multi-disciplinary, but also there are elements whereby I think can all learn from each other. Yeah, yeah."*

*SALADs- Sound alike, look alike drugs

*D&T- Drugs and Therapeutics Committee

*NCHDs- Non-Consultant Hospital Doctors

As can be seen in the example, a refined conjectured CMO 2, a tentative programme theory was presented to Expert 3. The extensive response from Expert 3 clearly shows how he used his expertise to respond to the proposition put before him. This provides a clear demonstration of the utilisation of the teacher learner cycle.

5.4 Data Analysis

The principles of realist evaluation were maintained during the analyses of interview data in Stage 2. The analysis of data throughout this evaluation project involved moving back and forth between all stages. This process is in line with Pawson's (2006) recommendation whereby realist analysis should not be defined as a separate stage of the research process

but as an on-going iterative process. Likewise, Manzano (2016) theorises that the analysis of realist data should not be a technical process consisting of coding verbatim text on completion of fieldwork, then trudging out a few themes constructed from multiple subthemes and labelling them as contexts, mechanisms and outcomes. An example of the iterative process of moving between stages is discussed in 5.5.2.2 Critical thinking skills.

Interviews were transcribed verbatim and entered into NVivo™ (10). Interviews were analysed using a hybrid approach of inductive and deductive analysis. The majority of analysis was conducted deductively. The deductive analysis used a framework provided by the three conjectured CMO configurations. There were seven codes which related to context mechanism and outcome. The framework for the code book can be found in Appendix 10. The focus of the expert interviews was to confirm the context and mechanism configurations and linkages between both. Analysis of the transcripts was not confined to the predetermined codes, but inductive codes were assigned to sections of the text that were not covered by the predetermined codes. In this data analysis only two inductive codes were created; these were the code 'reasoning' and 'organisational governance structures'. The inductive application of only two new codes can be attributed to the fact that this analysis was based on realist interviews where the subject of the interview was the conjectured CMO configurations.

5.5 Findings and Discussion

5.5.1 Introduction

For the purpose of this chapter, findings from the analysis are reported in a linear manner. However, as discussed earlier the analysis of findings were iterative with the findings of one interview influencing the interview schedule for the next interview. The findings from the analysis of this phase were utilised in the development of the observation tool for Stage 3 of this study.

5.5.2 Conjectured CMO 1

Registered nurses, who undertake a safe medication administration education programme in an acute hospital with a positive patient safety culture, may adopt critical thinking skills in medication administration, which may lead to reduced patient harm.

5.5.2.1 Positive patient safety culture

Analysis on a patient safety culture was mainly conducted from the data extracted from Expert 2 and 3 as this was their specific area of expertise and purpose of selection. The experts agreed that the culture of an organisation needs to have a positive patient safety focus in order to support medication safety.

Expert 2 described what a positive patient safety culture looks like.

Expert 2 *“ to me a positive culture in relation to patient safety are people actively dealing with and freely talking about incidents as well, so this would be done in clinical teams, MDT settings, morbidity or mortality meetings - a willingness to discuss what went wrong and I suppose, while I know the medical world quite well in that we're trained from day one to be perfectionists - nothing goes wrong - I think it's probably the same in nursing and other healthcare professions as well - in that almost a denial that errors happen, when in fact in reality, errors happen every single day, and we know that”*

Likewise, Expert 3 used similar language to describe what a culture of patient safety looks like and described medication safety.

Expert 3 *“I think the culture needs to be one that fosters a healthy level of reporting for incidents. So if it's a medication safety system there should be a healthy system whereby, again focused on the process rather than the individual, that incidents are reported; there's a feeling by the person who's reporting the incident that the incident will be reviewed and that there will be appropriate action taken based on the incident”*

A positive patient safety culture is also based on the structure of the organisation and governance structures which are in place. Expert 2 was internal to the organisation under study and gave a clear description of how the organisation's structures support patient safety and medication safety.

Expert 2 *“Well, it's setting out a clear direction and a clear commitment that patient safety is top of the list, and in terms of priorities. You know, there's good governance structures; there's a patient safety executive chaired by the CEO, so that's a very strong sign of commitment that this is serious. It meets every month. That reports into the executive management team - again, very strong. The board of the hospital has a quality, risk and patient safety sub-committee, so again that's going up the line. So from the floor of the ward*

to the board, there's a clear line of communication and a clear message, that's the underlying message that safety is important. So that's at an organisational level, that's setting the tempo and the culture”.

Patient safety culture within the organisation was accepted as a context which was brought forward to Stage 3 for testing.

5.5.2.2 Critical thinking skills

As already discussed, the purpose of the realist interview at this stage was to refine theories proposed. The exploration of the mechanism ‘critical thinking skills’ was an element which was found to require further refinement. During the interview with Expert 1, specific questions were asked in relation to critical thinking. However, in response she spoke about knowledge requirements for medication administration rather than critical thinking.

Following the analyses of the data from Expert 2, it became clear that the mechanism ‘critical thinking skills’ would require further refinement.

Expert 2: *“While I know the phrase critical thinking and critical reading and if you put that phrase out there it scares the bejesus out of people and puts people off because they don't quite understand it and as I said, it's an academic... it has its place and it's very important but it does tend to worry people a little bit”*

Stage 2 is about the refinement of programme theory, with the role of the interviewee to further refine the theory (Manzano 2016) and thus, I had anticipated that refinements would be required. Following the interview with Expert 2, I attended a realist methods workshop in London where I had the opportunity to discuss refining this mechanism and presenting it at the next expert interview. I presented this issue to peers and the facilitator of the workshop. The topic of the Expert 2 refuting my mechanism on critical thinking was discussed, and the advice and discussion recommended that, perhaps, in my next interview I change the wording and use terms such as thinking about practice or reasoning.

There was only a short period of time between doing preliminary analysis on the Expert 2 interview and undertaking the interview with Expert 3, so I was unable at this stage to revisit the data collected from Stage 1.

Questions posed to Expert 3 related to change of thinking following education programmes and how this was applied in practice. Expert 3 responded positively to questions on this theme.

Expert 3: *"I think when somebody has an understanding of... when you look at it in terms of process and system, that the administration part of medication is one loop in the chain of lots of other steps that take place, and having an understanding of each of the steps and where things can go wrong, creates a good awareness of risk; risk awareness and risk identification, and potentially creates an opportunity for people to be more proactive. So, rather than the actual incident or something happening all the way, that by doing a programme in safe medication administration, you'd hope that the individuals that come through that programme would also, because of their awareness of incidents and risk, may also be more proactive in terms of identifying certain administration steps or processes that they feel they'd like to change".*

As the process of analysis in realist methods is iterative, following the Stage 2 interviews, I revisited the data collected from Stage 1 in relation to the critical thinking mechanism and retraced the process of this theme formation. In doing so, I applied a principle from Pawson (2006) who put forward that a programme theory may be gleaned, refined or consolidated not necessarily in the next interview, but also while digging for nuggets of evidence and thus reviewed existing data.

The label critical thinking originated from interviewee 4 (Stage 1), who was involved in the education programme development. She had spoken about how the education programme incorporated elements of '*critical analysis*' and aimed to promote '*critical thinking*'. The mechanism had been named critical thinking after the amalgamation of the themes individual motivation and change of thinking/reasoning. In view of the responses from the experts in Stage 2 and revisiting the data, this mechanism was relabelled as reasoning skills.

5.5.2.3. Linkage

Realist evaluation emphasises the links between contexts, mechanisms, and outcomes (Jackson and Kolla 2012), as different programme mechanisms are triggered in particular contexts (Wong et al. 2016). Therefore, attention in data analysis was also given to establishing linkages between the context and the mechanism. This was undertaken by attending to dyads of context and mechanism found in the data from Stage 2 interviews.

The expertise of the three interviewees in Stage 2 took advantage of the knowledge and experience of the experts in interconnecting elements. Analysing the data looking for relationships between the context positive patient safety culture and the mechanism reasoning proved practical and all three experts provided clear accounts of the importance of the context firing the mechanism.

Expert 1: *“very quickly when they get back into the environment, because it's the environment, it's the policies, it's the structures and it's even just how things are laid out, that constrict people ensuring that they have safe practice and ensuring that they're able to change. It's very hard for one individual to come back and change a culture, even though they want to change a culture”*

Expert 2: *“I think in theory that's correct. I'm... in the present job, I don't think I've seen enough data to definitely say yes to that, being honest with you. But I would probably positively be disposed to agreeing with it. I think it would be heavily influenced by how well embedded that safety culture is”*

Expert 3: *“... creating the culture. So if you have an individual, so say you have a nurse that does the medication administration programme and they come away from that and they want to effect a change. There's probably an element there whereby, whether it be through transformation, or whether it be through Lean, or through any other element whereby there's probably a requirement to give them the tools to do that”*

5.5.2.4 Conclusion

The refined conjectured CMO configuration to be tested in Stage 3 is:

- 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.

5.5.3 Conjectured CMO 2

Registered nurses, who undertake a safe medication administration education programme in an acute hospital which adopts national policy on medication safety, may adopt a quality improvement approach to medication administration, which may lead to reduced patient harm.

5.5.3.1 National policy

National policy as a contextual factor was supported by the experts but little elaboration was provided.

Expert 1 identified that a ‘*huge gap*’ existed between the Department of Health and the Health Service Executive (HSE) in relation to policies with individual areas not taking responsibility for their own strategic approach. Expert 3 identified that there is a need to implement national policies such as the HSE serious reportable event policy.

Expert 3: *“But yes is the short answer to that. I think... but in that there should be a realisation that translating a national policy to a local or an organisational implementation plan, sometimes needs a little bit of tweaking as well. Sometimes what's written on paper you can't quite make happen on the ground in a particular setting? So I think there has to be some tolerance of a little bit of deviation, as long as it doesn't deviate so far that it renders the principles of safety that they're trying to cover..”*

Expert 2 discussed reasons why national policies may not be implemented:

“Well, I would I hope that in the drafting up of those policies, they were based on organisational input and contribution, so my answer is yes. If they're not being implemented my question would... "Why not?" Because if they're developed by the profession or the area's subject matter experts, there should be no issue with that. Implementation is slightly different”

Following the analysis of the expert interviews and revisiting the data from Stage 1, it appears that adopting a national policy may not be a strong enough contextual factor as part of the conjectured CMO configuration. Working in a similar fashion to refining conjectured CMO configuration 1, I revisited the data collected from Stage 1 in relation to adopting national policy as a context and retraced the process of this theme formation. As national policies are only effective in organisations where they are applied, the organisation and

governance structure of the organisation may be a more relevant context aspect to examine. Indeed the examining of the organisation and governance structure in Stage 3 of programme theory testing will reveal if national policies are applied and how they are applied in the organisation.

This is supported by the extract taken from Expert 2.

Expert 2: *"Yeah, well I think it would start from... you know, creating that culture has to come from... as I said, it's not intended to be a cliché, but it has to be led from the top down. There has to be a very clear message that quality, and the use of that word - hang on...(Noise interference) The use of that word encompasses a lot, from timely access to patients not being harmed, being given the right treatments, evidence-based. You know, there has to be a commitment from the hospital senior leadership team, that this is a number one priority for the organisation, and there are various ways they can do that"*

5.5.3.2 Quality improvement approach

Quality improvement approach as a mechanism was strongly approved of by the experts.

Expert 1: *"there's a huge amount of goodwill and expertise out there in relation to improving quality, and that's what people want to do. People don't want to go into work to harm anybody and they want to do their very best and whatever"*

All experts discussed the mechanism quality improvement while linking it to contextual factors. The extended extract from Expert 2 is necessary to illustrate the proposal of a new context.

Expert 2: *"Yeah, I think I've seen people go to patient safety conferences or go for an immersion course in quality improvement and demonstrating if you do X it results in Y, and the typical bit is that people get exposed to the positive sides of what can happen if you really get engaged with incident reporting and looking after safety and trying to pick out harm. But the problem is I think when they come back to their own workplace, in that suddenly, their enthusiasm and their desire to do something about it - they can't do it in isolation; it has to be done in teams, and I think that's where the gap sometimes falls down. And, you know, you need some good stamina to come back with some training, see where it can take a team or a clinical department or whatever, and push it forward because people are busy, and sometimes this type of work... you know, you're shining a light on areas and*

people feel a little bit uncomfortable in shining a light on. So that's the barrier that people who want to get involved in this have to overcome"

Again, Expert 1 emphasised that it is not just the quality improvement approach or agenda on its own that can make changes but the organisational support to apply it in practice.

Expert 1: *"and the problem with sometimes the quality agenda is that, and even in metrics and all sorts of things, it turns out for the individual nurse on the ground who is stretched and pushed, they need a tick box exercise in order to say, "Yeah, it's done" or "We meet the requirement" or "That standard is done." But does it actually really happen? So what I suppose I'm saying in relation to policies, while we're great, and I worked in the Department of Health here, great at writing policy and that, but very poor in implementation and that's across the board in relation to it. Great quality principles, great values, great all of that - but how do you actually translate that into practice, okay?"*

5.5.3.3 Conclusion

The refined conjectured CMO configuration which was tested in Stage 3 is:

- Registered nurses, who undertake a safe medication administration education programme in an acute hospital, with safety focused governance structure, may develop a quality improvement approach, which may lead to reduced patient harm.

5.5.4 Conjectured CMO 3

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.

5.5.4.1 Multi-disciplinary collaboration in medication safety

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. Medication management is a complex multi-stage and multi-disciplinary process, involving doctors, pharmacists, nurses and patients (Adhikari et al. 2014).

Multi-disciplinary collaboration within the environmental context was strongly echoed and supported in Stage 2 when discussed with the experts. Experts felt that a *'Multi-pronged*

approach' (Expert 2), was the best method for management of medication safety with Expert 1 stating that *"everybody brings something to the table"*.

This was further emphasised by Expert 3:

"it has to be multi-disciplinary, yeah. There are elements within each discipline that are specific to them, so if you take even something like the medication process, so the medication process even though it starts in a lot of cases with the prescribing, and we talk of the triangle between, or even probably the fourth element in terms of the monitoring, but you've got the prescribing, the dispensing, the administration and the monitoring"

The essential need for collaboration between all disciplines was also discussed by the experts:

Expert 1: *"For a multi-disciplinary team to come together and say, "Okay, what's happening with the day-to-day running of this ward?" And for medics, or pharmacists or healthcare assistants to say, "Look, we're always delayed on that" and what's happening and how can we run the system a little better in relation to that. So, it's about having really a case analysis of what we're doing, how we're working with, how does the system work?"*

Expert 2 and Expert 3, who work in the organisation where the study was undertaken, both commented on the multi-disciplinary nature of the organisation.

Expert 2: *"...here, for medication safety we do have quite a multi-disciplinary approach to it"*.

All experts discussed the importance of shared learning across disciplines.

Expert 3: *"I do believe that it's better to have it multi-disciplinary, but also there are elements whereby I think can all learn from each other"*

Expert 1: *"So nurses got used to, within the education environment, talking to the pharmacists, asking them the questions, figuring out what needed to be done, and then when they went back into the clinical area"*

Expert 2 discussed how each disciplinary can learn from sharing critical incidents from practice:

"I think a large component of that is the multi-disciplinary approach to it and the airing of all medication incidents that happen every month at the quality and safety exec"

The expert interviews support the use of a multi-disciplinary collaboration as a context component of a conjectured CMO configuration.

5.5.4.2 Receptivity to change

The mechanism 'receptivity to change' was presented and discussed with the experts.

Expert 1: *"it's making people more aware of what they're not doing and what they need to do"*

Receptivity to change was discussed by experts in relation to contextual issues in particular in relation to the culture of the organisation. The views of the experts in relation to receptivity to change very much emphasised that it is a mechanism that is activated or fires in the right context (Dalkin et al. 2015).

Expert 2: *"So I think the main block to the level of degree of receptivity to a new idea, is what's going on in the wider... and it comes back to the culture"*

Expert 3: *"People's ability to receive new ideas are very much determined by what's going on in the wider environment as well and sometimes if the environment, and by environment I mean the busyness, the level of busyness - sometimes people's ability to receive new information or a new approach is heavily influenced by that."*

Expert 2 described the relationship between a multi-disciplinary approach and receptivity to change.

Expert 2: *"the simple approach is that if anyone tries to impose anything on a particular profession, however well intentioned, it won't work. It just won't. People are too busy and they like to be involved. If you want people to get on board with a quality improvement or patient safety initiative, you have to take the time, and it's almost like investing a fair bit of time to explain what it is the destination is; how we're going to get there and "this is something that I think might help."*

5.5.4.3 Conclusion

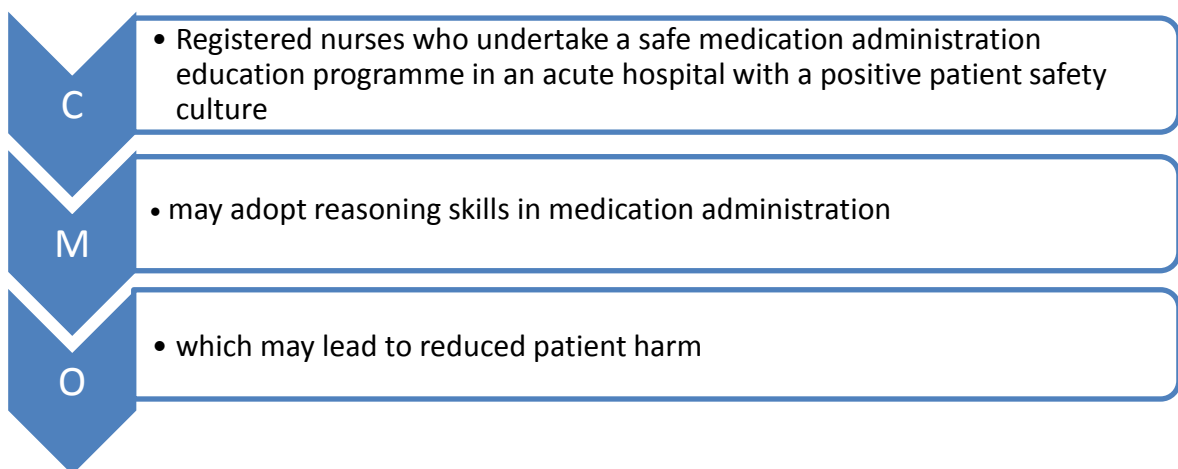
The third conjectured CMO configuration was accepted with no refinements required following Stage 2 of programme theory refinement. The conjectured CMO configuration to be tested will be:

- Registered nurses who undertake a safe medication administration education programme in an acute hospital, where medication safety is multi-disciplinary, may develop individual receptivity to change which may lead to reduced patient harm

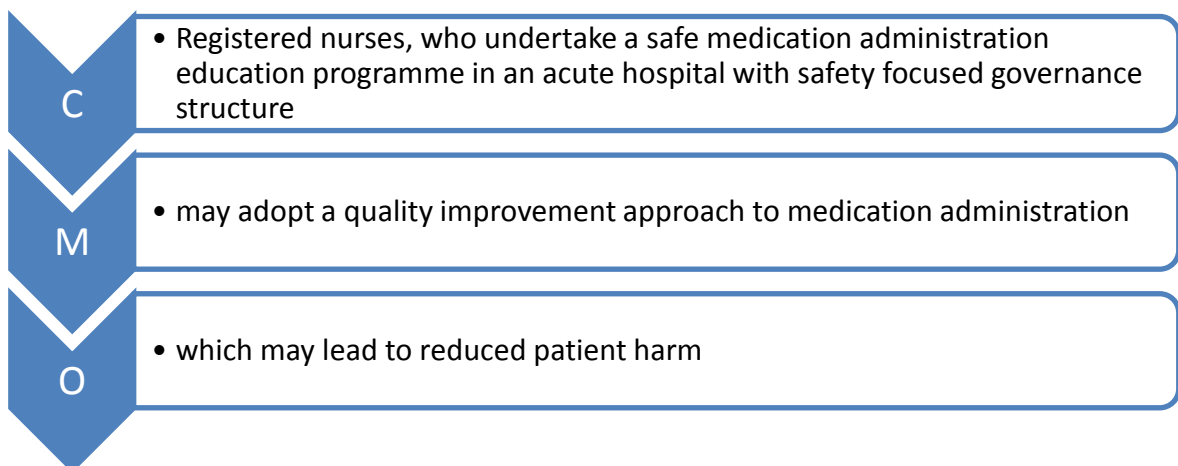
5.6 Conclusion

The refined conjectured context mechanism outcome configurations which have been produced at the end of this stage will be tested in Stage 3 and analysed and reported in Stage 4. The conjectured CMO configurations brought forward to Stage 3 are as follows:

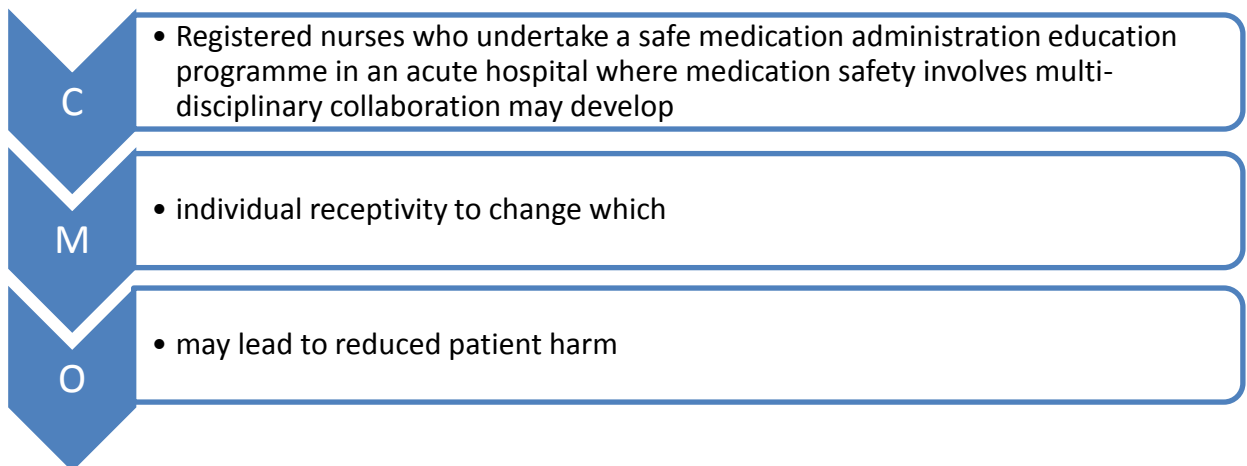
Conjectured CMO 1



Conjectured CMO 2



Conjectured CMO 3



As described at the start of this chapter, the process of programme theory refinement of conjectured context mechanism outcome configurations was not a linear process. It required moving between data collected in Stage 1, both during and after collection of data for Stage 2. The example of review and revising the mechanism ‘critical thinking’ to ‘reasoning skills’ clearly demonstrated the iterative nature of the realist process of evaluation. Stage 1 and Stage 2 data collection and analysis informed the construction of the observation tool and interview schedule for Stage 3, that is the programme theory testing.

Chapter 6- Stage 3 Testing the CMO Conjecturers

6.1 Introduction

The realist evaluation approach which guides this study required that I seek out data related to the three conjectured CMO configurations which I developed in Stage 1 and later refined in Stage 2. This chapter focuses on methods used during Stage 3 of the evaluation which set out to test the programme theory and conjectured CMO configurations. This stage was designed as an explanatory single case study with three embedded units of analysis.

6.2 Case Study

6.2.1 Introduction to case study

Adopting a case study method for this stage allowed me to study the complex social phenomenon of transfer of education to practice, while retaining the holistic and meaningful characteristics of real-life events, (Yin 2018) such as organisational and managerial process, group behaviour and other factors implicated in the conjectured CMO configurations. Case study is a method suited to how and why questions (Yin 2018), such as my research question, as it is explanatory in nature (Easton 2010). The objective of Stage 3 was to recover the 'situated rationality of action'—the ways in which, in context, people's actions make sense, even when they seem, to others outside the situation, to be inappropriate or counter-productive (Murphy and Dingwall 2007).

6.2.2 Case study in realist evaluation

Case study research does not ascribe to a fixed philosophical perspective, methodology, or method (Carolan et al. 2016) and was chosen as a design for Stage 3, as it is methodologically complementary to the theory-driven approach of realist evaluation. Case study research has been found to be compatible with realist evaluation which seeks theoretical propositions about what works, for whom and in what contexts (Williams et al. 2013). Case study and realist evaluation are, in both design and methodology, linked by recognition of the importance of context (Rycroft-Malone et al. 2010). Case study is concerned with the desire to understand complex social phenomena (Yin 2018) such as in this case, the transfer of an education programme in clinical practice. As with case study, realist evaluation calls for making sense of various datasets (i.e. plurality) in order to develop coherent and plausible accounts (Rycroft-Malone et al. 2010). Williams et al. (2013) further

describes case study as akin to the principles of realist evaluation, where the aim is to unlock the underlying mechanisms of action. Multiple research reports now exist which include case study within a realist evaluation framework (Koenig 2009; Rycroft-Malone et al. 2010; Marchal et al. 2012; Rycroft-Malone et al. 2013; Williams et al. 2013; McGaughey et al. 2017).

6.2.3 The case

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 and at local level some of the context factors relate to the greater organisation as a whole. In Stage 1, documentary analysis and interviews including those with programme architects were conducted. The case was further explored in Stage 2, where two of the experts interviewed were from the case.

The use of a single case study with three embedded units provided me with the opportunity to continue to explore the organisation/case as presented in Stages 1 and 2. It also provided the opportunity for data analysis within the case and of the embedded cases. This single case study is viewed as a critical case, it is critical to my theoretical proposition (Yin 2018), which were the three conjectured CMO configurations put forward at the end of Stage 2. The single case has allowed me to determine whether the propositions (that is the conjectured CMO configurations) are 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).

A single case study may involve units of analysis at more than one level called embedded units (Yin 2018). An embedded case study design can serve as an important device for maintaining a case study focus. In this study, three embedded units were examined within the case study. Figure 6.1 illustrates the study design in Stage 3.

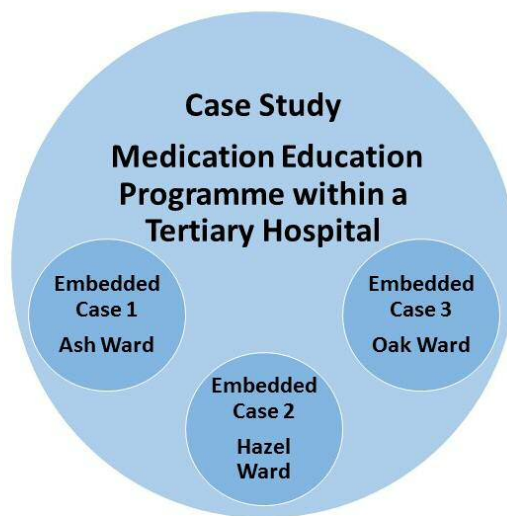


Figure 6.1 Stage 3 Embedded case study

As previously discussed in Chapter 4, the document analysis was used to develop an understanding of aspects of an organisation and its operation and these details were again used in Stage 3 to develop the case. These other sources of data will aid in analyses developing a contextual understanding of the documents and their significance. The organisation has previously been described in 4.3.1.

Data from Stages 1 and 2 will also be utilised and incorporated into the analysis in Stage 3. This is in line with the principle that realist evaluation provides continual programme refinement, which requires going back and back again to puzzle over present findings and their effectiveness of current practices, and then forward to attend to new puzzles which emerge from these deliberations (Pawson and Tilley 1997). To avoid a potential error in design, the case study analysis will not just focus on the embedded units, but return to the larger unit of analysis of the original 'case' (Yin 2018).

6.3 Sampling

6.3.1 Individual level participants

On 24th August 2017, the names of nurses who had completed the safe medication administration education programme were downloaded. Within the organisation under study (the case), a total 152 nurses had completed the education programme. All student

nurses and nurses no longer working in the hospital were excluded. The remaining population size was 130 registered nurses. The names of the registered nurses that had completed the safe medication administration education programme were cross referenced to allocation of clinical areas. In my proposal, the embedded case study sites were to be an acute medical ward, an acute surgical ward and a critical care area so as to allow diversity in cases. Bearing in mind the three specific specialists I had identified in my proposal, I looked for the largest number of staff who had completed the education in the specialist sites. A medical ward (n=7), a mixed medical and surgical ward (n=8) and a mixed transplant/medical speciality ward (n=5) were selected. The number of staff who had completed the safe medication administration education programme from critical care areas was limited and thus was excluded from Stage 3. Inclusion criteria can be found in Table 6.1.

Requirements for Inclusion
Have completed the safe medication administration education programme
Registered General Nurse
Working in the hospital
Complete the consent form for observation and interview

Table 6.1 Stage 3 - Inclusion criteria

Observation and follow-up interviews were conducted with participants who had completed the safe medication administration education programme and interviews were completed with the relevant Clinical Nurse Manager II (CNM) on the ward area. In Irish acute hospitals there are three grades of clinical nurse managers (CNM). The three grades are: CNM I (reporting to CNM 2); CNM II in charge of a ward; and CNM III in charge of a department. The list of final participants and the name of the embedded case is given in Table 6.2. All participants in Stage 3 were provided with a Participation Information Leaflet and Consent (Appendix 11 and Appendix 12).

6.3.2 Selection of embedded cases

The embedded cases were purposefully selected in order 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. Clinical Wards in the site under study have approximately

20 whole time equivalent registered nurses on their roster. Five would make up approximately 25% of the total population. The selected sites allowed a variation in potential factors that may have contributed to its success or failure of the safe medication administration education programme. The three sample sites were selected in order to contribute to the development, support, refutation or refinement of my conjectured context mechanism outcome configurations. This purposeful sample was also to allow for different activity types to be compared and different medication needs also.

6.3.3 Embedded cases

The three embedded case studies were Ash Ward, Hazel Ward and Oak Ward. Table 6.2 provides details of the wards and the participants from each ward. A brief description of each of the three wards is also provided in this section.

Embedded Case	Participants	Observation	Interview
Ash Ward	Grace	√	√
	Clodagh	√	√
	Leah- CNM II		√
Hazel Ward	Marcella	√	√
	Frances –CNM II		√
Oak Ward	Cathal	√	√
	Karen-CNM II		√

Table 6.2 Final Stage 3 participants

Ash Ward

Ash Ward is a 27-bed mixed medical ward. It is made up of a 4-6 bed 'Hawthorn' unit and 21-23 medical beds depending on patient requirement. Although it has a speciality bed base, patients from other specialities may be admitted there also. The CNM II, Leah described the typical patient acuity during interview:

"I suppose the patients tend to be sicker I suppose, than the general medical patients would be, just the nature of their illnesses.Inside in the ...Hawthorn unit we'd have type 1 and type 2 respiratory failures; we'd have patients with tracheostomies out from ICU; we'd have patients with sepsis; we'd have maybe patients in there for hourly neurological observations; we might have patients post a stroke, if they weren't suitable to go to the

stroke unit; and then just we'd also have patients with dementia or behavioural issues; patients with alcohol detox issues. So a lot going on in the ward, and then I suppose the dependency would fluctuate as well. "

The Hawthorn unit is classified as an observation unit where patients require a greater level of observation than at ward level. The Hawthorn unit consists of four monitored beds in one room. If required two further isolation rooms can be utilised on the opposite side of the corridor.

Staffing is allocated according to patient acuity in the Hawthorn unit and the remainder of the ward. Staffing allocation is normally broken up into three teams, and these teams are allocated to ward areas which are labelled A, B, C and D. One team are allocated to A and B, one team are allocated to the Hawthorn unit and the final team to D and E.

Leah, the CNM II, described the staffing levels:

'So generally, you would have on a day shift, you would have one nurse in the Hawthorn unit, so that would be one to four, and then you would have three nurses outside the Hawthorn unit, plus the carer. So that would be three, plus a care (Healthcare Assistant) , to twenty-three patients.....It would depend on which end of the ward you're working on, but it would be one to seven, or one to nine'

A CNM II, CNM I or charge nurse is also on duty Monday to Friday. They are supernumerary to the ward allocated staff nurse numbers.

Observations took place, both in the Hawthorn unit, and in the general ward area. During the period of observation, the ward had a number of patients who were confirmed as carriers of Carbapenemase Enterobacteriaceae Producer (CPE). As a result of this, the ward was closed to any new admissions. Thus, during observation the nurse-patient ratio may have been reduced. The occurrence of CPE on the ward may also have had some effects on the behaviour observed during my observation period.

Two staff nurses, Clodagh and Grace, consented to the observation and interview. Leah the CNM II also provided an interview.

Six periods of observation took place on Ash Ward with observation also taking place during weekends.

Hazel Ward

Hazel Ward is a 35-bedded general medical and surgical ward. It is made up of four bedded rooms, two bedded rooms and some single rooms. During observation, Marcella was observed at all times covering three four-bedded rooms.

Frances, the CNM II, describes the ward:

"So we get various different cases up on the ward. It's quite a big ward. It's very heavy. We also have a lot of long term care patients as well, a lot of discharge planning and a lot of people who would need a lot of multi-disciplinary input. We generally... and then we'd get a mix of surgical patients and medical patients "

The ward has no specific speciality or cohort of patients. Nursing care is allocated according to ward area, where a team of nursing staff will work together in the specific area. Frances described the allocation:

"we're supposed to have two nurses per twelve patients, but we don't generally have that luxury."

When asked to describe the ward, Marcella described it by its activity:

"It's difficult to work in. It's okay but it's not easy to follow policies because it's so busy. Maybe it's my efficiency- but I just can't manage everything".

Three periods of observation took place on Hazel Ward- two on weekdays and one on a Sunday morning.

Oak Ward

Oak Ward consists of 20 single bedded rooms. The ward has a speciality and is also the national transplant centre for that specialty; the ward also provided two HDU beds for patient post-transplantation.

Karen, (CNM II) describes the rationale for the single room layout:

"it's all ensuite for 20 beds, single rooms, in view of infections and in view of that immunosuppressant's, like the patients are more prone to having, getting all opportunistic infection. And it's a special unit with a HEPA filter" (A HEPA filter is a high efficiency

particulate air – filters used for infection prevention and control in immunosuppressed patients).

Nursing staffing levels on Oak Ward reflect the acuity of the speciality patient group. Karen the CNM II describes the staffing level:

“Staffing - we have 21 to 22 staff, including HCAs and I have one clinical facilitator, one CNM 2, two CNM’s; one is an acting post, and the rest are a few, like five to six senior staff nurses and then junior staff nurses. So I have nurses who have experience of working in high dependencies. So we have two high dependency beds. ”

Cathal (staff nurse) further describes his general patient allocation:

"We are assigned patients generally if their acuity level is not that bad, it doesn't require too much nursing care. So we care for six patients, otherwise, just like today, I have one HDU then two ward patients. "

Three periods of observation took place on Oak Ward, which were all on weekdays. This was in line with Cathal’s duty roster during the time period of observation.

6.4 Data Collection

6.4.1 Introduction to data collection

An exploratory, descriptive design, using semi-structured non-participant observation and follow-up semi-structured interviews, was used. Further documents were also collected such as Critical Incident Reports and Nursing Quality Care Metrics. Documents collected from Stage 1 were also utilised in order to develop the case. The multiple forms of data collected were tailored in order to allow for the testing of the conjectured CMO configurations put forward at the completion of Stage 2 (Pawson and Tilley 1997).

The purpose of this research observation, and the follow up interview, is to provide the data required to test the conjectured context mechanism outcome configurations developed and refined in Stages 1 and 2 of the study.

6.4.2 Observation

6.4.2.1 Introduction to observation

Medication administration is a complex procedure which requires an in-depth exploration of the interactions, interpersonal skills and behaviours that contribute to the overall experience (Duxbury et al. 2010). Observation allowed me to see how participants worked within the social setting in their clinical area and how they relate to their environment as it occurs (Mulhall 2003). Krueger (2017) puts forward that those who study human behaviour indicate that there is often a gap between what people say they do and what they actually do, and thus observed behaviour is often a more dependable indicator than what is self-reported. The use of observation provided information on the actual practice of administration of medication, where I could see with my eyes what the outcome is and not rely on the accuracy of self-reporting. Observation also provided the opportunity for me to gather further information about the context; which included the physical environment and the culture of the clinical area and compliance with organisation policy, procedure and guidelines. Thus, observation is a suitable method of data collection to observe events immersed within the real world (Yin 2018) in order to address the testing of the conjectured CMO configurations. For the purpose of this study, a medication administration episode was defined as an individual patient care episode, which began with the first medication administration task performed and ended when the nurses moved to the next patient. An observation period was defined as the period on the selected day that the nurse was observed in practice for.

It was proposed that each observation period would be of four hours duration. On Ash Ward each observation was of four hour duration, however when negotiation for site access commenced on Hazel Ward, the nurse agreed to the observation during medication rounds only, thus the period observed was less. Similarly, when negotiating access to Oak Ward the agreed observation time was for medication rounds only. Thus, the observation periods ranged from 1 hour 10 minutes to 4 hours and 10 minutes. The number of medication administration episodes also varied from 2-11. The number of medication administrations observed varied due the nature of the patient allocation of the nurses during the period of observation. For example, on day 3 of observation with Cathal, he had only three patients allocated to him, one HDU patient and two others. One of the other patients was undertaking the self-administration programme, and thus this medication episode was not

included in the observation details. Table 6.3 illustrates the observations periods and the number of medication administration episodes observed.

Ward	Observation 1 (medication administration episodes)	Observation 2 (medication administration episodes)	Observation 3 (medication administration episodes)	Total observation period	Total medication administration episodes
Ash Ward					
Grace	08.00-12.00 (8)	09.00-13.00 (9)	08.00-12.15(9)	12hrs 15mins	26
Clodagh	08.00-12.20 (8)	08.00-12.00 (5)	08.00-11.40 (7)	12 hrs	20
Hazel Ward					
Marcella	09.30-11.30 (11)	11.30-13.00 (8)	12.00-14.15 (3)	6 hrs 45mins	22
Oak Ward					
Cathal	09.00-10.15 (6)	09.00-10.15 (3)	09.00-10.10 (2)	3 hrs 40mins	11

Table 6.3 Stage 3 observation details

6.4.2.2 The approach chosen for observation

When undertaking observation as a method of data collection, I had several options on how to approach the observation depending on which role I adopted. The most commonly applied description for the approaches to observation is the seminal work by Gold (1958). The first approach is the complete participant where the *'the true identity and purpose of the complete participant in field research are not known to those whom he observes'* (Gold 1958, p. 219). The second approach is the participant as observer, in this form of observation, the participants are aware of the researcher's role and the researcher is a full participant in the setting. The third approach is the observer as participant, in this approach there is no established long-term relationship and the researcher doesn't participate in the work and is only a participant in the sense of being in the setting. The final one is the complete observer, where there is no participation by the researcher (Gold 1958). However, the four approaches to observation are not absolute positions (Moore and Savage 2002), and Gold (1958) has suggested and that the researcher's position is rarely at either end of the continuum of observer to participant, but that their role often changes as the research

progresses. The variation of roles is common in observational work, and Hammersley and Atkinson (2010) outline that the researcher can adopt a variety of roles throughout the data collection while maintaining a more or less marginal position, and thus allow the researcher to access to participant's perspectives but at the same time minimising the dangers of over rapport.

Prior to commencing observation it was necessary for me to acknowledge where my observation would be placed on the continuum, and to justify why this approach had been chosen. For my research study, I chose to adopt the role of passive participant observer; similar to that described by Delamont (2007), in which 'participant' does not mean doing what those being observed do, but interacting with them while they do it. By a participant observer, I was not acting as a member of the nursing team, but I had some interactions with the nurses which I was observing. For example, I often asked a simple question at the end of a medication round. By adopting this approach, it allowed me to be an independent non-judgmental outsider, who was not a member of the nursing group observed, but allowed me to step in and out of the group at will (Schneider et al. 2013). The chosen research site recently undertook a practice change initiative, which was targeted at reducing interruptions and distractions during medication administration. Thus, in order to obtain ethical approval in the chosen site, I had to clearly state that no interruption to practice would take place in order to comply with the local policy.

As I held a dual role of researcher and registered nurse, certain ethical, moral and professional responsibilities, when observing medication administration, had to be observed. Due to the ethical and professional responsibilities associated with the dual role, there were potentially occasions where I may have had to step in to be a member of the group. For the purpose of obtaining ethical approval, and to provide clarity for managers and staff in the observation areas, a protocol was developed. This was provided to managers and the participant during observation periods. These occasions and the justifications are discussed in details in 6.6.3 'Dual identity' and are outlined in Appendix 13. On two occasions during observation, it was necessary for me to work with the participants undertaking the observation.

6.4.2.3 The observation tool

There are two distinct ways of undertaking observation in the field, through structured and unstructured observation (Salmon 2015). The observation undertaken in this study was semi-structured. The primary aim of the semi-structured observation tool was to assist in describing what happens in the setting, how the people involved see their own actions and those of others, and the contexts in which the action takes place (Hammersley and Atkinson 2010). The use of the observation tool aided in reducing the amount of text recorded, as writing extensive information would have affected my observation of medication administration at crucial times. The purpose of the observation and follow on interview and subsequent data generation was to test the three conjectured CMO configurations presented at the end of Stage 2.

The observation tool involved two separate, but related components (Appendix 14 -Semi-Structured Observation Tool). Part A was completed on commencement of the observation period and at any time throughout the observation period. Spradley's (1980) observation framework was used to assist with guiding the observation. This framework contains nine phenomena that might occur in any setting of human interaction. The nine phenomena are: space, actors, activities, objects, acts, events, time, goals and feelings. This was essential, as the dynamic and unpredictable nature of the clinical environment adds to the complexity of medication administration (Folkmann and Rankin 2010). This semi-structured tool enabled deep exploration of the interplay of nurse, patient and environmental factors on medication administration (Popescu et al. 2011). These observations were recorded on the observation tool. This section was essential, as many previous studies have seen medication administration work as separable from other work nurses perform (Biron et al. 2009; Keohane et al. 2008). However, this is not the case. Section B of the observation tool was completed in a more structured manner for each medication administration episode observed. Most boxes required just a tick. A medication administration episode for the purpose of this study is defined as an individual patient care episode that began with the first medication administration task performed, and ends when the nurse moves to the next patient. To avoid bias during observation, an open mind was kept about observed activities, and clarification was sought as required during the follow-up semi-structured interviews.

Bearing in mind that the purpose of the observation was to test the conjectured CMO configurations, much consideration was taken to ensure that the data it collected would be relevant to this purpose. At the observation tool design stage, it was also necessary to ensure that it clearly related to the three conjectured CMO configurations put forward on completion of Stage 2. At this point a CMO Mapping Template (Appendix 15) was developed. This template mapped the observations to the associated context, mechanism or outcome which it set out to test. This mapping template was used for data analysis.

6.4.2.4 Field notes

Whilst using the observation tool, I also recorded field notes. Field notes act as an additional layer of qualitative data and are an essential component of rigorous qualitative research (Phillippi and Lauderdale 2018). They also helped to enhance the data collected and acted as a rich context for analysis (Mulhall 2003; Creswell 2013). The use of field notes aided me in the construction of thick, rich descriptions of the study context (Phillippi and Lauderdale 2018), that is the clinical ward environments where medication administration occurred.

Field notes recorded during observation and afterwards, were written in an objective manner and were free from judgements, explicit analysis and interpretation (Emerson et al. 2011). At the point of observation, my note taking was merely describing what had seen and not interpreting it. To ensure I remained objective during note taking, I engaged in reflexivity which acknowledged my values that I take for granted and this assisted in identifying personal bias. As well as taking notes in the field, I also drew out the layout of the ward to act as an aide memoire. This was of great assistance when data analysis was taking place.

As a novice researcher who was completing observation fieldwork for the first time, I was aware of the need to ensure that my note taking was appropriate and not uncomfortable for participants or others who entered the research field. Emerson et al. (2011) advise that one way to avoid possible awkward encounters and breaching trust between researcher and participant is to conceal the act of note taking while in the field. Many researchers undertaking observation write about retreating to private places to write their notes (Emerson et al. 2011). During observation periods, I did not conceal any note taking, while also being aware that continuous note taking may be perceived as inappropriate or intimidating (Hammersley and Atkinson 2010). Similar to Casey (2006) I had obtained ethical approval to use a discrete microphone for the sole purpose of recording my notes while in

the field. The purpose of this was to allow me to continue to observe while recording what I had seen. However, as negotiation for accessing sites was difficult this method was not used during observation.

Following each period of observation, I wrote further notes. Similar to notes taken in the field, I remained objective. Reviewing the field notes helped me to prepare for my next observation and work through any issues that may have arisen during the previous observation. I also commenced a separate log, where I recorded my personal reflections, feelings and emotions. This forms part of my reflective journey through my Professional Doctorate work. This is further detailed in Chapter 11.

6.4.3 Semi-structured interviews

In order to increase the completeness of the data, semi-structured interviews were conducted with each participant who was observed and also with the CNM II on the ward area. Similar to the interviews undertaken in Stage 2, the interviews in this stage adopted realist principles where the semi-structured interview schedules were dynamic (Manzano 2016). Table 6.4 provides a reminder of those who undertook an interview in Stage 3.

Interviewee	
Ash Ward	
Grace	Interview following observation
Clodagh	Interview following observation
Leah- CNM II	Manager Interview
Hazel Ward	
Marcella	Interview following observation
Frances –CNM II	Manager Interview
Oak Ward	
Cathal	Interview following observation
Karen-CNM II	Manager Interview

Table 6.4 Stage 3 interview details

6.4.3.1 Interview with participants who undertook observation

For the participants who had also undertaken observation, the interview served several purposes: 1) to 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) to further explore the conjectured CMO configurations. The Stage 3 CMO Mapping Template assisted with identifying topics for further exploration.

The semi-structured interview schedule varied for each participant. Questions during the interview were based on the observation, as well as the conjectured CMO configurations which were being tested in this stage. Variation in the interview schedules is grounded on the realist refrain that ‘nothing works unconditionally in all circumstances’ (Tilley 2000, p. 126). Manzano (2016) furthers this by acknowledging that intra-contextual variation will impact on the questions. A sample interview schedule is included in Appendix 16.

An example of variance in the schedule during Cathal’s interview is in relation to the physical environment. Oak Ward has only single rooms and during observation this was noted as a dynamic to be considered during medication administration. Thus, this was followed up during the interview with the question:

“How do you find administering the medications when the patients are in the single rooms?”

Likewise, an example of a unique interview question during Marcella’s interview was:

“During observation I noticed that you administered your medications from medication trolley on the corridor- do you ever bring them to the patient bedside? Why?”

This question for Marcella was based on the observation periods and previous document analysis. The medication management policy of the organisation recommends that best practice is to administer medications from the trolley at the closest point to the patient as possible. Thus, Marcella not doing so was an area identified as requiring further exploration.

Interviews were undertaken as soon as possible after completing the final observation period. Interviews lasted between 16 and 22 minutes. Interviews were recorded and later transcribed in full. Despite providing written informed consent, one participant (Marcella)

refused to have the interview audio-recorded. Written notes were taken during the interview and a record of the interview was written up immediately afterwards.

6.4.3.2 Interviews with managers

In all three sites, the CNM II's consented to interview. The CNM II's were key stakeholders in the local application of the safe mediation administration education programme. The interview schedule was semi structured and varied depending on the observations that had taken place and the development of the conjectured CMO configuration at the time of interview (Appendix 17). The varied semi-structured schedule demonstrates realist thinking, as the premise is that knowledge will evolve and questions will change as answers alter evaluators' knowledge (Manzano 2016). Conversations with participants were also guided with the help of the specificities of the individual cases (each ward) and were directed into developing the programme theory (Manzano 2016).

Similar to Stage 2 of the evaluation, the 'teacher-learner' approach was used in interviews with the CNM II's (Pawson 1996). Questions on the semi structured interview schedule were constructed to clarify any queries following observation, but mainly to test the three conjectured CMO configurations. These interviews aimed to further refine how the emerging programme theory or conjectured CMO configurations performed (Manzano 2016) in real clinical practice situations, and the stories of the interviewee helped with refining or discarding them. This assisted in uncovering concepts to do with 'outcome' and 'context'.

Interviews with all managers took place following completion of observation and interviews with participating staff nurses. All interviews were conducted in a private setting on the ward areas. In two interviews (Leah and Karen), the interviews were interrupted. Recording was paused until the CNM II was ready to return to the interview. Managers were provided with a separate Participant Information Leaflet (PIL) and Consent for the manager interview. The PIL and Consent were approved by Cardiff University and the Research and Ethics Committee of the organisation under study.

6.4.4 Documentation review

Documentation review was also undertaken in Stage 3 of this study. The collection of documentary evidence also helped to verify the data obtained through other means, such as semi- structured interviews and non-participant observations (Yin 2018).

6.4.1 Nursing Quality Care Metrics

Nursing Quality Care Metrics (QC-M) are in place in the organisation under study. The QC-M were introduced as a part of national project under the guidance of the Office of Nursing and Midwifery Service Director in line with the national strategy by the Health Service Executive and Patient Safety First. Nursing QC-M present ways of measuring the quality of nursing care utilising care process quality indicators, which provide a framework for the measurement of the fundamentals of nursing (Foulkes 2011). A random sample of 25% of the patient complement in each ward is selected for evaluation on a monthly basis. Data from these patients' records are entered on the electronic system called testyourcare (TYC) (www.testyourcare.com). Indicators in testyourcare include pressure ulcers, discharge, falls and medication safety.

Permission to use the data available from testyourcare was obtained from the Director of Nursing (Appendix 6) in the organisation. Due to my role in the organisation, I already had access to TYC.

A report on the QC-M for each month, January to December 2017, was run for Ash Ward, Hazel Ward and Oak Ward. The report displays percentage compliance with agreed national standards for that month. Three indicators were considered and were subject to analysis in this evaluation 1) medication storage and custody 2) controlled drugs 3) medication administration. The format of the online report uses a traffic light and percentage value system (Red/Orange/Green) to indicate level of compliance with standards as can be seen in Table 6.5.

Score	Action
Over 90% (Green)	Target achieved
80% - 89% (Amber)	Aim to achieve incremental improvement over the next 6 months
0 -79% (Red)	Areas of risk which require action as agreed with senior management

Table 6.5 Score Card Quality Care Metrics

The level of compliance report across 2017 was used in assisting with the evaluation of the outcomes within the context mechanism outcome configuration.

6.4.2 Medication incidents reports

A review of medication incident reports in relation to medication administration was also conducted. Reporting medication incidents is an essential competent of developing a safe patient environment. The WHO (2014) highlighted that the most important knowledge to maintain patient safety is how to prevent harm to patients during treatment and care. This knowledge can be obtained by reporting medication errors or potential errors. Error reports act as sources of information for the generation of preventive strategies aimed toward medication error reduction (Elden and Ismail 2016). Higher incident reporting rates both demonstrate and promote an improved culture of safety (Abstoss et al. 2011). While most medication errors do not result in patient harm, medication errors have, in some instances, the potential to result in catastrophic harm or death to patients (HIQA 2017).

The National Co-ordinating Council Medication Error Reporting and Prevention (NCC MERP) classification system is used nationally and internationally to categorise incidents in terms of patient harm. The NCC MERP utilises a Medication Error Index that classifies an error according to the severity of the outcome. This index provides healthcare practitioners and organisations with a method to track medication errors in a consistent, systematic manner. The NCC MERP can be found in Appendix 18.

Details of medication incident reports (MIRs) were obtained from the Medication Safety Officer for the year 2017 for the three wards under study.

6.4.3 Inspection reports

During the course of the study the organisation was subject to two external reviews. An announced Health Information and Quality Authority (HIQA) inspection for medication management was conducted in April 2017. HIQA commenced reviewing medication safety in acute hospitals in 2016. The purpose of their review was to monitor medication safety against the National Standards for Safer Better Healthcare (HIQA 2012), to determine if the hospital had effective arrangements in place to protect patients from harm related to medication use (HIQA 2017). The report on the hospital inspection by HIQA was available to the public on the HIQA website and was downloaded for analysis. This report was uploaded to NVivo™ (10) and analysis was conducted using the coding template.

In June 2017, the NMBI also visited the organisation in relation to nursing practice. One area which they examined was that of nursing medication management. The official report of this visit is as of yet not available, but informal feedback was provided to the Director of Nursing. This feedback was also entered into NVivo™ (10) and analysis conducted with the use of the coding template.

Both of these reports contributed significantly to the case study and also to the analysis of the conjectured CMO configurations.

6.5 Rigor

6.5.1 Introduction to rigor

The use of observations and interviews increased the richness of the data and this kind of triangulation strengthened trustworthiness of the study.

6.5.2 Observation and the Hawthorne Effect

Many critics of observation as an accurate method of data collection, state that a Hawthorne effect is created by the presence of the researcher in the field. This is where participants consciously or unconsciously may alter their behaviour as a result of being observed (Casey 2006). Bloomer et al. (2012) state that the potential impact of the researcher's presence must always be considered, but there is no compelling evidence to support the notion that participants behaviour does change. Indeed, Mullhall (2003) debates that most professionals are too busy to maintain behaviour that is radically different from normal. The literature also supports that participants frequently forget the presence of the researcher (Patton 2015) and Houghton et al. (2010) reported that their participants become accustomed to the presence of the researcher and reported soon forgetting that the researcher was present.

6.5.3 Strategies used to aid rigor

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. 2011) some strategies were adapted in the research setting to minimise the effect where possible. I spent three periods of time observing each participant. This observation period allowed the participant to become accustomed to my presence; it allowed me to blend in and help to reduce this potential effect (Chiesa and Hobbs 2008; Bloomer et al. 2012).

Another strategy which I undertook in order to address the potential impact of the Hawthorne effect was a follow up interview. During the interview, I asked participants directly if they changed or modified their behaviour, and I also asked them to explain as to why they did or did not. Manias (2012) reported using follow on interview after observation as a measure to assist with rigor in their study on medication administration in older persons. Popescu et al. (2011) also utilised interviews following observation. During observation they had found that nurses were observed to check patients' identity bands during only 63.3% of medication episodes. However, during the follow up interview, they uncovered that the figure may not accurately reflect usual practice because some participants stated that they checked identity bands only because they were being observed. The interview proved crucial in identifying this.

In my study, an example of where the interview allowed me to clarify details of the observation was with Cathal in relation to the wearing of the red alert apron. He was the only nurse, whom I had seen on the ward, wear the apron during medication administration. When I asked him in follow up interview if he always wears it, he acknowledged that he only did so in order to alert others that I was observing.

6.6 Ethics

6.6.1 Ethics in observation

Unlike experimental research, I had no control over who entered and left the area of observation. Thus consent issues in observational studies can be complex (Walshe et al. 2012). Written consent from all participants might be considered the gold standard (Walshe et al. 2012). However, in an unbounded setting such as a ward, it would not have been feasible to obtain written consent from every person who entered or left the setting. While the purpose of the observation was the nurse participant who had given consent and not about these people, they may have an influence over the data collection. Such peripheral people include staff and visitors who enter the field and patients. While many people entered and left the field, they were not central to the objectives of the study and thus are peripheral.

Much consideration was taken in relation to the necessity to consent patients, in order to observe the nurses interaction with them while medication was being administered. Different approaches to consent of patients are discussed in the literature. Bloomer et al. (2012) did not obtain consent from patients or families, as they identified that it was nurses who were the subject of the observation, and those of whom the research was deemed inconsequential did not need to be consented. This is also supported by Parahoo (2014) and Murphy and Dingwell (2007). Similarly, Moore and Savage (2002) and Griffiths (2008) reported that there was no need to obtain either verbal or written consent from patients. Moore and Savage (2002) found that patients became worried when asked to sign a consent form, because it suggested that something considerably important was about to happen to them. Griffiths (2008) rationalised the decision as patients were already ill and there was no need to bother them with details of the research process and the process of consent. Thus, supporting the idea that obtaining written consent from the patient may not be in their best interest. Houghton et al. (2010) originally designed their study to obtain written informed consent from the patients who would be indirectly involved in the observation. However, they reported that the reaction from patients, when approached for consent, was positive but when asked to sign something, they became apprehensive and following observation in three separate sites, it was decided by the researchers to just seek verbal consent from patients.

Following a review of the literature and based on the ethical principle of beneficence, in this study, patients were required to give verbal consent only. It was proposed that obtaining written consent would cause anxiety to the patient who was already unwell. The justification for doing so was provided to the research sites the Research and Ethics Committee who approved the proposal. For ethical approval, I undertook to maintain patient confidentiality at all times.

Conducting an observational study in an open space such as a ward area can pose problems, as many people enter and leave the field of observation. The necessity to obtain consent from staff and visitors was also considered. Houghton et al. (2010) postulates that there is a need to inform people, who enter the observational area where data is being collected, the purpose of the study and their right not to be involved. Again the literature was reviewed as to elicit how this issue was addressed in other observation studies. Houghton et al. (2010) displayed posters at the entrance to the wards, and provided information sheets to the key

gatekeepers, which were the clinical nurse's managers on the ward areas where observation was conducted. Moore and Savage (2002) placed a notice at the reception desk in the clinic where they undertook their observation. Casey (2006) provided information sheets.

In this study, posters were displayed at the entrances to the ward area where observation was undertaken and also on the central notice board and at the Nurses Station. These posters were approved by the Research and Ethics Committee on the research site and are contained in Appendix 19.

6.6.2 Respect for patients' privacy

While undertaking observation, I was mindful of issues of patient privacy and dignity and did not want to intrude on sensitive situations without due regard. During observation, I was constantly careful to show discretion as to where and how I spent my time during observation. On one occasion while observing in Ash Ward, I left the room as a medical team were discussing a patient's deteriorating status with a family member. I felt this was inappropriate for me to be present at that time. On several occasions in Hazel Ward, the nurse Marcella, who I was observing, entered a bed space where the curtains were drawn. I did not enter the space behind the curtains. On these occasions my observation on the administration of the medication event was merely listening to Marcella's interactions with the patient.

6.6.3 Dual identity

The dual role of nurse and researcher has the potential to cause some challenges. Bloomer et al. (2012) warn that such a position may result in situations where the researcher has to choose one identity and its associated obligations over the other, in the best interests of the study participants or patients. In my instance, I am both a researcher and a nurse, and in line with my Code of Professional Conduct (NMBI 2014), I hold a duty of care to patients. As a non-participant observer, there may have been occasions where I, as a researcher may witness nursing practices that compromised the safety of the patient or of others, and as a registered nurse it would be my duty to intervene. This could have been made more difficult as I was a novice researcher in the field and would have to decide what would be a significant enough threat to patient safety or wellbeing, and also when and how to intervene may not always be clear (Parahoo 2014).

An ethical protocol provides guidance on when the researcher will intervene in the care of the patient (Houghton et al. 2010). It can be difficult though to find a precise definition for when a patient gets into danger or as to what constitutes an emergency (Casey 2006). Davies et al. (2000) intervened directly in patient care only when they judged a situation to be potentially dangerous, for example, when the observed nurse was about to make a drug error. Casey (2006) and Houghton et al. (2010) both reported the use of an ethical protocol prior to entering the observational field. However, both researchers reported never having to use the protocol. For the purpose of this research study, an ethical protocol was developed which provided guidance as to if/when I would intervene. This protocol was approved by the Research and Ethics Committee. This protocol was given to the participants prior to observation and to the CNM II's in the ward areas prior to periods of observation.

While undertaking observation, I acted in accordance with The Professional Code of Conduct (NMBI 2014) to ensure that patient safety was not compromised at any time. The extent and purpose for which I would intervene in a situation that goes against standard nursing practice was adapted from an ethical protocol put forward by Casey (2006). I would intervene in patient care only when a) a patient is experiencing a life-threatening event such as a cardiac or respiratory arrest b) patients' lives are at risk from other patients or fire c) no nurse or carer is present and a patient is at risk of injury, for example, a fall. In addition to Casey's (2006) three points, I would intervene if a potential serious incident were to occur in relation to medication administration (Appendix 13). I identified that I would deal with any such instances on a case by case basis, in accordance with The Code of Professional Conduct for Nurses and Midwives (NMBI 2014) and in accordance with local policy.

There were two occasions where it was necessary for me to take on a nursing role. While observing on Ash Ward, Grace was attending to a patient whose oxygen saturations were dropping despite her intervention. She called for assistance and for the cardiac arrest trolley. I was able to obtain the Emergency trolley and seek further assistance. When further help arrived I returned to my observation role. When observing on Hazel Ward, I was standing back from where Marcella was administering oral medications. I heard the patient fall in the bathroom. I was able to highlight this to Marcella and assist in gaining access to the bathroom and obtaining further help for Marcella to safely assist this patient.

6.6.4 Dress during observation

As the case study took place in the organisation where I am employed, and the sites chosen for observation were clinical ward areas, consideration took place as what attire I should adopt during observation. Some suggestions were that I should wear a white coat, a plain white nursing tunic, scrubs or plain clothes. Following discussion with my supervisors, it was decided that I would wear basic smart dress during observation periods. I am a staff member within the organisation and continued to wear my staff security badge during observation.

I chose to attire myself in black trousers and top during observation period. Indeed during my period of observation on Hazel Ward, Marcella, who I was observing, informed me that other staff members referred to me as 'the lady in black'. During my observation period in Ash Ward, a serious hospital acquired infection was identified and Infection Prevention and Control Department applied strict precautions on the ward. I was advised, that if I wished to remain observing, that I would be required to wear scrubs during observation. This meant I was dressed the same as all other staff on the ward. On Oak Ward, I again reverted to smart dress during observation periods.

6.7 Data Analysis

As previously discussed, Stage 3 of this realist evaluation focused on testing and refining programme theories in the form of conjectured CMO configurations, which allowed me to explore the interactions between the contexts, mechanisms and outcomes. Analyses of data in this project was not seen as a separate process for each stage of the research, but as an iterative process of placing nuggets of information (Pawson 2006) within a wider configuration explanation (CMO) (Manzano 2016). While Chapters 7, 8 and 9 reports the findings from Stage 3, the discussion presented in Chapter 10 integrates data collected during Stages 1 and 2 and other data as it emerged during the course of the study. Insights pursued during data analysis should ideally be both contemporary with and retrospective to fieldwork (Manzano 2016).

Similar to the previous stages, NVivo™ (10) was used in the analysis of data in Stage 3. Data from this stage was analysed, both deductively and inductively. The conjectured CMO configurations provided the framework categories for analysis, and the code template/framework developed in Stages 1 and 2 was applied for deductive coding. Inductive coding was also applied to capture any new themes which emerged from the data

with multiple new codes emerging. The Stage 3 CMO Mapping Template was also utilised to assist with mapping findings to conjectured CMO configurations. 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). Based on the recommendations by Wong et al. (2016), analysis in this stage also focused on examining whether an identified theme functioned as a context, mechanism or outcome in and also about the relationships between the contexts, mechanisms and outcomes.

6.7.1 Semi-structured observation tool

The purpose of the observation tool was to assist me in maintaining my focus on details which were relevant to the testing of the conjectured CMO configurations when undertaking observation. Prior to entering into the field the Stage 3, CMO Mapping Template was developed (Appendix 15). This tool mapped observable actions to the conjectured CMO configurations. Thus, for each context, mechanism and outcome, the associated observable action was identified. An example of the context mapping for CMO 1 – patient safety culture is detailed below in Table 6.6.

Each completed observation tool was scanned into NVivo™ (10), which was used for analysis. The completed observation tools were read and re-read to get a sense of the data they conveyed. Data from the observation tool was both deductively and inductively coded. The deductive coding was based on the a priori code template developed in Stage 1 and 2. The Stage 3 CMO Mapping Template also assisted with this process, as illustrated in Table 6.6. The particular aspect of interest had been mapped to the three conjectured CMOs prior to data collection.

During observation, the observation tool also allowed for me to tick a 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. This quantitative data was incorporated into the findings in qualitative findings in Chapters 7, 8 and 9. These were later indicated with the qualitative codes to further explain the data.

CMO 1 – Context- Positive Patient Safety Culture		
Observation Tool Section	Spradley (1980) Dimension	Observation
Part A	Acts	Further information sources available example computer with Medecines.ie or hospital formulary, BNF etc)
Part A	Space and Objects	Medication storage
Part A	Act and Actors	Leadership style local level – visibility of nurse manager
Part A	Actors and activities	People entering and leaving the observation field and their activities
Part A	Events	Recording any significant observed events
Part B	Acts	Checking name band
Part B	Acts	Application of policies
Part B	Acts	Checking the 5 rights

Table 6.6 Example of Stage 3 mapping document – Context - Patient Safety Culture

6.7.2 Field notes

Some jottings on the semi- structured tool were taken during observation, and field notes were written up immediately after the observation period. These documents were also entered into NVivo™ (10) and coded, both inductively for any new emerging themes, and also deductively based on the conjectured CMO configurations.

6.7.3 Interview data

Audio recordings of the interviews were listened to while the transcriptions were read. This allowed me to assure the quality of the transcription, and also to immerse myself once again in the interview data. All interview transcriptions were entered into NVivo™ (10) and inductively and deductively coded utilising the Braun and Clarke (2006) thematic analysis framework. Even though Stage 3 was about testing the three conjectured CMO configurations the previous coding template from Stage 2 was utilised. This aided in ensuring that data analysis in Stage 3 was not done in isolation but it continued the iterative nature of data analysis associated with realist evaluation. Table 6.7 illustrates the coding template.

Context	Mechanism	Outcome
Professional standards	Education and resources	Error Reporting
Multi-disciplinary collaboration	Change Management-Quality Improvement	Patient harm
Organisational structure	Individual motivation Change of thinking reasoning	Professional practice
National Initiatives and structures	Philosophy of education	Measuring impact
Leadership and peer support	Enabling behaviours	
Organisation Values and Goals	Opportunity to apply learning	
Physical environment- Work setting		

Table 6.7 Coding template

6.7.4 Inspection reports

Since Stage 1 was conducted, two new inspection reports in relation to medication management in the organisation understudy had been published. These were also entered into NVivo™ (10) and analysed utilising the previous codes and Braun and Clarke (2006) framework.

6.7.5 Medication incident reports

The focus of analysis was to examine the number of reports and what reports were in relation to administration of medication.

6.7.6 Quality Care Nursing Metrics

The scores achieved in each of three medication indicators were reviewed for each ward area. These are reported associated with the context and mechanism configuration.

6.8 Conclusion

This chapter has presented the methodology tools which were utilised in Stage 3 to collect data in order to test the three conjectured CMO configurations. An introduction to case study, and its suitability for use in this study was provided. The sampling framework, my case study and the embedded cases were presented. Next the various methods of data collection were discussed. A detailed description of observation as a method of data collection was given and its place in this study was provided. Continuing to address observation as a data collection method, a detailed discussion of rigor in this study and the ethical principles which I applied during observation followed. The methods of data analysis were also discussed.

This was a limited discussion as Chapter 4 and 5 have already addressed the use of thematic analysis in this study.

Chapter 7-Stage 4- Testing Conjectured CMO 1

7.1 Introduction

This chapter is the first of three chapters which reports the findings of Stage 3. This chapter, along with Chapter 8 and Chapter 9, make up Stage 4 of this realist evaluation. The themes/headings, which the context, mechanism and outcomes are reported under, are those which had been identified in Chapter 6. The findings in relation to context and mechanism are reported under Ash Ward, Oak Ward and Hazel Ward. The findings in relation to the outcome for each of the three wards then follow. Table 7.1 below reminds us of the embedded case studies and the participants from each embedded cases.

Embedded Case	Participants	Observation	Interview
Ash Ward	Grace	√	√
	Clodagh	√	√
	Leah- CNM II		√
Hazel Ward	Marcella	√	√
	Frances –CNM II		√
Oak Ward	Cathal	√	√
	Karen-CNM II		√

Table 7.1 Stage 3 participants

This chapter, reports on the findings related to conjectured CMO 1. Conjectured CMO 1 stated that: 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**.

7.2 Ash Ward

Ash Ward was a 27-bedded mixed medical ward. There were five participants on the ward which met the inclusion criteria. The first two participants approached, Grace and Clodagh, agreed to take part in the study. The CNM II positively promoted the study to the participants.

7.2.1 Context- Patient safety culture

Patient safety culture was identified in Stage 1, and confirmed in Stage 2 as influencing medication safety. Two factors identified in Stage 1 and 2 as components of a patient safety

culture were leadership and the local or ward culture. These concepts are further explored during Stage 3.

7.2.1.1 Local Leadership

The CNM II, Leah, was clearly visible during periods of observation when she was on duty. When the CNM II was not on duty during observation, the CNM I or person in charge was clearly visible providing support to Grace and Clodagh. On one occasion, when Grace was preparing an intravenous antibiotic, she requested the CNM II Leah, to complete the independent double check. Following checking, Leah questioned the duration of the patient's treatment and the medical team's plan for review of treatment. This fostered reasoning and thinking skills with Grace. On a second occasion, when asked to do a double check of an intravenous antibiotic, the CNM II and Grace had a discussion in relation to the cautious use of the medication in patients with a history of seizure.

When I followed this up in interview Grace responded that:

"Yeah. Oh, Leah would be very good, ""Why are they still on that?"

Leah supported this when interviewed:

"I would, yeah. And I think that as nurses, you always need to be thinking, ""Why are these patients on their medications? Should they continue on these medications?"" And I know there's other members - our pharmacists would be looking at that, the medical team would be looking at that. We also need to remember that we're the ones that are physically administering it and encouraging the patient to take this tablet, and we need to think, ""Do they really need this?"" And we need to be able to justify why we gave that tablet."

When the CNM II was absent from the ward area, clear leadership and support was also observed. On one occasion during observation, Clodagh found medication on a patient's locker which had not been taken. She was observed discussing the options available to her with a senior staff nurse, and she then safely disposed of the medication and documented that it had not been taken on the chart. When Clodagh was asked about support from others in the ward in an interview, she responded with:

"It's very busy. It's very busy, but it's a very supportive environment, because I'm only a newly grad. It's a very supportive environment. Like, there's plenty of nurses I can ask questions to

and get help and I know where I can get a lot of the information from, and I know who to call if I need to call someone”

7.2.1.2 Ward atmosphere /culture

There was no instrument or tick box on the observation tool for ward atmosphere or culture. As culture is the set of values, behaviours, goals, attitudes, practices and beliefs shared across the ward (Scott et al. 2003) this could not be reduced to a mere tick box. On my first day of observation when writing in my reflective journal, I noted that I felt welcome on the ward. A Healthcare Assistant gave me a high stool to sit on while I was observing, and I felt that this was a welcome gesture and an offer of acceptance. Similarly, both Grace and Clodagh reported Ash Ward as having a very positive supportive environment.

Grace: “It's lovely. I love working here. I'm a year here now next week. And I trained here as a student and I loved it. It's very busy, a very, very busy ward. But it's a great ward to work on and I've got great experience even in the last year. So I really like it here.”

Clodagh: "It's very busy. It's very busy, but it's a very supportive environment, because I'm only a newly grad. It's a very supportive environment. Like, there's plenty of nurses I can ask questions to and get help and I know where I can get a lot of the information from, and I know who to call if I need to call someone. But other than that, it is very busy. It's very... it's a high demand ward, I feel. It can be very hectic, but sometimes you just have to take the time just to be like, ""one minute, and I'll be fine."""

When asked to describe the ward she was manager on (meaning speciality, bed numbers etc.), Leah began her description as:

“So, it's a fun ward (laughs). It's an exciting ward. No two shifts are the same. No two days are the same. For me as a manager, no two days are the same. One day I could be completely clinical and I could be spending the full day with a staff nurse and a very sick patient. Another day it could be pure management. “

7.2.2 Mechanism- Reasoning skills

Reasoning skills was a mechanism which was refined during Stage 2. Two themes were identified as contributing to reasoning: seeking out further information and problem solving.

7.2.2.1 Seeking out Drug information

The safe medication administration education programme emphasised the necessity of having knowledge of the rights of medication management prior to the administration of any medication. The semi-structured observation tool collected data on the use of information sources. In the hospital, there was limited availability of British National Formulary medication booklets. No mobile electronic devices were available on medication trolleys.

On Ash Ward, there was a computer available in the nurses' station in the Hawthorn unit, and two computers were available in the nurses' station where the medication was prepared. Another computer was available in the CNM II's office at the back of the nurses' station. These computers were used for multiple purposes including by the multi-disciplinary team for ordering investigations, checking results etc.

During observation, Grace was seen checking information sources in just three of all 26 medication administrations observed. These were all for intravenous medications. The source of information used for these three checks was the antibiotic quick guide poster, which was available on the wall in the drug preparation area. During interview, I asked Grace how she knew the medications she was administering when she did not refer to an information source, she responded:

"No. I mean, I was happy to know the meds that I was giving, but if there was something, I could look up the BNF or I could look up the A-Z guide there."

Clodagh was seen referring to medicines information in just four (20 observed) of her administrations. Three of these checks involved using the Hospital A-Z on the computer in the drug preparation area. The fourth information check was when she discussed finding medications with a senior staff member. When discussed at interview about not referring to any information sources for oral medications, Clodagh replied:

"Yeah, I'm comfortable that I know most and then the ones that I don't, because I always have... because the BNF is hidden. It's in the corner behind us, but it is hidden away and then

if you've to come out and get it, it is a delay. So most of the time if I need to, I will just look it up on my phone."

When asked about using information sources for intravenous medication preparation, Clodagh clarified she always checks information sources:

"Yeah, because I am always... unless it's something I definitely know. There's a few I would know like co-amoxiclav and there's just a few I would know. But then most of them I would always have to look them up because some of them sound so similar so yeah, I have to check how much water I am putting into them, and what am I putting them into."

7.2.2.2. Problem solving

Reasoning skills, in relation to medication administration, were observed on Ash Ward. One example was when on Day 2 of observation; Clodagh found oral medications left on a patient's bed locker. She proposed to a senior staff nurse that she would dispose of the medication and amend the drug kardex. The patient had been unable to take the medication when given earlier due to nausea. Clodagh was then seen to check the patient's prescription and prepare and administer an intravenous anti-emetic to manage the nausea. When asked in the follow up interview, Clodagh stated that:

"I just know that man at the time was very nauseated and then he ended up being very sick. So yeah, it does happen. I don't like taking the responsibility then for giving them, so oftentimes if they're not important meds, or if they're once daily's, I'll throw them out and I'll give them again later."

Likewise when observing Grace, she found medications on a patient's locker which had not been taken from a previous drug round. Following discussion with the patient, she disposed of the medications and amended the medication kardex.

Grace: *"So yeah, like this morning now, that shouldn't have happened. The nurse that was there ideally shouldn't have given that. You can't just leave medication and walk away. The only thing I could really do was just take it away, or either let her take it there and sign it for then, or take it away and let her have it now."*

The follow up interview also gave me a chance to explore further if the staff felt that there had been any change to the thinking following undertaking the safe medication administration education programme. Both Clodagh and Grace had been nursing students within the hospital and had undertaken the education programme upon registration as a staff nurse.

Clodagh: *"I don't know because I know as a student I was always very nervous when administering medication, so I think I always try to be as safe as I can and always check things. But then, since doing the medication administration and working with students as well I would notice that I'm cautious and I'm trying to relay to them while they're watching that, ""this is what you do. You're checking the expiry date. You're checking the frequency. You're checking the route."" So I think with a few things, with the students and doing the course, then yeah, I have changed my practice."*

When Leah was asked about staff using information sources to check medication details, she confirmed that staff appear to do so following completion of the safe medication administration education programme:

I think they are more cautious. I think now they're... they understand more the reasons why we're checking things. I think... am I being clear enough? It re-focused a lot of people. So maybe they hadn't really thought much about medication management. It had become maybe routine to them and they hadn't thought it as a safety issue. But I think by re-doing the course, it re-directed them that drug rounds, medication safety are a priority for nurses."

7.3 Hazel Ward

Hazel Ward was a 35-bedded mixed medical and surgical ward. There was no speciality associated with the ward. Recruitment of participants on Hazel Ward proved challenging. When approached, the CNM II agreed that the ward would participate in the observation, but no assistance was provided with the recruitment of participants. Six staff met the selection criteria, the first participant approached agreed to take part in the study and the first observation period was mutually agreed. When I went to the ward to undertake the observation, the potential participant informed me that she no longer wished to take part. A second staff member approached, refused to participate even before full details of the study were explained. The third staff approached, Marcella, agreed and consented to take part in

the study. Three other staff nurses who were eligible were not available to participate due to leave and night duty shifts.

7.3.1 Context- Patient safety culture

7.3.1.1 Local leadership

On the first day of my observation on Hazel Ward, there was no CNM II in post on the ward, and the ward was being managed by the CNM I or the senior staff nurse on duty. Following the observation period, an existing staff member, Frances, was appointed to the CNM II post on a temporary basis. Frances later undertook the CNM II interview following completion of my observation with Marcella.

On the first day of observation, the CNM I, who was in charge of the ward, said *'it's a bad day to start- it's very busy'*. One of the CNM I's who was on duty and visible behind the nurses' station on two days of observation, but had no interaction with Marcella or did not enter the ward area where Marcella was working. Therefore, no interaction with a manager was noted during observation periods. On Day 2 of observation (a Sunday), there was no CNM on duty and the nurse in charge was not evident. There was also no evidence of any interaction with a clinical leader during this observation period.

The topic of leadership on Hazel Ward was explored with Marcella during interview. When asked about who was responsible for medication safety in the hospital, Marcella responded in a negative manner to the management in the area:

"The nurse is supposed to be. But blame comes on you and it may not be you".

When leadership and support was discussed with Frances during interview, her views were quite different to those offered by Marcella. Frances spoke very positively of the leadership provided on Hazel Ward. However, she did not strongly identify her role in leadership in general on the ward area:

"Well, I try and provide the support for the girls while I'm here and then Anne-Claire (CNM I) is a great support as well, and Justine (previous CNM II) and Adelene (ADON) as well. Justine has been great since she got the xxxx post. She's been great support to the ward and Anne-Claire has always been great to me since I started and she's helped me an awful lot in this post as well."

As discussed in Chapter 6, Marcella refused to allow me to record the interview I completed with her. Immediately following interview, I wrote up the details of the interview and I also completed some personal notes. An extract from these notes reflects my understanding as to why Marcella did not allow the interview to be audio-recorded:

"I can understand why Marcella may have been anxious about me recording it, as she conveyed a sense of a working environment where she received very little support, both in every day practice and also in particular reference to safe medication administration."

The changes occurring with local management on the ward may have affected the leadership on the ward at the time of observation. However, it is important to note that the appointed CNM II had previously been a staff member on the ward.

7.3.1.2 Ward atmosphere/culture

Another factor which was identified in Stages 1 and 2, which may contribute to the patient safety culture on the ward, is the ward atmosphere or culture on the ward.

During observation periods on Day 1 and Day 3, the ward was very busy with multiple staff, medical, cleaners, catering, porters, physiotherapist and occupational therapist constantly present and moving up and down the corridors. Indeed, an extract from my field notes taken on Day 1 of observation on Hazel Ward, identifies my feelings about the atmosphere on the ward:

"the chaotic environment was palpable"

Day 2 of observation took place on a Sunday, with a marked difference in the atmosphere on the ward. There were very few other staff on the corridors and music was audible on the corridor from a radio in the nurses' station.

The atmosphere of the ward was further explored during follow up interview. The first question at interview was when I asked Marcella to tell me a little about the ward she is working on:

"It's difficult to work in. It's okay but it's not easy to follow polices because it's so busy. Maybe it's my efficiency- but I just can't manage everything."

My next question was, *'What's it like to work here?'* and *'what's the atmosphere like here?'* This question yielded no response, but a puzzled look. I then I followed up with: *'Is it a supportive clinical area?'* There was a pause and Marcella responded with:

"What is this about again? "

At this point I decided to leave further probing in relation to the ward atmosphere and culture and move on to other topics.

The lack of response to questions from Marcella raises concerns as to the culture and atmosphere on the ward. It also needs to be considered that, on this ward; I had difficulty in recruitment of participants. Further discussion on the culture in relation to reporting medication incidents on Hazel Ward is discussed in 7.5.2.

As with the theme leadership, Frances's views on the culture and atmosphere on Hazel Ward were very positive. I can't identify these as being in contrast to Marcella's, as Marcella did not respond to the questions posed. Frances described Hazel Ward as:

"Everyone gets on so well. The staff... there's a great relationship with all the staff. I've been here for five years since I qualified and everyone's been so helpful. It's busy and it's very hard when we're short staffed, but everybody gets on so well. We all pull together and help each other out, so definitely one of the best wards I've been on in the hospital anyway."

7.3.2 Mechanism- Reasoning skills

7.3.2.1. Seeking out information

During all observation in the administration of oral medication (n=19), Marcella was not observed referring to any medication information. On Day 3 of observation, when Marcella was preparing intravenous medications (n=3), she discussed the dilution and required concentration of one of the medications with another nurse. She did not refer to any other information source. The intravenous medication was prepared in the treatment room/medication preparation room, and a computer was present in the room. During observation, the computer was not turned on and the keyboard was left on top of the processor, it did not appear to be in operation. On the follow up interview, Marcella was asked if the computer is used and if it worked and she said it did. An antibiotic quick guide poster was present in the medication room also.

7.3.2.2 Problem solving

Throughout the observation periods when Marcella was preparing medications, she was seen to use her finger to run over the name and dose and expiry date of medications and appeared to voice this out loud as well.

On Day 1 of observation, she was also seen to use some reasoning skills when encountering a patient who had taken her own medications earlier and this had not been recorded. Marcella discussed the taking of own medications with the patient, and advised her on how best to proceed. Marcella then made the relevant entry into the patient's medication chart.

When undertaking interview with Frances she was asked about the support provided by others in relation to thinking and reasoning in the context of medication administration. Frances outlined her current practice:

"So I always try, especially the girls who are just newly qualified, who wouldn't really be looking into the medications when they're training, always to just to look, to understand what you're giving and why you're giving it, and what the side effects of that drug are."

Marcella was also asked during interview if she was encouraged to think critically about medications she was administering. She responded that it is not her experience:

"it's just so busy the manager would not have time or interfere with your work to ask you about it. Well, Justine when she was here, he would know that you are just so busy he won't ask or question you cause he would know that you would just not have time for that."

7.4 Oak Ward

To remind ourselves, Oak Ward is a 20-bedded unit with single patient rooms. Cathal was the staff nurse who agreed to undertake three periods of observation and this was followed up with an interview. Karen, the CNM II, also partook in an interview. The number of medication administrations observed was less than in the other wards due to the patient allocation. All observations took place on weekdays.

7.4.1 Context- Patient safety culture

7.4.1.1. Local leadership

Oak Ward was the only ward that had a full-time Clinical Facilitator in post. The role of the Clinical Facilitator is to provide clinical nursing support to new staff and existing staff, in

order to ensure they achieve the required competence required to work in the clinical area. They are also involved in practice development in the local area as required.

On Day 1 and Day 3, the CNM II and Clinical Facilitator (CF) were briefly visible on the ward corridor. On Day 1, there was only one interaction observed between them and Cathal and other staff, as both the CNM II and the CF left the ward following this interaction. On Day 3 of observation there were multiple interactions observed between the CNM II and other staff on the floor.

Analysis of interview data with Cathal (staff nurse) indicated that not all leaders are managers. During interview, Cathal spoke on multiple occasions about the support he received in relation to medication management from his 'seniors'. When asked if he is encouraged to think critically about medication administration, Cathal responded positively and identified that those encouraging critical thinking are his 'seniors':

"Yes, sometimes, for example this diuretics, they've encouraged us that before giving any diuretics to check the creatinine levels, and if the creatinine level is high, just try to ask the doctor 'shall we continue in giving this diuretics or not, or is there any management for correcting these levels?'"

Later in the interview when asked about support in relation to medication management, Cathal again identified the role of his 'seniors' in providing this support:

"And my seniors were really strict that time, they were really strict. So at first I was really irritated, 'ah, why do I have to go through this?' But then it became a practice. It's your routine. So once you follow it, it's within your working habit, it becomes a habit. So now I've developed the habit of checking everything. If we hadn't gone through the course then maybe the habit wouldn't be there."

During interview, Karen, the CNM II, acknowledged her role in providing support to staff in relation to medication management:

"Safe medication programme, like if we see if anybody is constantly making errors here and then, so as a support we send them so that they get upgraded and they improve their knowledge and improve their betterment and their practice and they have knowledge. So in the future I'm hoping to train all the staff in medication management to have a good base."

Karen also discussed the role of the Clinical Facilitator in supporting staff on Oak Ward:

“Definitely, supporting staff. Clinical facilitator has a very good, , main role in clinical support for the staff, especially the new staff and especially the courses that we are running, CCNS (Critical Care Nursing Skills) course, in which supervision is much, much needed, and to upgrade and to improve the quality of care and continuous professional development of the staff as well. So yeah, we work conjointly together (laughs) as a manager and as a clinical facilitator”

It was clear that there was a strong sense of leadership, of the hierarchical nature on Oak Ward from the CNM II, Clinical Facilitator, but also senior nurses on the floor.

7.4.1.2 Ward atmosphere/culture

The culture and atmosphere on Oak Ward was calm with a sense of order and control. On Day 1 of observation, I recorded that the corridor was busy with two cleaners present when Cathal started his medication round, but the cleaners did not appear intrusive. The physical structure on Oak Ward with its wide corridors and individual patient rooms may have contributed to this.

When asked during interview to describe the ward, Karen stated that the:

“Atmosphere is good. There's good teamwork. Everyone works and takes care of each other, and patients are benefitted.so education wise we are giving support for the staff to have their continuous professional development, and any problems with staff, or any conflicts, they come to me as a manager, and I try to deal with it then.”

During analysis of data, a culture of supportive learning emerged in Oak Ward. There was also a sense of self-responsibility, with Karen stating in relation to nursing staff and medication management that:

“we teach them hospital policy, so everyone has their pin numbers. They are liable to do what they are told. If they are reasoning, they are responsible as well. ”

Again this statement from Karen supports a hierarchical approach to leadership.

7.4.2 Mechanism- Reasoning skills

7.4.2.1. Seeking out information

During observation, Cathal was not seen to refer to any information sources for medication he was administering. No discussion was observed either with other staff members in relation to medication. During interview, I asked Cathal if he ever uses sources to check details for medication administration.

"Yeah, at first, during the first months I really had to do reading, a lot of reading, because I'm not familiar with the medication and the doctors use this brand name, so 'oh, what are these?'. So after a while these xxxxx patients have the same medication so you become familiar with it. Otherwise, if I encounter any medication I have to look through it. "

When asked what sources he used to gain this information, she responded:

"I gathered a lot of information about these medications from the Google." And if she requires any information now she stated she: "I would go through BNF in the computer now."

The CNM II, Karen, described how she encourages staff to refer to medication information resources:

"What I do is, in between like, and I just go along when they are doing the medications and just ask, especially if it's a junior staff, I'll ask, ""What are you taking? What is the medication like and what is the action, side effects and all?"" We have great staff who know... I mean, we have BNF in the trolley. So they have to read if they are not sure about any medication, to read about that medication before they give. So I encourage the staff to know as much as possible, to know the medications. "

7.4.2.2 Problem solving

During observation, it was noted that Cathal appeared to review all medications prescribed and due to be administered at that time, and when required go and obtain the nutritional supplements from the fridge in the medication room for the patient. This meant that Cathal did not have to go and leave the medication administration during or after the process and once the other medications were prepared, he was able to take them directly to the patient.

This was coded as an example of problem solving in order to avoid interruption in the preparation of medication. When asked about this practice in interview, Cathal responded:

"I always do that. Because it's really annoying opening the drug trolley and, okay, opening the medication and put it in the medication cup, then you realise in the middle of the kardex there's nutrition supplement, so you have to close the trolley again and go to the press where you keep all these energy drinks and go back. So it's really time consuming for me to be going back and forth, back and forth, and especially if I have this MDAs included in their regular medication, it's better to take note of the timing as well so you won't be running back and forth"

During interview, when Cathal was asked if he did anything different after completing the safe medication administration education programme, he spoke about how it reminds him to keep patient safety in focus no matter what else is going on around:

"What you've told me from the course, it's really the ideal set-up, but then when you come into practice it's a different set-up, so we really have to adjust but we have to keep in mind patient safety always. Yeah, the basic things about patient safety even though you are interrupted but keep in mind that we always have to..."

When Karen was asked during interview about changes that she may have noticed in staff following undertaking the medication administration programme, she highlighted that:

"..because they have the base of getting this online education, they are more cautious than the others who do not have the knowledge. So I think that is beneficial"

7.5 Outcomes

During the design for Stage 3, reporting medication errors was included as a sub theme for governance structures. However, during data analysis of this stage, it became apparent that reporting medication errors is indeed an outcome. The original outcome proposed for this configuration was that of patient harm. However, the reporting of medication errors is also an important outcome due to the importance of reporting and its contribution to a patient safety culture. The safe medication administration education programme under evaluation also dealt with the importance of reporting potential and actual errors. All interviews were conducted prior to the data on medication incidents becoming available.

7.5.1 Reporting medication incidents -Ash Ward

During the periods of observation with Clodagh or Grace, no medication incident reports (MIRs) were completed. During interview, when asked if she had ever reported a medication incident, Clodagh said she had and when asked how she felt about it, she responded:

"It depends on if it's been something I've done, or something out of my control. So if it's something I've done myself, you feel... you do feel guilty that whatever happened, happened and you're putting your name down saying, ""I did this. I did that."" Or, ""I didn't do this."" So there is a guilt, but I've never had any negativity come back about anything because I suppose it's all just... they look at the whole scenario that happened with it."

She also reported that *"... nobody is coming down on you"*, and also stated that she would encourage others to report an error.

"Yeah, and on the ward I know we always try to report everything because you don't know what's going to happen if you don't report it."

Grace also shared her experience of reporting a medication error, and how she *"felt awful"* after making it, even though the patient did not sustain any harm. When asked what support she had received, she described a very positive support system.

Grace: *"it was at night and I informed the ADON (Assistant Director of Nursing). The ADON was brilliant. She came up straight away, and she just told me all the mistakes she.... she gave me loads of examples of the mistakes she has made, and she told me that it's okay, these things happen too. But yeah, it was... I just felt really stupid (laughs). But it was okay."*

When the interview was conducted with Leah, she stated that staff do report errors and when asked how she manages that, she responded:

"You would sit down with them and you'd try to... you'd go through the form and see whether it was a lack of knowledge. Was it a lack of knowledge of checking procedures? Whether it was a lack of knowledge of the pharmacology of the medication? What was going on in the background at the time? Were they distracted? I know that at one point maybe someone... there was a cardiac arrest took place. Immediately after they gave the wrong..."

that there was contributing factors to it. What was their understanding of it? Could they explain why it had taken place? What could we learn as a ward from the drug error that had taken place?"

During 2017, there were 50 reported medication incidents in Ash Ward. Nineteen (38%) of these incidents were related to administration alone, with a further four related to administration and prescription or pharmacy. Incidents reported as A and B did not reach the patient. So it can be seen in Ash Ward, that nine (18%) of the incidents did not reach the patient. In total seven (14%) of all reported medication incidents lead to patient harm.

As discussed previously, a high number of reported errors are a positive aspect for patient safety. Higher incident reporting rates both demonstrate and promote an improved culture of safety (Abstoss et al. 2011). The medication incident reports support the interview data of an open positive culture towards the reporting of medication incidents.

NCC MERP Classification	Number
A	2
B	7
C	21
D	13
E and above	7
Total	50

Table 7.2 NCC MERP Classification of MRI's for Ash Ward

7.5.2 Reporting medication incidents-Hazel Ward

No medication errors were reported by Marcella during my observation period on Hazel Ward and on no occasion did I observe any medication incident that indicated that a

medication incident report should have been completed. During interview, Marcella 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”.

Similarly, when asked about who is responsible for medication safety in the hospital, Marcella responded:

“The nurse is supposed to be. But blame comes on you and it may not be you.”

Marcella continued on to provide an example of where she had been spoken to in a negative manner by a senior nursing manager after they had found medications left with a patient which had not been taken.

Frances was also asked about reporting medication incidents during interview, and if she encourages staff to report incidents if they occur. She responded positively.

Frances: *“Yeah. Oh definitely, because I suppose it's the only way you're going to learn that you've made a mistake, you know?”*

On Hazel Ward there were only 20 reported medications incidents in 2017. Seven (35%) of this total were listed as relating to administration with one (5%) attributed to administration and prescribing, and one (5%) attributed to administration and other factors which were not specified. Table 7.3 details the NCC MERP classification of the reported medication errors for Hazel Ward. Incidents reported as A and B did not reach the patient and nine (45%) of such incidents were reported in Ash Ward. In total, two (10%) of all reported incidents led to patient harm.

As discussed previously, 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 Hazel Ward, 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.

NCC MERP Classification	Number
A	3
B	6
C	5
D	4
E and above	2
Total	20

Table 7.3 NCC MERP Classification of MRI's for Hazel Ward

7.5.3 Reporting medication incidents-Oak Ward

During observation with Cathal, no medication errors were reported and there was no occasion observed that indicated that a medication error report should have been completed. During interview, Cathal was asked if he had ever reported a medication incident. Again the influence of the 'seniors' on the ward came through strongly:

"It was, at first it was a bit scary, but then one of my seniors told me that it's better to tell your mistake rather than keep it to yourself and repeating it again. So at that time I thought, yeah, it makes sense. At least you were able to say that 'I made a mistake' and it was corrected as well."

When Cathal was asked if, following his experience, he would encourage others to do so, he agreed:

"Yeah, it's better to report. At least you know what's going on, rather than adding up to the problem."

During interview with Karen, reporting medication errors was also discussed. Karen was asked if she encourages her staff to report medication errors:

“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. ”

To further explore Karen’s attitude towards medication errors, she was asked if she had ever reported an error herself. She responded that she had displayed a positive attitude towards making an error:

“Myself? It's like long time when I was working on the ward definitely (laughs). I think sometimes it is the stress of work. It is not that you don't know the medicine, its stress of work, like if you have too much, and too much disturbance when you are doing the medication. I think that is the time when you make mistakes. So I have done as well (laughs). Everyone does (laughs) once in their career”.

Oak Ward reported a mere fifteen medication incidents in 2017. Eight of these were attributed to errors with administration (53%) and one (7%) attributed to error with administration and prescribing. Details of the NCC MERP classification for the medication reported incidents for Oak Ward can be found in Table 7.4. No reported medication incidents led to patient harm. Again similar to Hazel Ward, this is a very low number of medication incident reports for the bed capacity of the ward.

NCC MERP Classification	Number
A	0
B	1
C	10
D	4
E and above	0
	15

Table 7.4 NCC MERP Classification of MIR’s for Oak Ward

7.6 Conclusion and Reconfigured CMO 1

Through the testing of this context on the three embedded sites, it is clear that leadership and ward culture contribute significantly as a context and thus, can be accepted. Leadership and ward culture were originally proposed as dimensions of a patient safety culture. In light of the findings from this study, leadership and ward culture should be stand-alone contexts and tested independently in future evaluations.

A patient safety culture was identified to trigger reasoning skills in staff, which led to a positive approach to reporting medication incidents and to the number of reports. This was very clearly demonstrated in Ash Ward. Hazel Ward had not established a patient safety culture on the ward and thus, reasoning skills did not appear to be activated and there was a negative approach to reporting medication errors. On Oak Ward, where there was somewhat of a patient safety culture but with authoritative leadership, some levels of reasoning skills were observed. However, there was a reasonable attitude to reporting, but a low number of medication incident reports.

Therefore CMO configuration 1 is accepted:

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**.

The recommendation for further testing is that leadership and ward culture should be established as separate dimensions and tested as such.

Chapter 8 -Testing Conjectured CMO 2

8.1 Introduction

This chapter is the second of three chapters which reports the findings from Stage 3. This chapter, along with Chapter 7 and Chapter 9, make up Stage 4 of this realist evaluation. The themes/headings which the context, mechanism and outcomes are reported under are those which had been identified in Chapter 6. This chapter reports the findings uncovered in relation to CMO 2 for context and mechanism from Ash Ward, Oak Ward and Hazel Ward. The findings reported relate to **CMO 2**: 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.

8.2 Context- Safety Focused Governance Structure in the Organisation

The governance structure in relation to medication management and safety had previously been established in Stage 1. Prior to commencing observation in April 2017, HIQA visited the organisation and completed a review on medication safety in the organisation. HIQA (2017) 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”

HIQA (2017) also identified that the Drugs and Therapeutics Committee provided structured governance for medication safety in the organisation.

“There was a clearly documented structure relating to medication safety in place in It was evident that the medication safety agenda was being actively progressed at the hospital. Operational implementation of the medication programme was effectively facilitated by the Medication Safety Co-ordinator and supported by the Pharmacy Department, the Drugs and Therapeutics Committee, the Senior Management Team and staff at the hospital. The Drugs and Therapeutics Committee was responsible for oversight and implementation of the medication safety operational plans.”

It can be seen that at organisational level, or what Pawson (1996) would refer to as the broader infrastructural system, the outermost layer, there was safety focused governance. I also set out to test the application of these structures to local practice at ward level. The physical environment had previously been identified as a sub theme of the organisation structure. A new theme identified during observation was that of interruption to medication administration. It has been identified as a context factor, as it was seen as a cultural aspect of the given contextual domain (Pawson 2006). The organisation had a policy document in place which identified practices that should be applied by nurses when administering medication to assist with the reduction in interruptions.

8.3 Ash Ward

8.3.1 Context- Safety focused governance structure

8.3.1.1 Physical environment

On Ash Ward, oral medications were stored in the medication trolley, and the trolley was taken into the six bedded room and left on the corridor for single rooms and the three bedded room. There was no dedicated medication preparation room. Intravenous medication was prepared on a counter behind the nurses' station. The nurses' station also contained the patient's medical notes and two computers which are used by the ward clerk, other staff nurses and multiple members of the multi-disciplinary team for checking investigation reports, ordering investigations etc. The nurses' station also contained the two main ward telephone numbers. On one occasion on Day 1 when observing Clodagh while she was preparing an intravenous medication, there were six other people also behind the nurses' station, these included a pharmacy technician, plumber, porter, registrar, ward clerk and another staff nurse getting some equipment. On Day 1 when observing with Grace, eight staff were counted behind the nurses' station while she was making up the intravenous medications.

8.2.1.2 Interruptions

The semi-structured observation schedule had a tick box for interruptions during medication administration. Further details in relation to interruptions were also recorded. While the intention of the observation tool was not to quantify occurrences of any particular event, as interruptions occurred so frequently, it is of benefit to discuss the figures. Across the three observation periods for Grace, at least one interruption occurred during 13 of her 26

medication administrations. While observing Clodagh, 9 of the 20 medication administrations had interruptions. On the first day of observation for Clodagh, all but one of her administrations was interrupted (7 of 8). On the second day of observation (a Saturday), 2 of 5 of her administrations were interrupted, and on the final day of observation (a Sunday) no medication administrations were interrupted. Interruptions came from a variety of sources; patients, medical staff, physiotherapy, nurses, catering staff, cleaners and ward clerk. Another common cause of interruptions was medications missing from the medication trolley.

On interview, Clodagh spoke about how staff interrupt medication administration.

"They will often interrupt you but maybe they start it with, ""I know you're doing medications"" (laughs)."

On interview, Grace further discussed why interruptions may be necessary at times:

"And whatever about being down in D and E, but when you're in the Hawthorn unit, a lot of the distractions are probably necessary at the same time. If you get a phone call, you have to answer the phone. It could be biochemistry telling you a potassium is seven or something. You know, you can't ignore these things too. But whereas maybe down in D and E, if someone needs to go to the toilet or something like that or if a relative asks you a question and it's... yeah, it's hard. But I do understand the necessity for it too. But yeah, it's an issue."

The organisation had a policy in place in relation to reducing interruptions when administering medication and it utilised a red apron/ tabard and signage to support its policy. Data in relation to compliance with the use of red aprons and do not disturb signage was also collected. Again it was not the intention to quantify its use or lack of use, but it became important when reviewing the data and further examining the frequency of interruptions during medication administration. Grace only wore the red apron in 16 of 26 observations during medication administration, and there was no signage utilised. Clodagh's use of the red apron was lower and was only observed to wear it in 7 out of 20 medication administrations. Again, she used no signage.

On interview, both Grace and Clodagh were questioned about the use of strategies to assist in the reduction of interruptions. Grace, at interview, said she does wear her red apron

(only observed in 7/20), but finds that it is not useful at reducing interruptions and distractions.

Grace: *"No. It doesn't work at all. I think we could probably push it a little bit more. I will say that. But I really don't feel it works at all. You know, someone is still going to come you and its a matter of you then saying, ""No. You can't come. You can't speak to me."" And I know I probably don't help things either, like, I probably would speak to someone as well, or ask them a question. "*

Clodagh further expressed that she didn't feel that it worked:

"No. I just feel like when you wear it, only the other girls on the ward will know, 'Oh well, maybe I'll leave Clodagh until she's finished.'" But then when other family members are asking, often it's that they need something so you can't say, ""I'm wearing a red apron"" because they don't understand."

Clodagh went on to say that other hospital staff may know why she is wearing it, but still continue to interrupt:

"They will often interrupt you but maybe they start it with, ""I know you're doing medications"" (laughs)

The use of the red apron and signage was further discussed with Leah in relation to its inconsistent use.

Leah: *"I think at least it focuses the nurse on the fact that medication safety... that they have to reduce down the distractions. But I think from a patient point of view, if they need something they're going to ask you regardless of what you're wearing, and I wouldn't want them not to ask because whoever they're asking for, even if it's a glass of water, it's important to them and I wouldn't want them to think that they can't ask us for something. The MDT, often they need to tell you information. They're here maybe for five minutes; they need to tell you that information; they want to tell you that information straight away and they want to know that it's passed on to the correct person. I think it's reduced, in that I think we introduced that policy about five or six years ago, I think I can remember. I think the amount of distractions has reduced. At least it focuses the nurse on trying to minimise disruptions, but I don't think you're ever going to get it that you won't be disrupted during a*

med round. And sometimes in the Hawthorn unit, it's kind of a case that you want someone to interrupt you. If there's an emergency in the Hawthorn unit, you want someone to come running and shouting at you and saying, "There's an emergency in the Hawthorn unit. Stop your drug round and come in," you know? "

8.3.2 Mechanism- Quality improvement approach

During observation, I was unable to detect any behaviours or actions which would indicate that a quality improvement approach was being adopted by either Grace or Clodagh.

From the analysis of the interview transcripts, I was also unable to find any linkages between adopting a quality improvement approach following undertaking the safe medication administration education programme. What was clear though is that Ash Ward and their CNM were focused on quality improvement as a whole and also in relation to medication administration safety. During the course of the interview with the manager, Leah, it transpired that a number of her staff had completed the safe medication administration education programme, as there had been a serious incident in relation to medication management, and further staff education was identified as part of the quality improvement plan.

Leah: *"So, we had a serious incident involving MDA checking, which took place, and one of the actions that we took following that was that they did... the people involved and I suppose everybody was encouraged to do it, but more importantly, the people who were involved in it were encouraged to do this course".*

Leah: *I suppose the... following on from the medication error with MDAs, we did a quality improvement plan, a whole ward quality improvement plan, and it was a culture of, I suppose, checking MDAs at shift changeover; there was a culture of whoever was finished handover first was the person who would be responsible for checking MDAs, but that didn't really work because nobody specifically took ownership of checking MDAs. So one of the things that I have done is that on the roster, the official roster, there's an allocated MDA checking nurse. So following on from that the MDA... because somebody knows, ""I am designated to check the MDA and it's recorded. I am the responsible person for checking them."*

Clodagh also identified how a quality improvement plan had been put in place as a result of the same incident:

“I think earlier on in the year, there were... I suppose with all of us coming in as newly grads and overseas nurses and kind of being unfamiliar with some policies, there were maybe errors that were made, like the time that we were told we had to go and brush up on the medication administration, and there's MDA's. So we do... I think because we were so low on numbers when I was an intern here and now the numbers have come up, there was a lot of focus on being extra safe with patients, so that we were all on the same page. So I think patient safety is a big thing on the ward.”

While acknowledging that she had not been involved directly in any quality improvement approach, Grace spoke about how she now works as part of the team in the implementation of the changes in relation to MDA management and accountability:

“I wouldn't have led out any changes, but they'd be days where I'm the MDA nurse, so I'd have to make sure that the MDAs are signed in the morning and at night time before I go, that everything is there or if there's any medication, say MDAs, that need to be ordered up for the day, I'd make sure because we get a slot for pharmacy that we'd make sure that all the medications, that we have them for the night staff. So that would be the job of whoever is MDA nurse and if I was that nurse then I'd have to do that. “

There was a quality improvement approach on the ward, but these cannot be related to undertaking the safe medication administration education programme. The quality improvement approach appears to be driven by the approach of local leadership.

8.4 Hazel Ward

8.4.1 Context - Safety focused governance structure

8.4.1.1 Physical environment

All observations with Marcella on Hazel Ward took place when she was allocated to Team B. Team B consisted of three patient rooms, with four beds in each room. The medication trolley was chained to the wall and located just outside of these rooms. There was also a

small work station and patient medical notes located next to the medication trolley. This trolley was also shared with Team A. Other oral medications and top up medications were stored in the medication room. All intravenous medications were also stored and prepared in the medication room. The medication room had two access points- one directly off the corridor next to Team B work station (this was closed off at the time of observation), and a second access through the main nurses' station and doctors' office. As discussed in CMO 1, the corridor was an extremely busy spot with much traffic. During observation, Marcella always administered her oral medication from the trolley which was chained to the wall. At no time during the observation did a manager or pharmacist advise or recommend that it be moved.

During the inspection by HIQA (2017), they did not visit Hazel Ward, but in one of the areas they visited a similar drug preparation room was present. They commented that:

“During a visit to XXXX inspectors were informed that the treatment room had been redesigned to support and promote the safe preparation and administration of medications. The redesign of this room aimed to improve the physical design and organisational layout of the room, reduce interruptions and create a standard medication preparation and storage area for enhanced efficiency and patient safety. This was an example of good practice.”

8.4.1.2 Interruptions

Similar to Ash Ward, there were a significant number of interruptions noted during medication administration.

Marcella administered her oral medications from the medication trolley, which remained locked to the wall on the corridor at all times. On Day 1 of observation, the pre-registration nurse, who was working with Marcella to care for 12 patients, went to break during the medication round. The corridor was constantly busy with multiple people entering it all times.

On the first day of observation, it took Marcella 1hour and 20 minutes to complete the oral medication round for 12 patients, 11 of whom required medications to be administered. The interruptions during administrations were continuous. This observation took place on a Friday morning.

Across the three observation periods, Marcella had 14 of her 19 medication administrations interrupted at least once. On one occasion it was noted that one administration was interrupted four times. Interruptions occurred at a variety of stages of administration, either on preparation or on route to the patient. Observations on Day 2 were carried out on a Sunday and had fewer interruptions, with 3 of the 5 medication administrations interrupted. Medications administered on Day 3 of observation were all intravenous medications and were prepared in the Medication Preparation Room, but yet all three of these preparations and administrations were interrupted. All these interruptions were made by other nursing staff. Interruptions came from a variety of sources; patients, medical staff, physiotherapy, and nursing, catering staff, cleaners and ward clerk. Another common cause of interruptions was medications missing from the medication trolley.

On Day 2 of observation, it was noted that a member of the medical team advised Marcella of the risk of error involved in filing a patient's medical chart in an incorrect place, and then a couple of minutes later interrupt her when she is undertaking her medication round.

An extract from my field notes taken on Day 1 of observation described some of the interruptions encountered by Marcella:

"Between observation 6 and 7 patient had fall in bathroom."

"Med Admin 7, Marcella was interrupted twice when at the trolley before commencing putting medications in pot. Then during her administration she was interrupted 4 times- catering re fasting patient 2) HCA re patient and a bedpan 3) Pre-reg* from team C re drug keys 4) physio re patient notes"*

*HCA- HealthCare Assistant

*Pre-Reg - Pre-Registration Nursing Student. A final 4th year nursing student who has successfully completed training but awaiting RGN registration with the registration board.

Interruptions recorded during observation on Hazel Ward included beds being moved up and down the corridor, catering trolleys, patients in wheelchairs, cleaning trolleys, medical teams, physiotherapy teams and occupational therapists. An extract taken from my notes written following leaving the ward recorded my feelings of the environment and the constant distraction:

“the chaotic environment was palpable, constantly new people entering the environment. Taking medications records- walking up and down the corridor, interpreting the staff nurse. I could sense the nurse was tense- probably increased due to my presence. I would find it impossible to think clearly in this environment and critically question medications.”

Marcella did not wear the red apron or display the Do Not Disturb signage during any of the three days of observation. When observation first commenced, Marcella said without questioning that:

“I know I am supposed to wear the red apron but it’s not possible on this ward”.

When further explored, Marcella felt that the ward was just ‘too busy’ to utilise the red apron and signage. During interview, Marcella identified that multiple interruptions were having an impact on her ability to administer medications safely. When asked in interview if Marcella is doing anything different after the safe medication administration education programme, she responded:

“We learnt how to follow here what you do here. So yes it was good. But it is not working because of the interruptions”.

During interview, when I was discussing interruptions with Frances, I informed her that during one of my periods of observation it took the nurse 1 hour and 20 minutes to complete the medication round.

Frances: *“No. I mean, no. I think she was one of the newly qualified nurses from overseas and I suppose I'd say, maybe she wasn't saying, ""I'll get back to you."" Again, I think as well, you were probably coming around when the staffing wasn't great. Now, the staffing is so much better and it's allowing... we have one nurse to do the medication round and then the other nurse can float around and do all the other little things to prevent the other nurse from getting interrupted. But yeah, it can be hard when you've got a lot of fallers, a lot of confused patients and then you've got”*

Frances did not identify any solutions, or discuss any other strategies which may assist in reducing interruptions. Frances came across as defensive during interview. When asked about the red apron, she discussed why she does not wear the red apron herself.

Frances: *"I wouldn't... some people use it, some people don't. I don't, personally, I don't wear it because I don't see it ever making anybody stop you interrupt them."*

Again this illustrates that the formal leader is not leading by example, and applying the organisations policy on the reduction of medication interruptions.

8.4.2 Mechanism- Quality improvement approach

Similar to observation on Ash Ward, no quality improvement approach was seen during the periods of observation.

On interview with Frances, she initially answered that she had not been involved in any quality improvements in relation to medication management on the ward. However, during the period of observation, the times for medication rounds had changed. The knowledge gained from observation helped me to prompt Frances on this matter. When I asked her about the initiative, she provided details of why and how they went about undertaking this quality improvement.

"We did two drug rounds for the night shift and three drug rounds for the morning shift, or for the long day. But it just turned out... because we had so many washes and things like that in the morning, that we just scrapped the morning one. So we started... we do our 6, at 6 o'clock you'd give your tens, your ten o'clocks or anything that could be given early in the morning and then we'd do a drug round at kind of lunch time, 12 o'clock, and you'd be given your lunch time meds then. So it actually turned out, so we do two on days and two on nights and it's freed up loads of time, yeah. "

This demonstrated that Hazel Ward had recognised some of the difficulties with their medication rounds, and had taken some positive steps towards making improvements. However, this cannot be related to the safe medication administration education programme.

There was a quality board present on Hazel Ward which displayed the ward Quality Care Nursing Metrics and other quality indicators such as falls. These quality boards were provided by Nursing Practice Development.

8.5 Oak Ward

8.5.1 Context- Safety focused governance structure

8.5.1.1 Physical environment

Oak Ward consisted of 20 single rooms with individual ensuite bathrooms. It was divided into two corridors, with 10 rooms on each corridor which ran parallel to each other, with offices and storage facilities separating the two corridors. A large office was situated at the top of the ward, and on each corridor there were two nursing bases. There was a computer available at each nursing base, with access to medication information. There was separate medication room for the storage and preparation of medications. The medication room contained a computer with access to medication information. During observation with Cathal, he was observed obtaining a MDA medication from the medication room. All medications were administered from the medication trolley. The trolley was locked to the wall when not in use. The medication trolley was moved by Cathal to outside the room where he was administering the medications. As discussed in Section 9.5 Correct Patient Identification, Cathal identified that he found the process of the correct identification of patients easier as each patient had their own rooms. Conversely, the single room layout was identified by both Cathal and Karen as inhibiting the use of the red apron, particularly when caring for patients on the ward who also require infection prevention and control precautions to be used.

Karen: "Wearing red apron, like, I can't say only 40-60% of times because of the infection, because with the flu patient we have to wear the full jacket and all the gear before we go in. And then you are wearing the red apron to go in and come out (laughs). So you don't know what you are doing, you are confusing yourself. So the staff, if they are going in, they wear whatever is required and then..."

The single rooms also make nurses less visible on the corridor, and both Cathal and Karen identified this as leading to interruptions when nurses are administering medications from the trolley. When discussing interruptions to medication administration, Karen stated that:

"..because it's a single room and the nurse is gone into the room and one nurse is on the other corridor giving the medicine, it's highly likely that people come and approach them. "

When discussing one of the interruptions, in relation to a member of the medical team following Cathal to the medication room while he was preparing a MDA, Cathal felt that this occurred as the doctor may not have been able to find anybody else to deliver the patient information to:

"Because maybe they were having difficulty looking for some nurses to ask for a procedure to be done, so maybe that's the time she followed me."

8.5.1.2 Interruptions

Medications were administered from the medication trolley or directly from the MDA press as required. Cathal always had the medication trolley outside of the room of the patient to whom he was administering medication.

During all observations, Cathal wore the red apron but did not display the 'Do not disturb signage'. On a follow up interview, I asked him if he always wears the red apron or was it just because he was being observed. Cathal responded:

"Honestly I just place it when you're here because I don't want other people to disturb me, yeah, because I just want the drug round to be finished. Because sometimes people, other people would be disturbing you, and then you'll be putting the one that is started back in the trolley again, close the trolley, and you'll be attending to some needs. At least if they knew that you were in the red apron, okay, she's focussing so I won't disturb her for now. "

The statement from Cathal acknowledged that he did find the red apron beneficial in avoiding interruption, but he does not normally wear it. When Karen was asked in her interview about the practice of wearing the red apron, she responded that:

"That is the one area we have to improve. Like the girls are wearing, but what happens because of the infection status of the rooms, like you're going in and out. You're wearing the red apron and then wearing the white apron. So that becomes difficult and time-consuming as well. So that is why probably the girls are not wearing the red."

On all three days of observation, multiple interruptions were noted when Cathal was administering his medications. Interruptions were made by medical teams, family members and phone calls. On Day 1 of observation, 2 out of 6 of his administrations were interrupted, while on Day 2 and Day 3 all (2 /2 and 3/3) of observed administrations were interrupted at

some point during the preparation or administration. On one occasion on Day 1, it was noted that a student nurse was waiting for Cathal to complete his medication preparation, before interrupting him to ask a question in relation to patient care.

On Day 2 of observation, Cathal was allocated to the B side of the corridor with a patient allocation of two HDU patients. One of his patients required a controlled drug, and he proceeded to the opposite corridor with a second staff nurse to sign out the required medication. While he was in the drug preparation room, a member of the medical team entered the room and interrupted the checking process. This member of the medical team started the conversation with:

"I know you are checking medication but....."

A factor which Cathal added for consideration was that there are times when interruptions cannot be prevented. He provided an example:

"It's really annoying. It's really annoying but we really have to prioritise. Even though you're focussing on this drug round but then the HDU patient a while back rang the bell so I really had to go to him and that's it"

8.5.2 Mechanism -Quality improvement approach

Similar to the previous two wards, no quality improvement approach was observed. Quality boards were seen on the corridor of the ward. However, the information on the quality boards was outdated and related to a different specialist cohort of patients. No information in relation to the current ward was displayed, and therefore was not relevant to the ward. During interview, the quality improvement approach was further explored with Karen. Karen's leadership, and her approach to education and training of staff in medication management, display's some traits consistent with a quality improvement traits.

Karen: *"Safe medication programme, like if we see if anybody is constantly making errors here and then, so as a support we send them so that they get upgraded and they improve their knowledge and improve their betterment and their practice and they have knowledge. So in future I'm hoping to train all the staff in medication management to have a good base."*

During interview, Karen also discussed the Nursing Quality Care Metrics (QC-M) and the approach to QC-M taken by Oak Ward. The endorsement of the QC-Ms by Karen again displays the quality improvement approach on Oak Ward.

Karen: "Getting good in metrics means your documentation has to be... So I always encourage staff to have good documentation because anything... like if they have... and that will be your sole proof for your future if there is any problem comes, because we don't remember what will happen in the last two years, so if you have documented well that will stand for you. So that is will stand for you. So that is what I encourage staff to do it."

8.6 Conclusion and Reconfigured CMO 2

At organisational level, there is safety focused governance (outer context). However, this has not been passed down to local level (inner context), where the application of the policies and procedures, which were derived to support safety, were poorly applied or not applied at all.

Testing of this CMO was conducted on three wards where the physical layout and structures varied greatly. On all three ward areas, the physical structures were identified by staff as affecting the safe administration of medication. The layout may also have contributed to the number of interruptions which occurred. On Ash Ward, the medication preparation area was directly behind the nurse's station. However, on Hazel and Oak Ward, there were also multiple interruptions when preparing medication in the dedicated medication preparation room. The most significant finding was the absence of application of organisational safety strategies across all three ward areas. Even though, during observation, some of those nurses observed who wore their red apron later discussed, at interview, how they do not usually do this in practice and changed their behaviour due to being observed. The context at the local level was found not to be that of a safety focused organisation as was proposed.

A quality improvement approach was proposed as a mechanism, and this stage set out to test it as a mechanism. During this stage, no quality improvement approach was identified to be held by participants. A quality improvement approach, where it did exist, was driven by the managers. There was no evidence of this approach being triggered in participants and thus, acting as a mechanism.

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. In this study, the context was found not to match what had been proposed, and thus the mechanism was unable to activate. No outcomes have been associated, as the mechanism failed to activate in all three clinical areas.

Chapter 9 -Testing Conjectured CMO 3

9.1 Introduction

This chapter is the final chapter which reports the findings from Stage 3. This chapter, along with Chapter 7 and 8, make up Stage 4 of this realist evaluation. The headings which the context, mechanism and outcomes are reported under are those which had been identified in Chapter 6. This chapter reports the findings uncovered in relation to CMO 3 for context and mechanism from Ash Ward, Oak Ward and Hazel Ward. A new mechanism, correct patient identification, is proposed and the chapter then examines the outcomes in relation to CMO 3 for each of the three wards. The findings reported relate to CMO 3: 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.

9.2 Multi-disciplinary Collaboration at Organisational Level

Document analysis conducted during Stage 1 of this evaluation had identified that medication safety within the organisation under study involved had adopted multi-disciplinary collaboration.

Further evidence of multi-disciplinary collaboration for medication safety was obtained during Stage 3- testing the conjectured CMO configurations. The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered (HIQA 2016). From October 2016, HIQA began the process of undertaking announced inspections in public hospitals, in order to examine and analyse systems in place to support safe practice in relation to medication safety in line with international best practice and research (HIQA 2016). During the later stages of this research in April 2017, HIQA conducted an announced inspection in the organisation under study. Their report contained numerous positive references in relation 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 within the hospital. All medication-related policies, procedures and guidelines were approved by the Drugs and Therapeutics Committee prior to implementation. Medication policies, procedures, protocols and guidelines were readily available to staff through the hospital's controlled document management system. The implementation of changes to hospital policies, procedures and guidelines were supported by staff education and information sessions" (HIQA 2017, p 12)

HIQA (2017, p 3) also reported that they found that the multi-disciplinary collaboration to medication management reflected in the Drugs and Therapeutics committee within the hospital:

"was multi-disciplinary to reflect the fact that medicines management was the responsibility of a number of clinical professional groupings. Membership included clinicians, pharmacists, nurses, hospital management, and other healthcare professionals who participated in the medication-use process."

At an organisational level, medication management and safety was found to be multi-disciplinary. Observation and interview in the embedded sites of Ash, Hazel and Oak Wards also identified that this multi-disciplinary collaboration is present at local level. Thus, within this case the context of a multi-disciplinary collaboration for medication safety is accepted.

9.3 Ash Ward

9.3.1 Context- Multi-disciplinary collaboration

During observation on Ash Ward, both the pharmacist and pharmacy technician were observed numerous times. Ciara was the Clinical Pharmacist allocated to Ash Ward. The role of the clinical pharmacist in the organisation under study was described by HIQA (2017).

"Clinical Pharmacists reviewed inpatient medication prescription charts to prevent, identify and intercept medication prescribing-related incidents. The role of clinical pharmacists was documented in the hospital's own guidelines for the provision of pharmaceutical care to patients. Inspectors were informed that the clinical pharmacy service endeavoured to see

each patient on every working day. Clinical Pharmacists documented pharmaceutical care on the clinical pharmacy worksheet and the medical notes. The clinical pharmacy worksheet also formed part of the healthcare record and was retained with the medication record or filed in the healthcare record.” (HIQA 2017, p 9)

Clodagh was observed crushing medication for administration via a Nasogastric tube on multiple occasions. She later spoke with the pharmacist and sought advice in relation to a medication that was difficult to crush. She questioned if it was available in another form. On follow up interview, when asked if it was common to have this type of conversation with the pharmacist.

Clodagh: “Yeah, because I know when you start out as a student, like because I've done everything in ...(name of hospital) when you start out as a student you're told, ""Oh, you can't crush anything without looking it up"" and then now, it's not that I'm lazy about looking it up but I know our pharmacist knows everyone that's being NG or everyone that's NPO (Nil per orum- nothing by mouth) , and they'll always leave a note in green pen or in the comments box saying... But there are a few things that, like that tablet, it was just that it was coated and I was just checking to make sure... like, he had to get the tablet anyway, he is NPO. So I was just checking to make sure that it was okay to give it that way, and there was no other way to give it. So, yeah.”

When Leah was interviewed and questioned about pharmacy involvement in advising about crushing medication, she responded:

“Yeah. So, our ward pharmacist is actually really good at identifying if someone is NPO and they're on NG feeding and suggesting alternative routes for giving medications, and sending up liquid forms, or writing on the kardex, ""There is no other alternative other than to crush this medication and give it.”

Grace was also observed crushing medications. On interview, I asked her did she know it was safe to do so, and if so, how she knew. I had not asked or spoken at this point about the multi-disciplinary team. She responded:

"That's really the only thing that you'd be watching for in there, and I'm sure there's other medications that I don't know of, but usually Ciara would be quite good. She'd know that and he'd flag that with us, because everybody that we have in the Hawthorn unit, they're all NPO. So everyone is NG fed, so the tablets are all going in NG. But to be fair, we would have a good... Well, Ciara would really be the one to flag it with us. Yeah, so everyone is crushed and yeah, Ciara would be the one to tell us, ""Oh, you can't crush that"" or ""You can crush that"", and if we didn't know, we wouldn't give it."

When asked about the role of the multi-disciplinary team in medication safety Grace responded:

"I think there is. Like Ciara is our pharmacist here and she's brilliant. She'd say to you, ""Well, why are they still on that? At this stage they don't need that."" And then I might question... She might be the one to kind of tip me off or I might not be sure about something and I might have to ask Ciara, ""Do you know?"" And then once the two of us might be sure then we'll ask the doctors and the doctors will say, ""Yeah, they don't need to be on that"" or ""No. The consultant said we'll give them another day or two of that antibiotics IV before we change it to PO or something like that."

Leah also provided evidence that medication safety and management is a multi-disciplinary approach on Ash Ward:

"I know that our pharmacy would have always been... that's their area, and I know the MDT, I suppose from a medical team perspective, I think they're getting a lot better at it. They're getting a lot better at looking at medications and seeing what ones can be stopped or changed."

9.3.2 Mechanism - Receptivity to change

Both Clodagh and Grace had commenced work in staff nurse posts on Ash Ward immediately on receiving their registration. Completing the safe medication administration education programme was advised as part of their transition to becoming a registered nurse.

During interview, Clodagh was asked if she was doing anything different in her practice following completion of the education course:

"I don't know because I know as a student I was always very nervous when administering medication, so I think I always try to be as safe as I can and always check things. But then, since doing the medication administration and working with students as well I would notice that I'm cautious and I'm trying to relay to them while they're watching that, ""this is what you do. You're checking the expiry date. You're checking the frequency. You're checking the route."" So I think with a few things, with the students and doing the course, then yeah, I have changed my practice."

When Grace was first asked about doing things differently following the course, she identified that completion of the course was necessary for her:

"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."

Grace continued on to say that the course reinforced the practice as she had been taught:

"Well, policy of the hospital and because it's to know... that's the five... the safe way to make sure that we're giving patients the right medication; we're giving it at the right time; the right route and that everything is the safest way possible."

Change was also discussed with Leah during interview and she also identified that undertaking the course had positive benefits for staff. She also identified that this change may not be immediately evident:

Leah:"Yes, but what I would say, and some of the people who've done this course would comment, is that a lot of nurses if they make a drug error, they won't notice it, you know? So, it will be maybe the person that comes on the next shift or the shift after that, that will notice that a drug error has occurred. If they notice themselves, they'll report it straight away. But it's often not picked up until maybe a shift or two shifts after the error has taken place, and you'll go back to the person as part of your follow through, you'll go back to the person and say, ""Did you realise that when you administered that, that it was actually a once a day prescription but you had given it on a second time? So it was given twice a day instead of once a day."" And they will completely miss that, and they probably would have never realised it had it not been reported, and probably wouldn't have been picked up at all had

someone, out of curiosity said, 'Oh now, that doesn't look right. We have to investigate that and we have to report that.'"

Leah's responses highlight that staff who have undertaken the education programme appear to have a greater receptivity to change.

9.4 Hazel Ward

9.4.1 Context- Multi-disciplinary collaboration

The Clinical Pharmacist was observed on the ward on Day 3 of observation. She was observed behind the nurses' station reviewing patient's notes and medication charts. She did not have any interaction with Marcella during the observation period. The observation periods on Hazel Ward were of short duration and may not have captured interaction between the nurse and pharmacist and medical teams in relation to medication. When asked about multi-disciplinary collaboration, Marcella agreed that there was collaboration and that the pharmacist comes around, but did not elaborate any further.

Frances was also asked about multi-disciplinary collaboration for medication management at interview. Frances described the pharmacist involvement with day to day medication management on Hazel Ward:

"Yeah. She... there's a new girl has just started. She's one of the girls who has just qualified so she's on the ward, but we had one of the head pharmacists on the ward. Now she would have been very vigilant with checking the medications, the kardexes and everything like that. Now she did... there was one instance I think that somebody had given a tablet that was OD but had been given it BD. Now we did fill out an incident report form and a MIR and things like that and we addressed the issue. But she would be very... checking up the kardexes and making sure that..."

She also added that they communicate well.

9.4.2 Mechanism- Receptivity to change

Marcella had joined the organisation six months prior to participating in the study and had come through the adaptation process. As part of the adaption process, all staff are required to undertake the safe medication administration education programme. It was mandatory

that she take this CPE course. When asked if she did anything different after doing the education programme she stated that:

"We learnt how to follow what you do here. So yes it was good. But it is not working because of the interruptions"

In this statement, Marcella seems to associate not being able to follow correct practice with the challenges faced in the clinical area.

During interview, the CNM II, Frances, was asked if she found staff who had undertaken the education programme different after completion. She responded that she had four or five staff nurses who had completed the education programme and that:

"they seem to be very good with medications. Like I don't see... There hasn't been any issues with them"

When asked to explain what she meant by this, she continued on to say.

Frances: *"Well I suppose I haven't noticed very many medication errors. I... Our pharmacist would be filling out the near misses. I haven't noticed, she hasn't come to me to say that she's been filling any out. Their medication... they're taking their time with the medication rounds, they're wearing the red aprons, they're making sure that nobody comes up and disturbs them and things like that. So they're making sure that everybody around them knows that they're doing something that's very important and not to be interrupted. "*

The above statement in relation to wearing red aprons and aiming to reduce interruptions is the contrary of what was observed at ward level and a clear benefit to the combining of methods of data collection.

9.5 Oak Ward

9.5.1 Context- Multi-disciplinary collaboration

During the periods of observation on Oak Ward, the Clinical Pharmacist was observed on Day 1. The pharmacist was positioned at the nursing base for a period during observation. No pharmacist was observed on Day 2 or Day 3. The Clinical Pharmacist aims to visit their allocated wards on a daily basis. The periods of time I was present on Oak Ward may not have occurred at the same time as the pharmacist's daily visit. This context was tested

through interview. When Cathal was asked if he had experience of a multi-disciplinary collaboration to medication management, he responded:

"Yeah, I am seeing that there is a multi-disciplinary approach. If the doctor prescribes a medication it is reviewed by the pharmacist, and then for us nurses, we have to think critically why this medication is given as well. Otherwise, if we're having doubts about it we can ask the doctor why he is prescribing this medication to the patient. So at least it's, there's a multi-disciplinary approach."

Multi-disciplinary collaboration towards medication management was confirmed by Karen who, when questioned during interview, agreed that there was this approach:

"Yes, definitely. So if there is any medication error, we'll 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. "

Karen also discussed, during interview, how the nursing, pharmacist and medical team work together to ensure that patients on complex medications are correctly managed.

Karen: *"Because if the patients... for example, we keep an eye on the levels if a patient is on immune-suppressants. So their levels are most important, and levels such as Prograf levels*. If it is low then we know that it has to be increased, so we give a suggestion to them and then if they keep an eye and we keep an eye as well.....So we know... on the rounds , if the patient's level is gone up, or platelets gone down. So we know all those things."*

* Prograf or Tacrolimus is an immunosuppressant medication used to prevent rejection of a transplanted organ. Blood monitoring is required to ensure the required and therapeutic level is achieved

9.5.2 Mechanism- Receptivity to change

Cathal had completed the safe medication administration education programme on arrival to the organisation just over a year prior to the period of observation. Similar to Marcella, he had gone through the adaptation process. When asked why he undertook the education programme, Cathal stated that:

"It's a requirement for the hospital. But then I think it's a must. It's a must even though you've been working in a different institution and you know everything, but then it's a good

refresher that this hospital is really focussing on the safety. Because I've worked in a previous hospital but we didn't have this kind of training before starting. And it's a nice refresher course just to remind us that safety is very important."

This illustrates that Cathal is open to changing his previous practice, and adopting the policies and practices in his new organisation:

"Yeah. For me my experience is I really have to check one by one. And sometimes if you're in the old building, the patients are in the same room, so sometimes you'd get confused. So it's really better to do it very slow. Even though you go slow, at least you are safe with the patient."

9.6 Exploration of a Potential Mechanism – Correct Patient Identification

Data analysis was conducted deductively as per the a priori coding template, but also inductively during Stage 3 of this realist evaluation. As the process of data analysis in realist evaluation is not confined to a separate stage of the research process (Pawson 2006), new themes emerged which required further investigation in order to assist with wider CMO explanation. One such theme was that of patient identification. In the conjectured CMO configuration, I had proposed that patient identification formed part of the patient safety culture. However, following data collection and analysis, I now propose that this may be placed more correctly as a mechanism which is triggered in an environment where a culture exists of patient safety. Correct patient identification is a key component in medication safety and is one of the points highlighted in the safe medication administration education programme. The observation tool included a box to indicate if patient identification was completed before administration. The correct way of identifying patients in this study was based on the definition provided in the organisations' policy *"At the patient's bedside the patients identity should be verified by name and medical record number, using the medication record and the patient's identity band and verbally with the patient where possible"*.

9.6.1 Ash Ward

During observation, both Clodagh and Grace were seen on all occasions to correctly identify the patient prior to administering the medications. In the majority of administrations observed, they also verbally asked the patient to confirm their identity. On all occasions in

the Hawthorn unit, when patients were unable to respond due to their medical status, identification was established with the patient's identity band only.

The compliance with patient identification, as per hospital policy and best practice guidelines, was further discussed in interview. While interviewing Grace, I commended her on her practice and asked if it was something they always do or was it a response to being observed.

Grace: *"Yeah. No, I would always do that, especially with the confused patients. Now, I'd sometimes with... let's say the likes of Patrick in there now, I'd ask him his date of birth, his name. I might not always check his ID band. I'd say that. But with confused patients, especially as the majority of our patients are a little bit confused, I would always do that."*

On commencement of my interview with Clodagh, I asked her if she did anything different because I was observing her. She did acknowledge that she may not always check the name bands if she knows the patient. However, Clodagh also acknowledges the importance of doing so and setting an example for students.

Clodagh: *"the one thing I notice I did and I was very conscious about checking was people's wristbands. Not that I wouldn't check them. I would always check new people, but when I'm in three days in a row or with our long... we've a good few long term patients, I feel like it's a bit silly for me to check the wristband. But I do know the importance of it and I would always check it with a student as well, so that they know this is what you do and you have to check it".*

Leah reinforced the importance of correct patient identification prior to medication administration:

"That is definitely how nurses are taught when they are nursing interns and they're doing their supervised drug rounds with a staff nurse or definitely with me, that would be what we would be embedding into their culture when they qualify and we're doing the ten supervised drug rounds, that is something that we're observing, that's something that you would not sign off on a nurse. If they were omitting to do that, you would say, ""No, we need to continue doing more than ten supervised drug rounds."" And I know that if there was an error related to patient identification, that might be... well, that would be something you

would put into their action plan, or their action plan would be that they need to be observing safe practice.”

On one occasion, Clodagh did not check the patient’s identity band while administering oral medication at 10.00am; she had previously been observed 30 minutes before that checking the same patient’s identity band when administering Intravenous medication.

9.6.2 Hazel Ward

During observation on all three days, Marcella was seen to check the patient’s identification prior to administration of medications. On multiple occasions, she greeted the patient by name and then proceeded to check their name band and confirm their date of birth with them. On Day 1, a patient was found to have no name band and Marcella was observed obtaining a new name band for her patient.

On interview, when questioned about identifying patients prior to administration, Marcella confirmed that she always does so. Frances also confirmed that staff on the ward have good practice in confirming the identity of patients prior to medication administration:

“Yeah, generally... I suppose the only other time that you mightn't is if somebody has been on that team for a few days in a row and they know their patients and things like that. But yeah, I would always be making sure that the nurses are doing that if they're on a team that they don't really know.”

9.6.3 Oak Ward

During observation, Cathal greeted his patients by name when he entered their rooms. In all observations but one, he checked their identity bands off their medication charts. In the observation where he did not check the identity band, I had observed him doing so for this patient a few minutes previously.

When asked about the ward layout contributing to medication safety, Cathal responded that he felt that it made patient identification easier:

“It’s a bit easier compared to patients having this cohorting in one room, because you’re familiar with the patients, so you know the patient’s name already, so the mistake of having a mistaken identity is decreased. You just have to confirm the birth date and if the patient

knows about the MRN then it's fine, but you're very sure that this patient's name is the same as the one in the kardex."

9.7 Outcome

9.7.1 Quality Care Nursing Metrics (QC-M)

As discussed in Chapter 6, the data in relation to QC-M will be presented as an outcome measure. This data is collected and reported by staff within the organisation. All data collectors have been trained in the collection and gather the data. Any recorded data over 90% is recorded as green and provides evidence of meeting the accepted standard.

Three standards were considered and were subject to analysis in this evaluation: 1) medication storage and custody 2) MDA drugs 3) medication administration. MDA drugs is the term used in Ireland to refer to Scheduled Controlled Drugs which are controlled under The Misuse of Drugs Acts, 1977, 1984, 2016 and the Misuse of Drugs Regulations, 1988, 1993 and 2007. The format of the online report uses a traffic light and percentage value system (Red/Orange/Green) to indicate level of compliance with standards (Table 9.1).

Score	Action
Over 90% (Green)	Target achieved
80% - 89% (Amber)	Aim to achieve incremental improvement over the next 6 months
0 -79% (Red)	Areas of risk which require action as agreed with senior management

Table 9.1 QC-M level of compliance

For the purpose of this analysis, the focus was placed on the third standard - medication administration. There are five indicators on which data is gathered in relation to medication administration, which are listed in Table 9.2. Data on the QC-M was downloaded for the 12 months of 2017 for the Ash, Hazel and Oak Wards.

1. The Individuals' prescription documentation provides details of individuals' legible name and healthcare record number on each page/screen
2. The Individuals' identification band has correct and legible name and healthcare record number or photo ID is in use
3. The allergy status of the individual is clearly identifiable on the front page of the prescription chart
4. Prescribed medication not administered has an omission code entered (72 Hrs)
5. The individuals' locker and bedside/ or surrounding environment are free of unsecured prescribed medicinal products

Table 9.2 QC-M indicators for medication administration

9.7.2 Ash Ward

The QC-M for Ash Ward for 2017 was found to be variable. The medication administration indicator which is the key indicator for this analysis shows that Ash Ward only achieved its target of above 90% for 5 of the 12 months. It fell into the amber section for three months and was identified as an at risk area, falling into the red category for four months.





































	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017
Medication Storage and Custody	 100%	 100 %	 100 %	 100 %	 67%	 100 %	 100 %	 100 %	 67%	 33%	 100 %	 67%
MDA Drugs	 100%	 100 %	 100 %	 100 %	 75%	 100 %	 100 %	 100 %	 100 %	 100 %	 100 %	 100 %
Medication Administration	 79%	 78%	 81%	 83%	 76%	 79%	 93%	 100 %	 93%	 96%	 93%	 87%

Table 9.3 QC-M for Ash Ward 2017

9.7.3 Hazel Ward

In Hazel Ward, the QC-M illustrates a progressive improvement in the medication administration indicator, and can be seen with its standards increase from the red 'at risk' category for January through to April, improving to amber for May and June and finally reaching the target of over 90% in July. It consistently maintained its target for the following five months until the end of the year.





































	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017
Medication Storage and Custody	 67%	 100%	 100%	 100%	 100%	 100%	 0%	 100%	 100%	 100%	 100%	 67%
MDA Drugs	 75%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%
Medication Administration	 73%	 73%	 79%	 79%	 88%	 89%	 95%	 100%	 97%	 97%	 97%	 100%

Table 9.4 QC-M for Hazel Ward 2017

9.7.4 Oak Ward

Oak Wards QC-M for medication administration can be seen to be at a high standard, consistently achieving its target for 11 months of 2017. On one occasion in December 2017, it missed its target and fell into the yellow category.




















	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017	Sep 2017	Oct 2017	Nov 2017	Dec 2017
Medication Storage and Custody	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%
MDA Drugs	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 100%	 75%	 100%	 100%
Medication Administration	 100%	 95%	 100%	 95%	 100%	 100%	 95%	 100%	 100%	 95%	 95%	 89%

Table 9.5 QC-M for Oak Ward 2017

9.8 Conclusion and Reconfigured CMO 3

Analysis of data suggests that there is multi-disciplinary collaboration for medication safety at organisation level across Ash, Hazel and Oak Ward's. Receptivity to change was also proven across Ash and Oak Ward. However, there does not appear to be a relationship between the multi-disciplinary collaboration as a context and receptivity to change. In other words, multi-disciplinary collaboration towards medication safety does not appear to activate the receptivity to change mechanism. The QC-M was seen as an excellent way to capture the quality of safe medication practices. However, the metric scores do not appear to be related to the context or the mechanism which was under test in this CMO configuration. These findings illustrated that Ash Ward had the poorest QC-M scores, but yet the participants demonstrated the strongest receptivity to change. Also, the QC-M on Hazel Ward scored highly, but no receptivity to change was evident.

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

The correct identification of patients prior to medication administration was identified as a potential mechanism factor. This needs to be further explored and the context where it is triggered needs to be explored.

Chapter 10- Discussion

10.1 Introduction to Discussion

This chapter teases out the findings from the realist evaluation study and examines them in association with existing evidence on the topic. For the purpose of clarity, the focus of this thesis and thus the discussion is on continuing professional education for the purpose of safety in medication administration. Therefore, the discussion is focused on CPE and its relationship with medication safety. Extensive literature and international policy documents are available in relation to patient safety which is beyond the scope of this thesis and thus does not form part of this discussion chapter.

As an evaluator it is essential that I develop an understanding of what works, for whom, and in which circumstances (Pawson and Tilley 1997) and that I place the findings in the context of the wider research field. The challenge in the discussion is to integrate the evidence on medication safety with that of continuing professional education.

This discussion chapter is presented using the headings from the context mechanism and outcome configurations which were explored and tested in this study. The first CMO configuration which addresses the context of a patient safety culture and incorporates leadership and ward culture is discussed. The mechanism reasoning skills is then explored within its constituent parts, seeking out information and problem solving. Finally the outcome, reporting medication incidents is discussed.

CMO 2 identified safety focused governance structure as a context construct. This is discussed in its constituent parts; interruptions to medication administration, wearing the red apron and the physical ward structures. A quality improvement approach was the mechanism which the study set out to test in this CMO configuration. Its failure to be verified as a mechanism is discussed.

In the third CMO configuration, multi-disciplinary collaboration was identified as a context construct. The findings from this study in relation to its contribution to the context and the existing literature are then debated. Following this, receptivity to change, as a mechanism construct is then discussed. The findings in relation to QC-M and their relationship to the context and mechanism and existing literature follows next. This chapter then further debates the new proposed mechanism of correct patient identification.

Finally, the chapter concludes by putting forward the final context mechanism outcome constructs and configurations which have been proven, and provides recommendations for further investigation.

10.2 Patient Safety Culture

Manley et al. (2017) identified four key elements that influence developing a safety culture in frontline clinical teams. These comprise of clinical leadership, team work, culture, values and meaning, safety behaviours and the environment. Similarly in this study, ward leadership and ward culture were identified as context components of a patient safety culture and were further explored.

10.2.1 Leadership

The role of the ward manager (CNM II) 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. This is supported by the findings of Manley et al. (2017), who reported that the most influential factor impacting the development and embedding of a safety culture in frontline teams is the quality of clinical leadership. Lin et al (2017) and Halligan and Zecevic (2011) also identified that leadership is one of the key dimensions of a safety culture.

At ward level, frontline leaders engage nurses in decision-making about patient flow and staffing, quality improvement activities, and continuous learning opportunities to improve overall care delivery (Wong et al. 2013). The literature review identified managers as key stakeholders in facilitating, or not facilitating, the transfer of CPE into practice. However, the evidence on the role of leadership for transfer of CPE is limited, as few studies have examined the application of new learning to practice. Clark et al. (2015) identified the role of managers in supporting staff for transfer of education into practice. However, Hughes (2005) found that participants reported a lack of managers' leadership in order to support the changes following CPE.

Across this study, three varying leadership styles were uncovered. On Ash Ward, the CNM II, Leah was found to be a transformational leader, leading on quality improvement initiatives, engaging staff in critical thinking and reasoning skills about their medication management. Manley et al. (2017) identified that transformational leadership enables a participative

collaborate and inclusive approach for working with staff and results in staff empowerment and an approach to improvement driven by asking 'what works?' This was also seen when the mechanism, quality improvement approach, was explored. Transformational leaders inspire staff towards a shared vision, as well as challenging and stimulating, enabling, developing trust and communicating (McCormack et al. 2002).

On Hazel Ward, the CNM Il Frances was new to her role and at the time of data collection had not established her leadership role or demonstrated her leadership traits in the clinical area. Her style at that time, while only in development, may have been described as *laissez faire*. This was clear during observation, as no visible leader was observed influencing the culture or practice on the ward. Leaders who adopt a *laissez faire* style do not offer the support and direction that nurses require when learning new approaches and skills and undertaking 'high risk' activities, such as medicines' administration (Vaismoradi et al. 2016). This was evidenced by the lack of support and guidance which Marcella reported during interview.

On Oak ward the manager was seen to be autocratic with hierarchical structures in place. Autocratic leadership styles that focus on task completion alone are less suited to evolving and complex health-care organisations (Cummings et al. 2010) where dynamic change is required.

Leadership's vital role has been explored in areas such as patient safety, patient outcomes and workforce. However, it needs to be further explored in the context of CPE and its application to practice. While leaders have a role to play in enabling the application of CPE into practice, they also have a significant role to play in transforming cultures and are influential in shaping a context that is ready for change (Rycroft-Malone et al. 2002)

10.2.2 Ward culture

Organisational culture refers to the values, behaviours, goals, attitudes, practices and beliefs shared across an entire organisation (Braithwaite et al. 2016). A patient safety culture was identified in the organisation through the completion of document analysis during Stage 1 and further developed during interviews with the experts (Stage 2). A subset of

organisational culture is workplace or ward based culture. This is a specific type of subculture involving an identifiable grouping within an organisation (Braithwaite et al. 2016). This is furthered by Abstoss et al. (2011), who have identified that safety culture is largely a unit-level phenomenon responsive to unit-level interventions. Thus, the embedded case study in Stage 3 allowed the local ward based culture of three different clinical areas to be examined. Observation and follow up interview revealed that local ward based culture did not always mirror the culture of the organisation. Across the three clinical areas, very different cultures were observed in relation to patient safety and openness in communication. Ash Ward had a very open, learning culture which was clearly observed. The culture of Hazel Ward was not supportive to patient safety, while the culture of Oak Ward was somewhat patient safety focused, albeit policy led.

As demonstrated in the literature review, evidence to support the effect of ward based culture on the transfer of CPE is limited. Organisational culture has been identified by Clark et al. (2015) as a variable affecting transfer of CPE into practice. In the similar field of knowledge translation, Squires et al. (2015) also identified that the context where knowledge is to be utilised influences its application. A link between the leadership and ward culture has also been established in the literature. The role of a transformational leader as a key enabler for the development of effective workplace cultures at the microsystems level, particularly when implementing evidence into practice has been identified by Manley et al. (2017).

The use of observation and follow up interview with participants provided an in-depth insight into this workplace culture. However, observation in clinical practice is open to critique with some concern that the presence of the researcher may lead to observational bias which is commonly referred to as the Hawthorne effect (Kurtz 2017). Literature debates that when people are observed in practice their behaviour may change in line with the expected practice/behavior and demonstrate conformity and social desirability to present the researcher with what the participant believes to be the right or expected behaviour (Bloomer et al. 2012 ; McCambridge et al. 2014). As discussed in 6.5.2 the possible effect of the researcher's presence must always be considered but there is no compelling evidence to support participants' behaviour does change (Bloomer et al. 2012).

Section 6.5.3 discussed the design features of the study which helped to minimise the Hawthorne effect one of which was the utilisation of the follow up interview which assisted in detecting if and where a Hawthorne effect occurred. During interview with Cathal, he confirmed that he does not normally wear the red apron but did so during observation as he was aware that it was best practice. To the contrary when observation with Melissa began she stated that she knew that she was meant to wear a red apron but was not going to do so as she does not normally do so. Other elements of her behaviour and practice such as leaving the medication trolley locked to a fixed point on the ward corridor would not have occurred if she were attempting to portray a positive image of her practice. Thus, the impact of the Hawthorne effect did vary during this study but its true effect cannot be always known (Bloomer et al. 2012). Such work based culture may not have been unveiled if this approach was not utilised. Observation of practice is an important element when evaluating transfer of knowledge gained from CPE. Not only can it inform the evaluator if knowledge is being transferred or not, but it can also provide insight as to the process which facilitates or inhibits the transfer.

The work based culture described may not have been unveiled if an observational approach was not utilised. Observation of practice is an important element when evaluating transfer of knowledge gained from CPE. Not only can it inform the evaluator if knowledge is being transferred or not, but it can also provide insight as to the process which facilitates or inhibits the transfer.

10.3 Reasoning Skills

From Stage 1 interviews, the original label for this theme was critical thinking and this was later refined in Stage 2 to reasoning skills. When designing the observation tool to test the conjectured CMO configuration, I was challenged as to how best to observe reasoning skills. Following extensive review, it was broken down into two observable elements; seeking out information and problem solving. Dickson and Flynn (2012) outline many factors that contribute to clinical reasoning skills in the safe administration of medication; two of those highlighted are application of knowledge and verifying with colleagues.

In order to ensure the safe storage, dispensing and administration of medications, the nurse must know the pharmacological principles for each drug he/she is to administer (Simonsen et al. (2014). However, medication knowledge has been reported as being unsatisfactory (Simonsen et al. 2011). The range of medications prescribed and administered in an acute hospital is extensive, and it is not the expectation that nursing staff would have perfect pharmacological knowledge of all medications on the formulary. As well as reinforcing the need to be knowledgeable about all medications administered, the safe medication administration education programme also highlighted how this information can be accessed in the organisation.

It may not always be possible for the nurses to have full knowledge of all the medication he/she is administering, and thus, the nurse requires information seeking skills (Sulosaari et al. 2011). To make decisions, nurses need to be able to look up and use information from a variety of sources. Nurses need to have the skills to search for valid information in medication handbooks, medication packages and hospital protocols (Sulosaari et al. 2011). On no occasions during observation of oral medications administration did any of the nurses observed refer to information sources during medication rounds. When asked during interview as to why they did not look up any further information, the most common answer was because they were familiar with the medications they were administering. On the contrary, when administering intravenous medications on both Ash and Hazel Ward all three nurses were seen to use the antibiotic quick guide poster and the organisations A-Z medicines guide on the computer to check medication preparation details. Studies have also reported a lack of knowledge or application of knowledge as a risk factor for error, with low risk of error associated with high knowledge of medications (Pape et al. 2005). The difference perhaps in this study is that nurses feel there is a greater risk of error from administration of intravenous medication, and thus prompted seeking further information, or perhaps it was due to the fact that the intravenous medication required preparation. This was not further explored during interview and no discussion in relation to the potential influencing factors was found in the literature.

Whilst also having and seeking out knowledge and information in relation to medications administered, clinical reasoning is required as an integral component of safe medication practice (Rohde and Domm 2018). During this study, I referred to this as problem solving.

Safe medication administration requires more than just managing medications to avoid errors; medication safety requires nurses to use clinical reasoning skills, prior to, during and following patient interventions (Folkmann and Rankin 2010). Dickenson and Flynn (2012) require the nurse to analyse data and engage in careful, evidence-based clinical reasoning to safely administer medications in a busy, active work environment. Clodagh was seen on one occasion to check a decision she made about withholding medications with a senior staff nurse. Dickson and Flynn (2012) refer to this as verifying with colleagues and a component of clinical reasoning. This allows for the development of relationships with peers who are recognised as expert nurses. During interview, Cathal also refers to seeking knowledge from his '*seniors*' again highlight the importance of verification with colleagues.

Clinical reasoning skills were observed on multiple occasions during field work in this study. Both Clodagh and Grace were seen to make decisions in relation to medication administration. Dickson and Flynn (2012) further identify that clinical reasoning skills are the principle factor that guide nurses' safe medication practices and is an essential component of safe medication administration. Nurses' clinical reasoning includes patient assessment and application of foundational nursing knowledge in the clinical setting to support safe medication administration (Dickson and Flynn 2012). Rohde and Domm (2018), in a review of international literature identified that the clinical reasoning skills of nurses were discussed in various articles and hospital settings to show how nurses engaged in clinical reasoning every day to administer medications safely to patients. While nurses' clinical reasoning is understood to occur as nurses administer medications, the reviewed literature did not explore nursing clinical reasoning in depth. The focus of medication administration is on errors which continues to populate the literature and has left little regard for medication that is administered safely to patient; and the value of nurse's daily use of clinical reasoning is not evident.

10.4 Reporting Medication Incidents

A component of the safe medication administration education programme focused on medication incident reporting, and thus one of the outcome measures further explored throughout this study. The education programme focused on the classification of medication incidents and also on the importance of reporting incidents. It also examined how most

incidents and errors are contributed to by a failure of the system. In Stage 3 of this study, reporting medication incidents was allocated as an outcome measure.

Medication errors have been shown to be a prevalent and an on-going problem which results in varying degrees of preventable harm to patients. The Institute of Medicine (2000) highlighted the alarmingly high rate of medication errors in the United States, citing that medication errors were estimated to account for approximately 7,000 patient deaths annually. Keers et al. (2014), in a systematic review looking at the empirical evidence on the nature and prevalence medication administration errors in healthcare settings, reported that a median rate of error was 19.6% of total opportunities for error. However, the exact rate of medication error is difficult to determine due to varying methods of error calculation (Popescu et al. 2011).

As discussed in Chapter 1, in the Republic of Ireland in 2016, there were a total of 5,505 medication incidents reported across 50 acute hospitals, resulting in an average of 110 medication incidents per hospital. This represents a significant under-reporting of medication incidents, when applying estimated error rates to the number of patient interactions occurring in Irish hospitals daily (The States Claim Agency 2017). The underreporting of medication errors can also be seen in this study specifically in Hazel Ward (20) and Oak Ward (15) with a very low number of medication incidents reported on each ward in 2017. Failure to report or under-reporting can comprise patient safety by disabling improvement methods (Rutledge et al. 2018).

In this study, Ash Ward had the highest rate of reported medication errors, reporting 50 in 2017. A high rate of incident reporting is considered a marker of a strong patient safety culture (State Claims Agency 2016). During interview, when asked about reporting medication errors, Leah spoke about how by reporting errors there was an opportunity to improve practice. Leah further provided an example of errors reported in relation to the management of controlled drugs, practice changes which had been made on the ward and the support given to staff whom were involved in the incident. Grace and Clodagh, the staff nurses on Ash Ward, also spoke in a positive manner in relation to reporting incidents and both acknowledged that they had made and reported medication errors in the past. Both Grace and Clodagh acknowledged that nobody is 'coming down on you' if you make an error or report an incident. Grace also spoke about how an out-of- hours nurse manager positively

managed a medication error which she reported. As previously noted, a positive safety culture is essential to establish a non-punitive response to medication errors. Leah and Ash Ward were identified as providing local leadership and a positive patient safety culture. Westrum (2004) postulated that if leaders encourage a free and open environment of information flow, incident reporting will increase. This in turn leads to increasing reports of medication incidents. Improved cultural measures have been found to be paralleled by higher medication error reporting but lower medication-related harm (Abstoss et al. 2011).

In contrast on Hazel Ward, the staff nurse, Marcella, spoke in a negative manner about reporting medication errors and mentioned blame on multiple occasions. She also provided an example of where a senior nurse manager who came to the ward gave her a rebuke for leaving medication on a patient's locker when she had not done so. Marcella also spoke about finding a medication error and not reporting it, as it was made by a nurse who was working in the area a lot longer than her. Traditionally, when dealing with medication error reports, blame was followed by punishments (Abstoss et al. 2011), and fourteen years ago Wolf and Serembus (2004) identified that blame and reprimand prevailed in hospital environments. In the years following this publication the patient safety culture has made multiple advances however, more recent studies have also reported staff having fear of reprisal and blame for making a medication error (Abstoss et al. 2011; Vrbnjak et al. 2016; Rutledge et al. 2018). Such punitive responses have led to errors being hidden, preventing the recognition, analysis and correction of the root causes and systemic problems. There were only 20 medication error reports made on Hazel Ward in 2017. Considering Hazel Ward is a 35 bedded ward the number of reported medication incidents is low.

Marcella still holds the perception of a 'blame culture' due to her experiences on Hazel Ward. Vrbnjak et al. (2016) identified that poor management behaviour affects medication error and near miss reporting, which does not take the system factors into consideration. In the era of open disclosure and patient safety, this approach has long been ill advised. Such under-reporting impedes collection of accurate medication error data and prevents hospitals from changing harmful practices. When Frances, the manager on Hazel Ward, was interviewed she acknowledged the importance of reporting medication incidents, but did not elaborate or provide any details of how she facilitates or encourages reporting. On completion of qualitative work, the reflections of the researcher are also important to consider. Marcella did not consent for the interview to be recorded. In my reflection I asked

myself was this an implicit fear that she could be reprimanded for what she had to say at interview?

In Oak Ward, Cathal presented an open reporting system and gave an example where senior staff actively encouraged him to report the error and that he could then see the valuable learning from it. Karen also spoke in a positive manner about reporting, and she acknowledged that by reporting errors, problems within the system can be explored and rectified. It has a smaller bed base with 20 beds, but still only made 15 reports of medication errors in 2017.

The difference in the reported number of medication errors and the attitude towards reporting errors is an important finding in this study. As identified in Stage 1 and Stage 2, the organisation (macro level) presents a no blame, safe reporting culture, but at the local ward level (micro level), where the CPE and medication error reporting is to be applied in practice, a different picture was found. Vrbnjak et al. (2016) identified that differences between clinical areas could be regarded as being due to varying unit cultures or different quality management processes on the unit. Differences between units could also be due to work environment elements, such as nurse staffing, resources and understanding of quality of care (Shanty 2011).

Abstoss et al. (2011) demonstrate that changing the safety culture within a specific unit may lead to improved reporting and reduced harm in a relatively short time period. In the organisation under study, this would mean working to develop the local leaders (CNM II's). This in turn would assist to facilitate the transfer of learning by staff nurses from the CPE on safe medication administration. Where leaders and frontline staff have greater awareness of risks, there is more likely to be an increase the reporting of errors, and thus, reduce the harm caused to patients (Abstoss et al. 2011).

10.5 Safety Focused Governance Structure

The second CMO configuration associated interruptions and physical environment to safety focused governance structure.

10.5.1 Interruptions in medication administration

During document analysis in Stage 1, it was identified that the organisation under study had a specific policy in relation to the reduction of interruptions during medication

administration. The policy provides guidelines and resources around the use of the red tabard, commonly referred to as the 'red apron' and also the 'Do not disturb' signage. The policy and resources had been implemented by Nursing Practice Development a number of years prior to the study taking place. Interruptions had not been highlighted as a significant issue affecting the safe administration of medication in the Stage 1 or Stage 2 of the study. When designing the observation tool, there were questions as to whether any interruption occurred and also in relation to the usage of the red apron and the 'do not disturb' signage. During observation, due to the large number of interruptions noted further investigation was required. The identification of such a high rate of interruptions, which were not identified as a theme during previous stages of the research, provides a clear rationale for researchers undertaking observation when evaluating the factors which can influence how a CPE programme works or does not work in practice.

There are various steps which any nurse needs to undertake in order to administer medication to a patient. These include reading the prescription, obtaining the supply, checking the supply and dose from the prescription, preparing the medication, taking the medication to the patient's bedside, correctly identifying the patient, administering the medication and completing the documentation. Nonetheless, nurses carrying out medication rounds have to contend with a whole array of competing pressures and interruptions (Cleary-Holdforth and Leufer 2013). Interruptions that occur during any step of the medication process have been associated with an increased risk and increased severity of medication administration errors (Westbrook et al. 2010). The seminal report by the Institute of Medicine Committee (2000) suggested that interruptions to medication administration are a contributing factor to medication errors. Interruptions affect staff cognitively by interfering with working memory and causing lack of focus (Potter et al. 2005). Any interruption diverts a nurse's attention from the task at hand, such that interruptions and distractions are considered of equal importance (Ebright et al. 2003).

Cottney and Innes (2015) identified that if, a nurse is required to stop administering medication so as to perform another task, an error was 48% more likely to occur. In this study, during a medication round on Hazel Ward, Marcella was interrupted on all (n=3) of her medication administrations and likewise, Cathal on Oak Ward was interrupted in all

(n=3) of his medication administrations, and thus, likely to significantly increase the risk of making a potentially fatal medication error.

During observation in this study, it was found that between 45-100% of all medication administrations were interrupted. This appears to be a very high rate of interruption and was seen to significantly interfere with the nurses' work processes. However, it is difficult to compare the rate seen here with the those reported 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). Biron et al. (2009) found that nurses were interrupted at least once in 53.9% of observations. Likewise, Westbrook and Li (2013) who explored interruptions in nursing work found that the highest proportion of interruptions occurred when nurses were undertaking medication tasks (27.3%, n = 102).

Interruptions can come from multiple sources. Bower et al. (2015) identified two main categories of interruptions, the individual and the technical. Individual interruptions are classed as healthcare workers, patients and family members, and technical sources are defined as interruptions from alarms and technical failures such as missing equipment or medication (Bower et al. 2015). During observation in this study, interruptions were noted from multiple sources. Surprisingly, the greatest number of interruptions came from nurses and other healthcare professionals. Similarly, Relihan et al. (2010), in an Irish study, found that one of the greatest sources of interruptions of medication rounds were nurses themselves. Biron et al. (2009) also identified that nurse colleagues were the main source of interruptions in 17.8% of all interruptions. Likewise, Craig et al. (2014), identified staff interruptions occurring 2.5 times more often than any other interruption. When investigating interruptions to nursing work in general, McGillis et al. (2010) found that 32% of all interruptions came from other members of the healthcare team, and 25% from other nurses. Also, when looking at nursing work in general, Westbrook et al. (2011) found that in 10.7% (n=333) of medication tasks, nurses were concurrently conducting professional communication with a colleague. Family or patient interruptions only accounted for 20% of interruptions with factors in the environment accounting for 19% of all interruptions.

Relihan et al. (2010) found that strategies to reduce interruptions led to a significant reduction in interruptions post implementation. However, the post-implementation data

collection was completed approximately two months after the introduction of the intervention, and thus, not evident that the strategy is sustainable and will impact over time. A literature search has provided no evidence of the sustainability of the reduced interruption rate with the implementation of such strategies. In this study, the strategies to reduce interruptions were part of the organisations policy, and staff obviously had an awareness of them, as on multiple occasions it was noted that staff members who interrupted the medication administration prefixed the conversation with '*I know you are busy*' or '*I know I shouldn't be interrupting you but...*'. During interview, Clodagh also spoke about how staff would insert a similar prefix prior to interrupting.

The assumption that interruptions have only negative effects ignores the benefits or reasons why these interruptions may occur (Hopkinson and Jennings 2013). Not all interruptions can be avoided, and at times may be necessary, such as to attend to an urgent phone call or provide a patient care activity. During interview, Grace spoke about an example of where she needed to take an urgent call from the laboratory in relation to a patient's abnormal blood chemistry result. Also, when observing Marcella on multiple occasions, her interruptions were to provide patient care, for example, assisting in transferring a patient to a commode or assisting the lady who fell in the bathroom. Biron et al. (2009) reported multiple interruptions during medication administration for what they termed co-ordination of patient care. Co-ordination of care is necessary at all times, as in the clinical area, patient conditions are constantly changing and require clear communication to relate this. Verweij et al. (2014), when exploring nurses perceptions, found that nurses expressed their opinion that patients should always feel free to ask the nurses questions. Additionally, the nurses reported that the main sources of interruptions during drug rounds are colleagues and not patients. In clinical practice, all interruptions cannot and should not be avoided, but as highlighted by Popescu et al. (2011), exercising clinical judgment is a core responsibility of professional nurses.

10.5.2 Wearing the red apron

The organisation had a policy in place on the reduction of medication interruptions. Significantly, the nurses observed were not seen to routinely wear the red apron or use the 'do not disturb' signage. During observation, there was a range from no compliance by Marcella, to full compliance by Cathal, with wearing the red apron. However, during

interview, Cathal did acknowledge that he does not normally wear the apron and was only wearing it because he was taking part in the study, and that the red apron would help to highlight that to other staff. On all observations across the three embedded cases, signage was not used as advised in the organisations policy. It was present on the trolley in Ash Ward and Oak Ward but not used. The use of the alert tabards or aprons or vests and the 'Do not disturb' signage is a widespread intervention internationally, which is thought to reduce the number of interruptions during medication rounds (Verweij et al. 2014). In a study by Verweij et al. (2014), they found a significant reduction in medication administration errors after implementing the tabards. Craig et al. (2014) also found a significant reduction in interruptions in two of three clinical areas where a 'white vest' intervention was conducted. Westbrook et al. (2017), using a bundle of interventions which included wearing an alert vest when administering medications, strategies for diverting interruptions, clinician and patient education and reminders, found Intervention wards experienced a significant reduction in non-medication-related interruptions from 50/100 administrations to 34/100. While a significant reduction in interruptions was found, a rate of 34/100 is still a large amount of interruptions when administering medications.

Hopkinson and Jennings (2013) caution that there is more to understanding interruptions than merely counting them, and thus, in this study nurses and managers' perceptions were further explored during interview. These interviews provided insight into nurses' perceptions and potential barriers to the use of the strategies recommended in the policy. None of the four nurses who took part in Stage 3 felt that the red apron was beneficial in reducing interruptions. Marcella reported that the ward was too busy to use them, and Clodagh felt that it may help reduce interruptions from other nurses but not from other healthcare professionals, families or patients. Two of the three CNM II's were not supportive in their use. One of the CNM II's stated that they are difficult to use due to infection prevention and control issues and the other reported that they don't work and she doesn't wear it herself. The third manager agreed with their benefits, but also highlighted that some-times interruptions are necessary so that the nurses can receive important patient information or communication.

If there is not a positive perception of the usefulness of these strategies, then organisation policy will not be applied in practice. The safe medication administration education

programme addressed all aspects of medication safety and had reference to these strategies, but did not focus on reporting their positive outcomes when applied in practice.

10.5.3 Physical structure

The three wards where observation took place were of different design and physical structure. It was proposed that the structure or design of the ward was an influential context. In line with the organisations practice for oral medication administration, all oral medications, with the exception of controlled drugs, were administered from a mobile medication trolley. The organisation policy outlined how this trolley should be brought to the patient's room (multiple occupancy room) where possible. Intravenous medications were stored and prepared in the medication room. Hazel Ward and Oak Ward had designated drug preparation rooms, but Ash Ward had a designated preparation area behind the nurses' station. The review conducted by NMBI in 2017 had recommended that a designated medication room be put in place on each ward area. However, the use of a designated preparation room was not found in this study to provide any greater reduction in interruptions.

On Hazel Ward when observing Marcella, my initial analysis of the multiple interruptions during her medication administration proposed that the position of the medication trolley on a busy corridor resulted in many of the interruptions. However, on the final day of observation, Marcella was positioned in the medication preparation room preparing intravenous medications and during this observation period she had all of her administrations interrupted (n=3). This was the highest rate of interruptions in all her periods of observation. Likewise, on Ash Ward when medication was prepared in the central preparation area (which was in the nurses' station), there were multiple interruptions. On the single occasion when Cathal on Oak Ward was preparing a controlled drug in the medication room on the corridor parallel to his allocated clinical area, he was interrupted by a member of the medical team who followed him there to communicate important patient information.

Bennett et al. (2010) reported that creating a dedicated room for medication preparation reduced the occurrence of interruptions. However, a later observational study by Popescu et al. (2011) found that nurses experienced more frequent distractions when medications were stored and prepared in a communal drug room, as such a room facilitated conversations that

distracted and delayed medication administration. Likewise, Tomietto et al. (2012), in an interventional study, introduced a dedicated medication preparation room but found that it did not reduce interruptions and resulted in removing nurses from the bedside.

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 being implemented. 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.

10.6 Quality Improvement Approach

The safe medication administration education programme did not allow for the development of a quality improvement approach as a mechanism in the participants. This mechanism did not activate because the context which I proposed did not exist. Realist evaluation emphasises that the context matters, firstly, because it influences 'reasoning' and, secondly, generative mechanisms can only work if the circumstances are right (Dalkin et al. 2015). Participants were unable to put new learning into practice because the context was not enabling them to do so.

Rather, quality improvement when observed was seen to be led by the CNM II on all wards and was found to be linked with the leadership traits of the CNM II. Manley et al. (2017) identified that, in order to develop teams with a positive safety culture, a quality improvement approach needs to be developed. Also in this CMO configuration, I have demonstrated that the context proposed, which was safety focused governance, was absent and thus, this mechanism of the quality improvement approach was not triggered.

One the outcomes set out for the safe medication administration education programme was that participants would be able to critically evaluate medication incidents presented in the learning programme. The anticipated clinical effect of this would be that participants would have a greater awareness of the importance of quality improvement strategies and behaviour. However, in the three ward areas, there was minimal to no adherence with

recommended strategies to reduce interruptions, and participants were unable to adopt a quality improvement approach.

10.7 Multi-disciplinary Collaboration for Medication Safety

Medication safety is a multi-disciplinary and multi-stage process in which nurses play a key role (Adhikari et al. 2014). In the outer context at organisation level, the data collected in Stage 1, and refined during Stage 2, found that a multi-disciplinary approach to medication management was present. Also, the inspection by HIQA (2017) on medication safety, identified the multi-disciplinary approach to the management of medications at organisational level. This multi-disciplinary working is part of the culture of medication safety within the hospital. The culture of the organisation already exists and was not changed by the safe medication administration education programme.

Across the three embedded case studies, medication safety was also seen to be multi-disciplinary. It was particularly strong on Ash Ward, where Clodagh, Grace and Leah discussed at length the working relationship with their Clinical Pharmacist. There were also multiple times during observation where interaction was seen between the participants and the Clinical Pharmacist. While on Oak Ward and Hazel Ward, the Clinical Pharmacist was seen on only one observation, and no interaction with the participant was noted. During interview, both Marcella and Cathal did discuss the role of the Clinical Pharmacist. Cathal also described the importance of the relationship with the medical doctor who has prescribed the medication, and gave an example of collaboration to ensure correct dose of an immune-suppressant medication is administered; this was reinforced by his manager Karen. Medication management is one of the functions in healthcare that is clearly multi-disciplinary, and therefore collaborative, in nature (Leurfer and Clearly-Holdforth (2013). The observation and follow up interviews with participants and managers demonstrated that the multi-disciplinary approach at organisational levels has filtered down into practice. The inner context reflects that of the outer organisational context.

Leufer and Cleary-Holdforth (2013) postulate that a collaborative approach has the potential to greatly enhance patient safety and care delivery, but qualify this by requiring a multi-disciplinary approach that is structured, cohesive and has clearly designated roles and responsibilities. Rohde and Domm (2018) found that patient-centred communication within

supportive multi-disciplinary team supports medication safety. Likewise, Dickson and Flynn (2012) found that open communication between disciplines, where the nurses advocated for their patients, ensured that their patients received their medications in a timely manner and that everything was right with the medications and their particular patients.

10.8 Receptivity to Change

Receptivity to change was identified as a mechanism in Stage 1, and was further advanced and refined in Stage 2. It was identified as a mechanism, as it matches the definition of a mechanism provided by Dalkin et al. (2015), which involves the reasoning and responses of participants. In Stage 3 of data collection, all participants demonstrated receptivity to change. On Ash Ward, both Clodagh and Grace described how they had recently taken part in a change process in relation to medication management of controlled drugs. However, no link between receptivity to change and a multi-disciplinary context was found.

Clark et al. (2015) have reported that after CPE, some participants have aspired to be change agents. However, they have reported that organisational structures have often prevented them from doing so. Participants also reported that they felt they had limited autonomy to initiate and sustain change. Indeed, while participants in this study did show receptivity to change, the context responsible for igniting that change was not identified. In Ash Ward, it somewhat appeared to be driven by the CNM and her leadership traits.

Dalkin et al. (2015), when discussing the nature of mechanisms in particular in relation to human volition (reasoning), described them as rarely been activated via an on/off switch. These type of mechanism, of which receptivity to change fits, has been described as being on a continuum (Dalkin et al. 2015). This would mean that the intensity of the mechanism would vary in line with the ever-evolving context. This analogy appears to be very apt when describing the position of receptivity to change in this study. Based on the recommendations of Dalkin et al. (2015), rather than looking at what fires or activates the mechanism, receptivity to change, there may be more explanatory value in understanding how it works. 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.

10.9 Quality Care Nursing Metrics

Nurses make up the greatest proportion of the workforce in hospitals in Ireland and yet nursing contribution to patient care often remains undervalued and virtually indiscernible to policy makers. It is often only significant when absent. Recent reviews of the healthcare system in the UK, such as the Report on Mid-Staffordshire NHS Foundation Trust Public Enquiry (Francis 2013), highlighted the impact on patients when healthcare workers, including nurses, fail in their duty to maintain high standards of patient care. There is increasing interest in measuring outcomes in nursing, driven by the need to determine and measure quality in healthcare by policy makers and managers (Foulkes 2011). As with all funded interventions, there is an impetus to identify patient outcome measures following CPE.

There are numerous measures available to determine nursing led outcomes. Nationally, Ireland has implemented the Quality Care Nursing Metrics (QC-M). These measures were first developed and used in the 2009 in the UK in the Heart of England Foundation Trust. These national QC-M collect data associated with nursing management of medication. The QC-M for medication management collects data on medication practice according to pre-determined evidence-based criteria. Continuing professional education provides a systematic way in which nurses can continue to learn and develop, in order to keep their knowledge and skills up to date and thus, maintaining and enhancing their professional competencies (Nsemo et al. 2013). A measure of professional competency in relation to medication management is the QC-M Medication Management Criteria. Thus, it was essential that the QC-M were used as an outcome measure in the study.

In this study, the QC-M's across all three wards for 2017 were examined with reference to the Medication Administration criteria. In the first six months of 2017, both Ash and Hazel Ward scored as red or orange. Red indicating that there were areas of risk identified and orange indicating that improvements were required. Oak Ward achieved their target and scored green over the 12 months of 2017. No association was found between the context, the mechanism and the achievement of target scores on the QC-M. 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.

10.10 Correct Patient Identification

During the data collection in Stage 3, correct patient identification was recognised as a potential mechanism. Correct patient identification is one of the essential components of the application of the 'five rights' of medication administration into practice and it was one of the constituents of the safe medication administration education programme. During data analysis, it emerged that correct identification of patients was an important indication or outcome from the education programme. The organisation's medication administration policy recognises patient identification as an essential component in the administration process. However, many medication administration guidelines are not followed in practice (Kim and Bates 2013). It had not emerged as a theme during the first or second stages of this study, perhaps as it was seen to be an integral component of nursing work. Accurate identification of patients during the medication process, especially during medication administration, is one important aspect for decreasing the risk of errors (Kelly et al. 2011), and according to previous findings, the correct identification of patients has been found to reduce the risk of medication errors by 56% (Westbrook et al. 2011).

Correct patient identification was included in the observation checklist and further discussed at interview. Excellent practice was observed in the correct identification of patients across the three ward areas. In only one medication administration episode from 79 observed medication episodes, was the patient identification not checked according to the pre-defined criteria, which is a compliance rate of 98.7%. In this case, the nurse had just minutes previously administered a medication and performed the identification check. This is a marked difference to the findings of previous studies. Manias et al. (2005) found that the patients' identification was checked in just 27% of situations. Dougherty et al. (2012), reporting on just twenty observations, found nurses performed identity checks as per hospital policy in only 35% of observations. Härkänen et al. (2015), using a much larger sample of 1,058 medication administrations, also reported the rate of checking patients identity prior to medication administration at just 33.2%. This was the rate for checking any element of patient identification and not the two patient identifiers as recommended by the Institute of Safe Medication Practices Guidelines (ISMP 2011). Popescu et al. (2011) observed a higher rate of compliance with nurses checking patients' identity bands with 63.3% of observations.

Similar to other observation studies (Dougherty et al. 2012; Härkänen et al. 2015; Popescu et al. 2011), and in order to verify if the Hawthorne effect may have occurred, the topic was further explored during interview. All the staff nurse participants and managers interviewed confirmed that it was their normal practice to check patient's identification prior to medication administration. While the nurses observed were familiar with their patients, and often addressed them by name prior to identity checks, they still undertook the identification checks and confirmed its importance during interview. Again, this clarification from the nurses in this study is different from that reported in the literature. The nurses observed in the Popescu et al. (2011) study reported that they only completed an identity check as they were being observed. When Dougherty et al. (2012) explored the lack of identity checks with the nurses in their study, they uncovered what they described as "a culture of knowing the patient" and in nurses' views, patients do not want to repeatedly have to say their name and date of birth. Popescu et al. (2011) also cited 'knowing the patient' as a reason provided by nurses for not completing identity checks. However, the World Health Organisation Collaborating Centre for Patient Safety Solutions (2007) recommends that, even if patients are familiar to nurses, the patient should be identified to ensure that the right patient receives the right care.

Excellent practice in the correct identification of patients was found on all three embedded ward areas in this study. The organisation under study holds accreditation with an international accreditation body. One of the patient safety goals advocated by the accrediting body is that of correct patient identification. The patient safety goal, correct patient identification spans all areas of practice within the organisation. It appears to be embedded in the culture of the organisation. Further refinement and review of patient identification is recommended and also, an examination of how it relates to the organisation and local ward context.

10.11 Conclusion to Discussion

CMO configuration 1 has been accepted and is being put forward as a mid-range programme theory which can be used as a template for further development of CPE programmes in relation to medication safety.

CMO 1: 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**.

While this CMO configuration is accepted, and put forward as middle range programme theory, I recommend that for further application the context positive patient safety culture is divided into the dimensions of leadership and workplace culture.

The case study undertaken in stage 3 of this realist evaluation did not provide evidence to allow for CMO 2 to be accepted nor rejected. Across the three embedded case studies, the context proposed was not identified. This highlights the importance of designing curriculum for continuing professional education in association with key stakeholders. If a curriculum is designed based on an understanding that certain contextual factors are in existence, the curriculum will be designed to 'fit' in with these. Therefore, if the contextual factors are not present, the learning from the CPE will not be transferable to clinical practice. Further research is required to test the mechanism and context factors. Therefore, following this study, CMO 2 stands as a programme theory but requires further investigation in order to develop it as a mid-range programme theory.

CMO 2: 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.

The testing of CMO 3 did provide evidence of the multi-disciplinary collaboration to medication management in the organisation and in the case study sites at local level. It also uncovered that participants, who undertook the safe medication administration education programme, did have receptivity to change. The QC-M was also identified as a useful outcome measure. However, no relationship between the multi-disciplinary collaboration to medication management, receptivity to change and QC-M could be established. While a relationship has not been established between the context, mechanism and outcome these elements need to be considered and further explored in order to develop the programme theory into a middle range theory.

CMO 3: 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.

It is recommended that these concepts are further tested to establish relationships between context, mechanism and outcome.

Correct patient identification was also found to act as a mechanism factor. The findings in relation to context, mechanism and outcomes for the CPE on safe medication administration education programme are summarised in Table 10.1.

Context	Mechanism	Outcome
Leadership	Seeking out information Problem solving	Reduce patient harm- through medication error reporting
Ward culture/patient safety		Reaching Target -Quality Care Nursing Metrics
Safety focused governance Interruptions and the physical structure	Quality improvement approach	
Multi-disciplinary collaborative approach to medication safety	Receptivity to change	
	Correct Patient Identification	

Table 10.1 Proposed context, mechanism and outcomes for CPE on medication safety

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.

This study attempted to outline programme theories by conducting document analysis and interviews with key policy makers and education developers and later refining these theories (stage 2). During the testing process (stage 3) as well as confirming and developing middle range theories new concepts were identified which had not been formulated as programme theories. These concepts are leadership, work based culture and correct patient identification.

Chapter 11- Conclusion to Thesis

11.1 Introduction

This final chapter concludes the thesis. The original contribution of this realist evaluation to the empirical body of knowledge on continuing professional education is presented. The limitations of the realist evaluation are next presented. The next section provides my reflective learning during the course of this thesis from its development right through to its completion. My plans for dissemination and publication of the findings from my realist evaluation are next presented. Finally, this chapter concludes with my professional learning and career pathway upon completion of this thesis.

11.2 Reflection on my Thesis Journey

Realist evaluation can be difficult to design and requires considerable researcher reflection and creativity (Dalkin et al. 2015). Thus, I have documented my reflections and learning during the completion of this study. Throughout my lengthy journey in the research design, data collection, data analysis and write up I have constantly learned from others.

11.2.1 Ethical approval and University Panel Reviews

My ethical approval process was a lengthy journey as it was necessary for me to seek permission from multiple committees within the organisation under study. Through the ethical approval process, which required clarifications and greater detail, my study design was further developed. The main focus of the Research and Ethics Committee was on the ethical principles, which I would apply in Stage 3 of the study where I would be conducting observation in clinical practice. Thus, when I commenced this stage all possible ethical principles had been clearly defined.

The University Panel Reviews also assisted me in learning. While the study was being progressed, the requirements for the reviews made me commit to writing the process as I was progressing. The questioning and comments of the University Panel also assisted me in articulating my methods and in defending the choices which I made in my design. The comments offered by the Panel always helped me to further refine my design.

11.2.2 Distance student

There are many challenges to completing a doctoral study as a distance student. One of the disadvantages of being a distance student is that I did not have a student community that I could 'run ideas' by and receive thoughts on. I feel that this challenge was overcome by responsive, accessible supervisors. Through the thesis journey, regular deadlines were set by my supervisors in relation to the submission of written work. Regular supervisions were also arranged via Skype. Outside of arranged supervision dates, e-mail queries or thoughts which I wished 'to run by' someone were always responded to. Rather than answering my queries, my supervisors encouraged my reflection skills. I was guided to reflect on my design and to explore what Pawson and Tilley would advise.

Numerous methodological challenges also were discussed during these supervisions. An example of a discussion was when I had completed data analysis at the end of Stage 1, there were numerous themes identified. These themes needed to be allocated as a context, a mechanism or an outcome. I had read and re-read the writings of Pawson and Tilley (1997), Lacouture et al. (2015), Dalkin et al. (2015) and Astbury and Leeuw (2010), but I was still unsure if I was allocating each theme correctly. During this supervision, each theme was presented, and under the guidance of my supervisors, I was encouraged to define each theme and then justify my allocation of each theme. Following supervision, this was written up in the same manner.

11.2.3 Learning from the community of realist researchers

When I commenced preparation of the proposal for my thesis, my supervisor informed me of the helpful discussion board for JISCMail for the RAMESES community. I frequently visited this board and reviewed the topics under discussion. After a period of browsing the board, I became a member and thus had all discussion topics arrive directly into my e-mail inbox. This assisted me in becoming familiar with the topic of realist evaluation, and made me familiar with the language and how it is used in everyday practice.

When commencing Stage 2 of the research, I encountered numerous areas in which I struggled to apply the realist principles in my study. Stage 1 interviews were for initial data generation and were conducted in a semi structured manner similar to any qualitative interview. When entering Stage 2, I was aware that I needed to conduct a 'realist interview'. I had read, and revisited on multiple occasions, the writings of Pawson (1996) and also

Manzano (2016), on craft of interviewing in realist research, but the practicalities of the application of the principles of 'a realist interview' were still proving to be a challenge. I was asking myself multiple questions; how do I get my experts to refine my theories? Do I send it to them beforehand? But if they are not familiar with the realist method, will they understand the process? Am I able to explain the process in writing? Perhaps, I could read it for them and ask –what do you think of that? My first expert interview had been arranged, and I was still unsure of how I was to proceed with it. I arranged an urgent Skype with my supervisor to seek advice. My supervisor recommended that I use the realist community to assist me with my dilemma. Thus, I sought the guidance of the realist community and posted a question on the discussion board for JISCMail for the RAMESES community. Ana Manzano who is the author, of the 'The craft of interviewing in realist evaluation' responded in a number of hours and advised me to ask broad questions in relation to my context, mechanism and outcome. Following this advice, I developed my interview schedule for my first expert. On completion of the interview, I was satisfied with my line of questioning and with how the information gathered in the first expert interview further refined my conjectured CMO configurations.

During Stage 2 of my data collection, I also struggled when, in my second expert interview, the expert refuted a potential mechanism 'critical thinking' which I had identified. I was unsure as to where to go from there and how I should proceed into my third and final expert interview. At that time, I attended a Realist Workshop facilitated in London which was hosted by Justin Jagosh from The Centre for Advancement in Realist Evaluation and Synthesis (CARES). During this workshop, each participant had an opportunity to discuss any theoretical issues which they had been struggling with. I put my dilemma to the group and received advice and logical discussion on the dilemma. The group reminded me that realist evaluation is iterative and constantly develops as the researcher progresses through the stages. Thus, my interview schedules for each expert could change depending on the stage of programme theory development. During this workshop, I also made contact with another PhD student from Dublin who was using realist methods.

Towards the end of 2017, I joined a realist group in Dublin which had been established by the contact I made in London. I have since attended this group on a six weekly basis. I have found group membership of great assistance, and I have regularly discussed methodology challenges with the group. One such example is that of the design of my case study, and as

to whether it was a single case study with embedded units or three individual case studies. I have found the opportunity to meet and discuss my work, and the work of others, with the realist community of great assistance in my articulation of my application of realist evaluation.

The realist network is also active on the social media site Twitter. I joined Twitter during my study, in order to enable me to follow ongoing updates and publications in relation to realist research. I follow numerous realist and evaluation groups/organisations, as well as some of the leading Realist Academics from the UK. I have also extended this network to Irish Academics who are developing the realist methodology in Ireland. These regular updates allow me to be constantly immersed in the world and language of realist research.

11.2.4 Reflection on observation

In total, I spent just under 35 hours in the clinical areas as a participant observer, and it was this aspect of the research project which I grappled most with. This is not uncommon, and the literature has recognised difficulties in conducting research in one's workplace, in terms of the researcher's status within the organisation and what the researcher represents to the other participants (Drake 2010). Prior to undertaking this study, I had an acute awareness of the potential pitfalls of undertaking qualitative research in the organisation where I work. Thus, in order to mitigate any potential bias as a result of my position, during the design and conduction of my research study, I applied techniques to ensure the trustworthiness of the data which I was gathering. Techniques such as the use of a semi-structured observation tool and semi-structured interview guides assisted with this process.

It is elements outside of the design which caused me to reflect on my experiences of observation. Conducting research in the organisation one works in, within the researchers' social group or culture is often referred to as insider research (Greene 2014). While I had many elements in common with the participants during the observation, I chose not to position myself in a binary position as insider or outsider, but acknowledged my position as someone familiar (Tilley 1998). This allowed me to establish and maintain an appropriate degree of social and emotional distance (Greene 2014).

A strategy which I applied throughout my research study to assist in acknowledging my position was the practice of reflexivity. I found this of great benefit, particularly during my

observation of clinical practice. Finlay (2002, p. 532) identify reflexivity as *“thoughtful, conscious self-awareness”* which involves a process of on-going mutual shaping between researcher and research (Attia and Edge 2017). For me, reflexivity was a continuous process, whereby I identified my value systems prior to commencing the study and my observation in clinical practice, and acknowledged my subjectivity. This assisted in enabling me to maintain an open-minded approach and develop a critical perspective through continuous self-evaluation. It also allowed me to acknowledge, as a nurse, educator and researcher, my taken for granted values, and consider how they may impinge on the data that I was collecting and my interpretation and analyses of this data (Jootun et al. 2009).

Through-out my research journey, I maintained a reflective diary. I found revisiting my reflective diary assisted me when analysing the data collected, and assisted in the preparation for the follow up interviews. It also provided me with greater sensitivity to the potential feelings of the participants. At times during the periods of observation, I utilised my reflective diary to acknowledge my emotions in relation to the practices which I observed, and to the difficult work environments in which the participants administered medications. I also acknowledged my feelings in relation to my position as a researcher, where I was not able to provide any guidance which I felt may have helped participants with difficult situations. Similarly, to Ross (2017), it allowed me to acknowledge the emotional work which I was also undertaking and place boundaries on my emotions.

During the research process, I also felt that my position enabled the development of a sense of trust and openness with the participants and also provided me with a deeper level of understanding afforded by prior knowledge (Taylor 2011; Dwyer and Buckle 2009). Participants have given me their trust and allowed me to observe their practice and spoke openly with me following observation. It was important that I reported the data but also be fair to the participants and not represent them in an unfair manner.

11.3 Original Contribution to Knowledge

The narrative literature review in Chapter 2 has provided for the extension of the Barr et al. (1999) evaluation framework. The extension of the framework provides for the acknowledgement that components external to a CPE programme may affect its transfer

into clinical practice. The new extended framework allows for the further examination of transfer of learning including the contextual and individual factors. Until there is a greater awareness of the ability of realist evaluation to be applied in the evaluation of CPE the extended framework provides a framework by which the limitations of outcome-only evaluation can be addressed. The use of the extended framework will assist in the advancement of understanding of how external factors impact on the transfer of learning from CPE.

Realist evaluation offers an excellent choice for evaluating continuing professional education. This research highlights the importance of contextual factors, which need to be considered when developing curriculum for continuing professional education. 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.

Whilst a relationship between context, mechanism and outcome was not established in two of the proposed CMOs, the factors which can influence and either facilitate or create a barrier to the application of knowledge developed in CPE into practice have been identified. This study has identified the key role that local leadership and work-based culture have in the transfer of knowledge and skills developed during CPE into clinical practice.

This study also identified the importance of the inclusion of stakeholders when evaluating CPE programmes. Observation was also 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.

In designing, developing and evaluating curriculum for continuing professional education, 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 would assist in identifying and overcoming the barriers to transfer and thus optimise patient outcomes.

11.4 Study Limitations

This study has been conducted in only one organisation and based on a single CPE programme, thus the findings are unable to be generalised to that of other organisations or CPE programmes. Only one CMO configuration can be put forward as a programme theory.

This may have been due to the way in which I developed my conjectured CMO configurations. It was my first experience undertaking independent qualitative research and I may have missed subtle details in the qualitative data in Stage 1 and Stage 2. It may have been beneficial to have included registered nurses who undertake CPE programmes in the development (Stage 1) or refinement (Stage 2) of the conjectured CMO configurations.

11.5 Post Doctorate Plans

An essential element of research scholarship is the dissemination of the findings. My strategy for publications from this thesis is as follows:

- Evaluation of Continuing Professional Education- The first publication which I wish to obtain a publication on is on evaluation in continuing professional education. This paper will be a discussion paper on the importance of evaluating CPE and the current methods reported in the literature. It will propose realist evaluation as an appropriate method which should be used for curriculum developers and key stakeholders. This paper will be based on my narrative literature review and my methodology chapter. I feel this paper would be suitable for submission to Nurse Education Today, which accepts articles of this nature in its Contemporary Issues Section.
- A Realist Evaluation of a Safe Medication Administration Education Programme in the Republic of Ireland- - I wish to publish the full study in a nursing education journal such as Nurse Education Today. I believe that it is important to publish it in such a journal, as this study has relevance to educators who are developing CPE with the intent to influence practice change. The findings from this study will assist other educators in identifying the contextual factors which may influence uptake of new knowledge and skills. This should then impact on their curriculum design, and also on the involvement of stakeholders in the curriculum design phase.
- Observation in Clinical Practice- My final paper will be on observation in clinical practice. As previously discussed, I found my experience of observation in clinical practice particularly challenging. Firstly, in obtaining ethical approval to undertake the observation, and secondly within my dual role. I wish to publish a paper on this

to highlight my experiences and the strategies which assisted me to overcome it.
This paper will be submitted to Nurse Researcher.

11.6 Conclusion

Throughout the period of this study, I have maintained my full-time position working as a Registered Nurse Tutor in a Nurse Education Centre in Ireland. My work is primarily in relation to the curriculum development of continuing professional education for registered nurses. Through completion of this study, my practice and underlying values within my role have developed and have undergone significant change. In the past three years, significant changes have taken place in my workplace in relation to the curriculum design and delivery of CPE. I have played, and I am continuing to play, a key part in this change process. While this change process is independent to my study, the learning from my study has assisted me greatly in all aspects of this work based action research project. I have taken the lead on evaluation of the change process and I have been responsible for ethical applications, data collection, and data analysis. The development of my academic writing skills has also assisted in my work-based project, as the group have published and prepared papers for publication.

Development of my research knowledge has also advanced my research position within my workplace. I am contributing my expert research knowledge to the Nursing Research and Innovation Committee. I have also been invited to join a research group, which is undertaking an evaluation of the role of the Advanced Nurse Practitioner within the organisation. My role will be to advise on the methods lead the design of a realist evaluation.

I anticipate that successful completion of this thesis will further allow me to advance my career in nursing academia and develop my knowledge and expertise in realist evaluation.

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ISBN978-1-909067-79-0. Available at:

[file:///C:/Users/owner/Downloads/SCQIREFinalReportwithISBN201217%20\(1\).pdf](file:///C:/Users/owner/Downloads/SCQIREFinalReportwithISBN201217%20(1).pdf)

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Appendices

Appendix 1: Critical Appraisal of Articles Included in the Literature Review

	Author	Research Question/Aim(s)	Population	Sample Size	Research Approach	Method of Data Collection	Findings	Limitations	Critical Comments
1	Yoshioka et al. (2014)	Is end-of-life nursing care continuing education for general ward nurses effective?	Nurses in 1 hospital in Japan.	50- 25 in control group and 25 in intervention group.	Nonrandomised, before–after trial 2 groups experimental and control.	3 self-reported evaluation questionnaire, before, immediately after and 2 months post the education intervention.	Scores for knowledge about end-of-life nursing care were significantly elevated both immediately after and 2 months after the programme compared with pre-intervention levels and the scores immediately after the programme were approximately equal to those at 2 months after the programme.	Possible selection biases.	At lower level of evaluation hierarchy and self-reported.
2	Lin et al. (2014)	Is the attitude of organ advocacy of ICU nurses more influenced by theory of planned behaviour (TPB) based education?	Taiwan- 3 ICU units in different medical centres- randomly assigned.	61 experimental 62 control.	Self- identified as randomised The ICU was randomised as to intervention or control but not the participants not participants.	The experimental group received the education programme and the control groups received a brochure only. The outcome parameters were measured by questionnaires at 3 different time points of pre-test, post-tests immediately after education, and 2 months later.	Before education, there was no difference in attitude and behavioural intentions between the control and experimental groups. After TPB training, the nurses significantly changed their attitudes and behaviour intentions on organ advocating, both immediately and 2 months after the education In addition, multivariate analysis indicated that TPB training is significantly associated with the change of attitude and behaviour intention of organ donation advocacy.	No limitations identified. No details of randomisation or control of external variables.	Only measured attitude and behavioural intentions and these have been self -reported- may not lead to behavioural change.

3	Philp et al. (2017)	Aim: to evaluate nurse confidence pre- and post-delivery of an education intervention in gynaecological oncology nursing, speakers' performances and course content.	Registered Nurses who had completed a 5 day gynaecological oncology education programme in Australia.	62 Registered Nurses.	Evaluation framework with pre-post questionnaire. Intervention 1 week module.	Pre-post questionnaire about programme content and nurse confidence. Nurses rated their confidence about gynaecological oncology skills one week prior to the programme, immediately post-course, 3 months post and 12 months post.	Improved confidence in participants- immediately after participating in the course. Confidence subsequently declined and stabilised up to 12 months post-course, it still remained significantly higher than before the course: Results support the value of continuing professional education for improving nurse confidence in the gynaecological oncology setting.	Only 24 RN's completed final evaluation at 12 months.	Reliance on self-reports of confidence.
4	Smith et al. 2017	Assessment of delirium in intensive care unit patients: educational strategies.	RN's in an Adult medical/surgical ICU in the USA.	34- American ICU nurses.	A pre-test-post-test design Intervention: multimodal online educational and simulation.	Questionnaire which included demographic, knowledge and confidence ratings.	Participants ($N = 34$) showed a significant increase in confidence in their ability to assess and manage delirium following the education. No statistical change in knowledge of delirium existed following the education. Although there was no significant change from pre- to post-test scores on the Knowledge of Delirium tool, the Educational Methodology Satisfaction tool revealed that the simulation helped participants feel educated about delirium.	Small sample size- only 50 % of nurses agreed to participate in simulation No content validity established for knowledge of delirium test.	Illustrates an increase in confidence only- not knowledge- small sample size- no higher level of evaluation.

5	Fleet et al. 2011	What is the impact of an internet-based CPD Asthma Programme on participants' knowledge and satisfaction?	457 Health Care Practitioners (HCP's) in Canada who completed an online CPD course on Asthma.	125 (HCP's)	Pre and post knowledge assessment Intervention: education was based mainly on principles of self-directed learning, whereby participants could start at any time. An asynchronous discussion board was also available, but the discussion was not facilitated.	Data collected was mainly quantitative in nature with limited qualitative feedback provided by participants. All evaluation instruments were available online as components of the CPD course.	Significant pre to post- test increase in knowledge High rate of overall satisfaction.	Participation bias	Proved gain in knowledge but not whether it was retained over time.
6	Smith and Topping (2001)	What is the relationship between undertaking a Children's Neuroscience Course and the perceived benefits to the practitioners?	17 nurses who had completed the Children's Neuroscience course.	14 nurses	Case-study methodology.	Self-report evaluations (completed at induction, midpoint and exit), academic performance, and data collected from a questionnaire. In addition, semi-structured interviews ($n = 9$) were undertaken and analysed using a thematic content approach.	Triangulating of the various data found that improved knowledge, improved care delivery and professional development, which were judged as benefits to the practitioners. Furthermore, there was a significant relationship between undertaking the course and participant's perception of their increased abilities in delivering care to the child with a neurological problem and their families.	1 centre and 1 course.	Small study with a small number of participants. Only self-reported application of new knowledge to practice.

7	Mockiene et al. (2011)	What is the impact of an education intervention to change nurses' HIV-related knowledge and attitudes?	The hospitals (n3) were randomly selected from among the nine largest hospitals in Lithuania. Nurses were randomised from pools of about 300 at each hospital into the study groups.	EG1, (n =63), EG2, (n =63) and one control group (n =59) in 3 Lithuanian hospitals.	A randomised controlled trial design with two experimental groups. Intervention: A 2-day teaching programme.	Pre intervention and post intervention knowledge and attitude test.	It was found that nurses' knowledge levels had improved, but the changes in attitudes were minor. Education can have a positive impact on nurses' knowledge levels.	The major limitation of the study was a change in the sample size between the baseline and follow-up data.	It is unlikely that If attitudes have not changed that nurses will apply the new knowledge gained into practice.
8	Yacoub et al. (2015)	What is the effectiveness of a diabetes education programme on nurses' knowledge of diabetes and its management.	Jordan- participants were recruited to the education and evaluation jointly.	129 participants represented a convenience sample from three hospitals.	Quasi-experimental, one-group, pre-test–post-test design. Intervention: 1-day education programme.	3 questionnaires- 1 demographics, 2 perceived knowledge and 3 actual knowledge assessment. Pre-test and post-test.	The education program had a positive effect on nurses' actual and perceived diabetes knowledge.	Use of a convenience sample.	Just examines knowledge not application. Participants were recruited for the education and evaluation possibility of bias due to convenience sample.
9	Wetta-Hall et al. (2007)	What impact does a CPD course have on participants' knowledge and self-rated ability, confidence, and competence to perform in a burn	Pre-hospital and hospital professionals in Kansas USA. Population size not given.	383	A pre/post survey design Intervention: a collection of 9 one day courses- only provided didactic learning.	Questionnaires were used to assess changes in participants' knowledge and self-rated ability, confidence, and competence to	Achieved desired goals for improved knowledge, which appear to have been translated to enhanced abilities, confidence and competence in burn assessment and treatment modalities.	Participant selection basis.	Duration of the course not clear. Based on self-reported abilities, confidence and

		disaster before and after training?				perform in a burn disaster before and after training.			competence. Post assessment undertaken immediately after the education no account for loss over time or application of theory to practice.
10	Tippett (2004)	What is the knowledge gain and retention of knowledge following an advanced trauma nursing course (ATNC)?	Purposeful sample of 16 qualified A&E nurses.	14 consented to undertake the study.	Pre-test–post-test design Intervention: Advanced trauma Nursing course- no details of the course provided.	Pre and post questionnaire at 4 time points. 1) Before the candidates received their ATNC and ATLS_ manuals. 2. At the commencement of the ATNC. 3. On completion of the second ATNC day. 4. Three months after the completion of the ATNC.	This study found that the acquisition of knowledge significantly improved as a result of attendance on the ATNC. Three months after the completion of the ATNC knowledge was not statistically significantly different to pre-course levels. Retention of knowledge appeared to be related to the length of A&E experience the number of trauma articles/papers read.	The acquisition of knowledge, whilst directed towards improving patient care does not necessarily equate with an improvement in patient outcomes.	Limited detail on the delivery method or content of the ANTC. Instruments for collection of knowledge do not appear to be validated.
11	Burhenn et al. (2016)	What are nurses' knowledge, attitudes, and perceptions of caring for older adults with cancer and to use that assessment data to	Cancer Centre in Southern California.	422 (baseline) and 375 (post-intervention).	Pre and post knowledge, attitude and perception questionnaire. Intervention: 4 hour didactic	Survey of oncology nursing staff conducted pre- and post-education regarding geriatric cancer care.	Comparisons from baseline to post-intervention demonstrated statistically significant increases in nurses' knowledge of geriatric care after the implementation of an educational programme.	Voluntary, convenience sample.	Increase in knowledge post education but not attitude. Therefore, it is unlikely that

		develop a training programme to improve skills in caring for older adults with cancer?			presentation.		Nurses' attitudes remained the same pre- versus post-education. A significant change reflecting a better perception was noted in the burden of behavioural problems; however, a worsening was noted in disagreements among staff; patients, and families.		this would result in an actual change to practice. Actual change in practice was not examined.
12	Schubert et al. (2012)	What is the effect of simulation on nursing knowledge and critical thinking in failure to rescue events?	Large Midwestern U.S. university medical centre.	58 nurses.	Intervention: failure to rescue simulation event (no details on duration of simulation).	Pre-test Knowledge assessment and learning transfer tool before immediately after and 2 weeks after.	Nurses' knowledge of failure to rescue events increased by 11% and critical thinking skills improved significantly, suggesting that simulation is a valuable tool to improve nursing performance, increase the efficiency of the health care system, and decrease patient complications and mortality.	The tool that was used to measure nurses' critical thinking was relatively new and untested. Low return rate (21%) for the 2-week post-test .	Failed to look at actual change in practice. Limited details on intervention therefore would be unable to replicate.
13	Wellings et al. 2017	What are the intentions to change practice and perceived barriers to Knowledge translation for participants who have undertaken a range of CPD seminars?	Australia, 1,292 participants who attended seminars working in settings ranging from rural and remote isolated practice to major tertiary city hospitals, residential and community	1,003-The data was obtained from a random convenience sample of 61 continuing education seminars.	Post seminar evaluation.	Paper based surveys- qualitative analysis of open-ended evaluation questions.	Themes identified for intention to change practice: patients, wound management, medications, health, and knowledge. The main theme identified for patient outcome was the positive term better. Barriers to implementation that emerged were: staff, time, work-related issues, hospital procedures and policy and the concept of	No questions in relation perceived facilitators of CPD transfer.	Wide ranging evaluation of topics with no consistent features such as length or level of seminars identified. Claims to measure at Kirkpatrick's level 3 and 4

			aged care, domiciliary, and primary health care.				change.		but these are self-reported intentions and not actual practice changes or outcome changes.
14	Lahti et al. (2014)	Aim: To describe the transfer of knowledge gained from an e-learning course to daily practice.	One hospital district in Southern Finland with three specialised psychiatric wards (acute, rehabilitation, geriatric wards).	Nursing staff (N = 53) were recruited and 35 participated voluntarily in the e-learning continuing education.	Qualitative study design.	The data comprised of nurses' reflective writing during the e-learning course and course evaluation forms completed after the course.	Nurses were willing and able to transfer what they learned to their daily practice including the course themes, communication and co-operation among staff members, understanding of preventive and alternative treatment methods and critical thinking regarding one's own work. After the e-learning course the nurses were able to identify development areas such as issues related to staff members' daily work, the patient's role on the ward, alternative methods to avoid coercion, issues pertaining to the care environment on the ward, psychiatric nurses' education, and making an action plan for aggressive situations. All nurses would recommend the course to other nurses.	Voluntary participation may have created a bias as those who are more willing to participate may have more positive attitudes towards the study intervention and research.	Claimed to address level 3 of Kirkpatrick's model, change in practice, but is self-reported intentions to change not actual change.

15	Moores and Allan (2008)	Aim: To identify the current practice for aspiration before intramuscular (IM) vaccine injection, provide education, and determine whether the education was effective in eliciting a change in knowledge and behaviour.	St. John's, Newfoundland and Labrador Community health nurses who administer immunisations. Population size not given – 150 people attended the conference where the sample was taken from.	Convenience sample of 140 taken at the provincial immunization conference.	Pre- test-post-test Intervention: a 30 minute presentation.	Complete a pre-education questionnaire on current knowledge, attitudes, and beliefs related to the administration of intramuscular immunisations as well as a post education questionnaire to identify changes in knowledge, attitudes, and beliefs.	Improved knowledge in relation to recommended speed of administration. The majority of participants identified best practice for vaccine administration technique and noted that knowledge translation had taken place.	19.3% reported that they were not currently in a position to administer vaccines each week. Reliability and validity of the modified questionnaire was not established.	Poor quality study. Short 30 minutes presentation- is change of practice expected after a simple 30 minute didactic presentation?
16	Steginga et al. (2005)	Aim: to assess the impact of the cancer nursing education course on nurses' (a) knowledge about cancer and its treatment, (b) attitudes toward and perceived skills in the psychosocial care of patients with cancer and their families, and (c) preparedness for cancer nursing.	Urban, nongovernment , cancer control agency in Australia.	30 nurses completed stage 1 but this dropped to 24 for stage 3.	Quasi-experimental, longitudinal, Intervention: Palliative Care Course and the Breast Cancer Nursing Education Course. The two courses include a total of 31 hours of educational content.	Pre-test/post-test design, with a follow-up assessment six weeks after the completion of the nursing education course and intervention group assessments: time 1: pre-test, preceding course attendance; time 2: post-test at the end of the course (day 5 of the course); 3: follow-up, six weeks after completion of the course.	Nurses in the intervention group rated the nursing education course as highly effective in improving their knowledge about cancer and cancer support services, their confidence in their ability to work effectively with patients with cancer, and their ability to network effectively with other nurses working in cancer care. The nurses described two barriers to implementing their new knowledge into their nursing care: not having sufficient time in the workplace and experiencing resistance from some physicians, particularly in relation to the management	Actual behavioural skills were not assessed. Thus, the researchers cannot assess whether the increases in self-efficacy for psychosocial skills reported by nurses in the intervention group were accompanied by actual increases in skill level.	Two very different courses but evaluated and reported on together. No details in relation to courses/interventions.

							of patients' pain relief.		
17	Oostrom and van Mierlo (2008)	Aim: to evaluate the effectiveness of an aggression management training programme.	Healthcare workers in home care situations in the Netherlands.	42 mixed sample. Participation in education and evaluation was voluntary.	Design: Internal referencing strategy, an unobtrusive and applicable evaluation method that rules out some major threats to internal validity without the need for a control group. Intervention: 12 hour training programme (3x4hrs)	Questionnaire to collect data before the training program (T1), immediately after the training program (T2), and 5 weeks after the training program (T3). At T1, 42 participants (100%) completed the questionnaire; at T2, 38 participants (90%), and, at T3, 27 participants (64%) completed the questionnaire.	Results showed a considerable and significant improvement on the experimental variables of insight into assertiveness and aggression and of ability to cope with adverse working situations, These improvements persisted after the training, indicating that the training resulted in enduring changes in knowledge and behaviour.	Self -reported measures— participants' beliefs in their abilities to cope with adverse working situations, may not fully have captured Kirkpatrick's behaviour level strategies.	No evaluation from managers or others in practice. As identified in limitations self- reports.
18	Bull et al. (2017)	Aim: to develop and refine a sustainable CPD training workshop for ward nurses on drug calculations.	300 nurses population of the hospital with 1000 beds in Mozambique. Workshop was delivered 3 times and 123 nurse participants attended.	36 nurses. Application of behavioural science principles in the development of an education programme ton drug calculations. partnership.	Intervention study. Intervention: 2 hour training package this involved a PowerPoint and a board game.	Facilitator reported correct and incorrect responses during board game. Participants' confidence and intentions following the training were also measured. Participants were asked two questions pre and post training and asked to respond yes or no.	Qualitative data suggested the training was acceptable, enjoyable and led to practice changes, through improved capability, opportunity and motivation. High confidence in drug calculations reported both before and after the training. Intentions to use a calculator increased. No difference in relation to confidence. Self -reported positive changes to behaviour reported during interview.	No measure of patient or health outcomes No measure of behaviours.	Just self - reported changes. Could have examined practice after the intervention. Knowledge assessment was through facilitators.

						Also short follow up interview with 12 participants.			
19	Tarnow et al (2013)	How will workshop participants and study unit change leaders describe their efforts to implement mindfulness techniques taught at a CE workshop?	157 people (90 nurses, 7 physicians, and 60 participants from other disciplines from nursing units across Kansas.	75 participants agreed to be contacted approximately 6 months after the workshop.	A mixed-methods approach was used. Intervention: 1 ½ day offering of CE on mindfulness Mixed methods of delivery –used storytelling and case studies to actively engage small groups in creative problem solving and specific communication tools useful in the practice setting. Participants developed action plans to implement at least one mindfulness practice in their work settings.	E-mail survey of participants and focused interviews involving 12 nursing units. Qualitative and quantitative data was used interviews with the 12 unit change leaders showed similar results.	Participants described efforts to implement mindfulness processes after a CE workshop on managing the unexpected. Focused interviews elicited examples and provided more information about the barriers and facilitators of change that can assist with future programme planning.	Self-reported assessment. 75 consented to follow up but only 19 completed the follow up questionnaire this was only a pilot study.	It did examine barriers and facilitators and actual change but again these were self-reported. No evaluation from managers or other key stakeholders.
20	Huba et al. (2000)	Aim: to determine the effects of HIV/AIDS education and training on patient care and provider practices: A	75 potential participants from each of the nine sites.	218- from 9 sites.	Intervention: training related to new developments and medical/psycholo	Telephone interviews on average 8 months after training - qualitative-data and quantitative	Acquired specific information about patient care. Changes related to protocols and practice Greater comfort and confidence, greater	No limitations identified by authors.	Training not standardised. No details surrounding the training intervention.

		cross-cutting evaluation.			gical issues around HIV/AIDs. Not standardised across the 9 sites.	questions scored.	compassion. Increased knowledge at patient and system level.		Self- reported changes. Positive-reports application of learning to practice over time- positive.
21	Cohen et al (2016)	Aim: to examine outcomes for the National Parkinson Foundation (NPF) Allied Team Training for Parkinson (ATTP), an interprofessional education (IPE) programme in Parkinson's disease (PD) and team-based care.	26 ATTP trainings were held across the U.S. (2003-2013) for Interdisciplinary healthcare practitioners. Trainees and controls were health care practitioners and students in the targeted professions voluntarily consenting to participate.	Trainee (n = 1468) and control (n = 100).	The study was a non-randomized, controlled before-and-after design using a modified Kirkpatrick Model. Intervention: An intensive, peer-reviewed curriculum featuring in-depth, multi-day training on best practices Knowledge measures. Details provided in another publication.	Mixed method - knowledge and attitude measured pre education and again at 6 months following education and practice change information collected at 6 months post education.	Compared to control participants trainees showed statistically significant post-test improvement in all major outcomes, including self-perceived and objective knowledge, understanding role of other disciplines ,attitudes toward health care teams and the attitudes toward value of teams. Despite some decline, significant improvements were largely sustained at 6 months post-training. Qualitative analyses confirmed post-training practice changes.	Self -selection basis The limited six-month follow-up response rate of just 26%.	Demonstrated practice improvement (higher level of evaluation) but this was self – reported.
22	Mann et al. (2009)	Specific research questions included: 1. What was the impact of the programme upon health professionals' knowledge, skills and attitudes?	Nova Scotia-Inter-professional.	411 participants nurses pharmacists and physicians Nova Scotia. Advertised and self- selected.	This was a mixed methods study. Intervention: 10 modules of 3 hours duration. Consisted of presentations and	Questionnaires to collect both quantitative and qualitative data immediately following an educational	High percentages of participants reported changes in both clinical practice and inter-professional interactions 3 months after the sessions. Frequently reported changes to inter-professional	Self -selection bias. Self –reported data.	Large sample size. Positive as it identified barriers and enablers. Did examine practice

		<p>2. What was the impact of the programme upon changes to participating professionals' practice, particularly their inter-professional interactions?</p> <p>3. What factors enabled or prevented these changes?</p>			<p>interactive activities focusing on collaborative, inter-professional practice.</p>	<p>intervention and 3 months afterward. Kirkpatrick's model was used and the PRECEDE model which includes assessment of the factors that influence change in response to an intervention.</p>	<p>interactions were improved communication, increased confidence and assertiveness in interactions with other health professionals and being more respectful of other professions. Participants identified time and work-load as major barriers to change as well as lack of micro- and macro-system level support. The most common reported enabler of change was having attended the educational session.</p>		<p>change even if it was self – reported.</p>
23	Mitchell (2017)	<p>Aim: to investigate ways in which primary care nurses changed their practice and management of venous leg ulcers, following the completion of the module.</p>	Community nurses.	<p>All 12 students consented to partaking in the evaluation. Reduced to 8 for the interview.</p>	<p>This is a before and after educational evaluation. Intervention: a university module which was theoretical rich and contained workshops, written assessment and OSCE examination.</p>	<p>Qualitative data was collected pre- and post-module. Interview and questions according to Kirkpatrick evaluation model.</p>	<p>All 8 identified that the module had changed or influenced their practice in some way.</p>	<p>Small scale evaluation and localised to one community health area.</p>	<p>Reported as evaluation audit – no robust research application.</p>

24	Pullen (2006)	Research objectives: 1.quantify the overall effectiveness of the web-based CPE instruction and 2. assess the influence of several factors (moderators) that are assumed to influence the effectiveness of the online learning event.	Healthcare professionals who had undertaken online CPE in one university in Australia.	300 healthcare professionals .	A timed convenience sample of responses was chosen from the institution Intervention: online CPE for Healthcare professionals offered by a large Australian CPE provider.	The study used both qualitative and quantitative techniques to describe and analyse learners' attitudes toward web-based instruction, from the perspective of effective instructional and pedagogical design. Used Kirkpatrick evaluation model.	Learning online was an effective means for increasing CPE knowledge and improving self-reported practice performance change. Courses containing a clinical tool resulted in an increased self-reported practice performance change over courses that did not.	Case study with small sample size.	Important finding that the clinical tool appeared to increase self –reported change of practice.
25	Tennant and Field (2004)	Aim: to evaluate the impact of an ITU course.	Nurses new to ITU.	5 nurses who had undertaken the ITU course and 5 who had not made the control group. Poor response rate post assessment down to 5 and 3.	Quasi-experimental design was used to compare the practice of nurses working in ITUs. Intervention: An education programme for new starters to ICU- no details provided.	Self –assessment pre and post intervention and manager assessment post education at the 4 months post the intervention.	Results suggest that the ITU course did make a difference to the development of ITU nurses, but the nurses who did not take the course also developed.	Self-reporting tools. Risk of the Hawthorne effect. Samples were small non-probability samples that limited external validity.	No details of the course so unable to provide comparison with the intervention.
26	Ryder et al. (2018)	Aim: to evaluate the current standards of and attitudes towards CPD delivered within the organisation.	Nursing staff and stakeholders who had undertaken or been involved in a structured specialist CPD course (n=49).	21 from across 5 specialist courses.	Action research.	Quantitative Audit and qualitative questionnaire. Overall, five CPD courses, each of 26 weeks' duration, were evaluated.	The curriculum content was identified as excessive and at a high level for introductory courses, with a large volume of classroom-based theoretical delivery. Participant learning was reported as excellent in the clinical areas; however, this	Only one organisation-lacks generalisability Limited details provided due to the nature of the questionnaire.	Did examine some of the barriers to transfer. Some self -reported changes. Involvement of stakeholder.

							was counterbalanced by heavy workloads and staffing shortages. Participant motivation was also found to influence learning. From an outcome perspective the development of new knowledge and skills was reported in participants who had undertaken the courses, and participants reported that the CPD courses assisted in recruitment and retention.		
27	Ilott et al. (2014)	Aim: to evaluate the learning effect and resource use cost of workplace-based, blended e-learning about dysphagia for stroke rehabilitation nurses.	Stroke rehabilitation ward nurses to become assistant dysphagia practitioners.	22 nurses and 10 HCA's.	A single-group, pre- and post-study with mixed methods. Intervention: e-learning for advancing dysphagia management with face to face learning in a small group.	Qualitative and quantitative pre and post intervention design. Pre-education observation also observation and questionnaire following the e-learning intervention.	All participants achieved a nationally recognised level of competence. The learning effect was evident on the post- and follow-up measures, with some items of dysphagia knowledge and attitude achieving significance. The most common self-reported changes in practice related to medicines management, thickening fluids and oral hygiene. Some changes to practice were observed –info displayed. HCA's reported more confidence with thickening fluids. No practice change was observed by the researchers.	Sample from a single ward in one hospital-limits generalisability. Effect on patients not considered.	A 100% response rate on all 4 questionnaire shows commitment from the ward to change practice.

28	Dennison (2007)	Aim: to develop, implement, and evaluate a technology-enhanced education programme about medication safety that was intended to reduce the risk of patient harm caused by medication errors.	The setting for the project was a 12-bed Coronary Care Unit with 31 registered nurses in the United States.	20 post intervention questionnaire. Observation: 37 before, 39 after.	A quasi-experimental design with pre-test–post-test. Intervention: Participants were required to complete two 30-minute computer modules focusing on medication safety.	Multiple tools were used to answer the evaluation questions. Questionnaire and observation.	A statistically significant change in the nurses' knowledge regarding medication safety was found. The nurses' behaviours were evaluated and no statistical difference was found between the use of the advocated behaviours before and after the education programme. The only behaviour showing a statistically significant difference before and after the education programme was labelling of the bag. No statistical difference was seen between the number of infusion pump alerts before and after the education programme.	The inability to isolate the data for change in behaviour, number of infusion pump alerts, and reported medication errors limits the internal validity of this evaluation.	When observation and practice data was collected there was no change or improvement in practice noted. One of the few studies that attempted evaluation at the actual level of practice.
29	Hickin et al. (2017)	Aim: to determine the impact of education on nurses' knowledge of delirium, knowledge and perception of a validated screening tool, and delirium screening in ICU.	A 16 bed ICU in a Canadian urban tertiary care centre.	During the study period, 197 surveys were returned; 84 at baseline, 53 at 3-months post education, and 60 at the final assessment period 18-months post intervention.	A quasi-experimental single group pre-test-post-test design. Intervention: A multifaceted educational knowledge translation (KT). Involved face to face, follow up information and individualised bedside follow up.	There were 3 separate survey collection periods: at baseline prior to the intervention, and then again 3-months and 18-months post educational intervention. Delirium screening was then assessed over 24-months.	Significant improvements in mean knowledge scores at 3-months post intervention were not maintained at 18-months. Screening tool perception scores remained unchanged. Improvements in the perception of utility were significant at both time periods. Delirium screening frequency improved after education demonstrating a positive correlation over time.	No control group. No control over other factors in ICU which may have influenced the findings.	Details of multi-dimensional education programme provided which did have an effect on increasing delirium screening.

30	Lyons and Kasher (2012)	1.Does a continuing education course improve the knowledge and skills of experienced nurses regarding the insertion of peripheral IV catheters? 2. Do nurses retain the knowledge and skills learned in a formal IV course over time?	Volunteer nurses from a Magnet® facility in suburban Philadelphia.	33 nurses completed the questionnaires.	A one-way repeated Measure design over time. Mixed methods (pre-test-post-test). Intervention: 1 day education programme.	Measures included pre-course test results, immediate post-course test results, and data collected 8 to 12 weeks after course. Key skills were observed by the educators with the use of a checklist.	The findings showed that the continuing education IV course improved the knowledge and skills of experienced nurses. Improvement in knowledge was shown immediately after the course and 8 to 12 weeks later. Skills improvement with regard to infection prevention and policy adherence was evident.	Small sample size in one organisation.	Little description of the intervention. Observation was conducted to determine in skills were retained; this is a positive aspect of this study.
31	Liaw et al. (2016)	Aim: to evaluate the impact of Web-based simulation on nurses' recognition of and response to deteriorating patients in clinical settings.	Nurses from 2 general wards in an acute tertiary hospital in Singapore.	99 nurses from the 2 wards.	A before-and-after study. Intervention: Web-based simulation was developed to enhance nurses' role in recognizing and responding to deteriorating patients.	Questionnaires were completed at various time points to measure nurses' motivational reaction, knowledge, and perceived transfer of learning. Clinical records on cases triggered by ward nurses from the 2 study wards were evaluated for frequency and types of triggers over a period of 6 months pre- and 6 months post-intervention.	The number of deteriorating patients triggered by ward nurses in a medical general ward increased significantly from pre- to post-intervention. The nurses reported positively on the transfer of learning from the Web-based simulation to clinical practice. A significant increase on knowledge post-test scores from pre-test scores was also reported but this was on the medical ward only. . The nurses also perceived positively their motivation to engage in the Web-based simulation.	No control group. Short time to measure trigger rates.	Failed to examine the reasons why the intervention was successful in the medical ward and not the surgical ward.

32	Stolee et al. 2009	What is the long-term impact and sustainability of the P.I.E.C.E.S. learning initiative and to explore whether supportive strategies affected the implementation of this continuing education programme in LTC homes?	LTC homes in Ontario, total of 439 homes.	20 interviews from 11 nursing homes.	Intervention: 18 hr programme, practice opportunities , 12 hr consolidation and training support.	Survey and follow on interviews.	Interview participants across homes identified increased staff knowledge, improved assessment and diagnoses, and enhanced resident care and quality of life as positive impacts derived from P.I.E.C.E.S. In addition, interview participants from homes that had success with P.I.E.C.E.S. identified linkages with other resources and family satisfaction as positive impacts.	Even though 439 nursing homes took part, only 20 interviews from 11 nursing homes undertook the interview this is a very small representation from the total population.	This is the introduction of a new practice with education support not education on its own.
33	Steven et al. (2018)	Aim: to explore the impact and perceived value of multi-disciplinary CPD workshops for Health Visitors who support families with children with complex health.	1 English Health Service Trust.	17 of 21 participants who attended the workshop.	Realist evaluation Intervention: Multidisciplinary workshop for health visitors who support families of children with complex needs.	Data collection included a questionnaire and semi-structured interviews.	Post-workshop participants reported examples of practice enhancements attributed to workshop attendance including: confidence building; improved team working; facilitation of early referral and accessing additional support for families.	Small sample size. Did not address the question it set out to answer- do workshops change practice.	The use of realist evaluation highlighted the context and mechanisms, associated the education programme which can prompt attendance, engagement and subsequent practice application.

34	Bernaix et al. 2008	Aim: to test an educational intervention designed to improve lactation knowledge, attitudes, and beliefs of NICU nurses and to improve their intentions to provide mothers with lactation support.	NICU of a Midwestern, free-standing, tertiary-care children's hospital with 120 nurses.	Convenience sample of 64 NICU nurses and 2 separate convenience samples of mothers of infants hospitalized in the NICU (n 5=19 and 13, respectively).	Quasi-experimental, time-series pre-test/post-test Intervention: A 4-hour educational programme.	Nurses were measured on study outcomes at multiple time points, beginning with 2 weeks before and ending at 3 months after. Mothers were sampled before and 3 months after the intervention.	This educational intervention was effective for improving NICU nurses' lactation knowledge and attitudes, and that these improvements were maintained over time. Further, the supportive atmosphere for lactation in this NICU significantly improved following the implementation of the educational intervention for nurses.	Small convenience sample of nurses and mothers limit the generalisability. Self –selection of participants.	Showed how the knowledge impacted on the mothers and improved the mothers experience. Self- selection of participants implies that participants were motivated towards making a change
35	Ellis and Nolan (2005)	What are the perceptions, expectations and motivations of students and managers before and following a programme of CPE?	Students who had taken a short focused CPE course aimed at meeting the knowledge and skills required to meet the needs of older people and their managers in one organisation in the UK.	15 students and 21 managers over an 18-month period, resulting in 121 in-depth interviews providing detailed insights into their perceptions and experiences at several points in time.	Case study-longitudinal study of continuing professional education. Intervention: a short focussed programme.	This paper focusses on the interview data collected from students and their managers at four points in time: prior to the course commencing; immediately post course; and 6 and 12 months post course.	A complex set of factors interact to influence the outcomes of CPE, including the nature of the selection process, students' expectations of the programme, the nature of the educational experience, and the receptivity of the practice environment to change. Whilst a multitude of factors influence CPE, the primary determinant in whether continuing education is successful is the practice milieu. Managers were identified as being key for the transfer of new skills into practice.	Case study design can lack generalisability.	No course details provided such as duration, delivery methods etc. The use of illuminative case study does highlight the contextual factors which is significant for the transfer of CPE into practice.

36	Hughes (2005)	Aim: to determine nurses' perceptions of the value of CPD and what factors contribute to and influence these perceptions.	Nurses from NHS hospitals and private nursing homes.	Questionnaires - 200 – response 86 staff working in two NHS trusts and 13 nursing homes 8 interviews.	The method of sequential triangulation was used in this study.	Questionnaires were used and then interviews held to follow up interesting lines of enquiry raised in the responses to the questions.	A positive perception of CPD was determined. However, it was shown that there were some barriers to professional development. Managers' leadership styles were found to influence nurses' perceptions of the value of CPD, as well as their ability to reflect, which affected the application of learning to practice.	Small interview sample Interviewees self-selected, thus selection biases possible. Convenience sample taken from one NHS trust.	Refers to nurses perceptions of all CPD activities not just CPE. Strong on identifying enabling and inhibiting factors for transfer of CPD to practice.
37	Tame (2009)	Aim: to obtain an overview of perioperative nurses' perceptions and experiences of continuing professional education (CPE).	Peri-operative nurses from one NHS trust who had completed CPE in the 3 months previous.	23 perioperative nurses.	A descriptive qualitative approach.	Interviews.	CPE is associated with increased social status and doctor-nurse Collaboration 1)Background issues - including cultural discourses and colleagues' attitudes 2) Going In - describing motivations and deterrents to formal study 3) Process - including participants' experiences as students 4) Going out - describing personal and professional outcomes from CPE.	None identified by the authors.	Small sample size, In just one specialist area. No discussion in relation to specific culture in the specialist area- could be a confounding factor.
38	Gould et al. (2007)	Aim: to explore nurses' experiences of continuing professional development.	3 acute healthcare trusts in the UK – random sample of 10%-629 questionnaires	This paper reports on one aspect of a larger study and includes 125 respondents. The overall	Survey questionnaire- this part of the study is descriptive.	Questionnaire- this paper reports the findings of open-ended questions which address nurses experience of CPD. All	The main findings were : Who and what is CPD for? _ Accessing CPD. _ One size does not fit all. _ Managing work, life and doing CPD. _ Making the best of CPD.	None identified by the authors.	Generic comments on CPD experience with no relationship to the type,

			distributed.	sample was 451.		qualitative data.			content etc. of CPD. A theme identified was one size does not fit all but this was not further explored or related to the CPD undertaken.
39	Clark et al. 2015	Aim: to identify the processes that key stakeholders perceive to be most important in facilitating a positive impact of CPE on practice.	2 healthcare trusts and two higher education institutions in one geographical region in England.	66 interviews Representatives from four stakeholder groups— students, managers, educators and members of each healthcare organisation's governing board.	A qualitative design with 66interviews over 2 rounds.	Semi-structured interview schedules were developed. Interviews were predominantly by telephone to accommodate geographical spread and a small number were face to face.	Four overarching themes were identified that illuminate stakeholders' perspectives of the important factors affecting the process of CPE: organisational structure, partnership working, a supportive learning environment and changing practice.	None identified.	Captures the essence of what my study is aiming to establish- not just evaluating outcomes but also looking at the underlying processes. Incorporates evaluation from all stakeholders- this is essential when evaluating CPE.
40	Nayeri and Khosravi (2013)	Aim: to explore nurses' experiences with applying new knowledge obtained from these programmes in	CPE participants and managers from hospitals associated with one university in Iran.	34 participants.	This study used a qualitative approach with conventional content analysis.	Interviews with CPE participant's and their managers.	Five main categories emerged: (1) personal interest and self-confidence; (2) organisational structure and atmosphere; (3) professional nature; (4)	Content analysis limits the generalisability of this study.	Use of managers and participants to review factors affecting transfer. Does

		clinical settings.					opportunity to put education into practice; and (5) design of educational programmes.		provide an important insight into the organisational environment and conditions in 1 hospital.
41	Lee (2011)	Aim: to evaluate how the process of positive change was translated from the learning environment to practice delivery and patient care.	Participants who had completed CPD in the 12-18 months previous. Managers from local hospital trusts.	26 CPD participants & 11 line managers from nursing and other healthcare professions.	Pluralistic evaluation approach.	Evaluation data was gathered using semi structured discussions with CPD participants, a convenience sample of line managers and University module leaders.	The individual personal drive and enthusiasm of practitioners was perceived as the strongest factor helping practice change, while policy drivers and national health targets were secondary. Findings suggest that professional peer attitudes and support, when harnessed effectively in the practice setting, strongly enhance positive change.	The range of healthcare trusts and CPD participants rendered generalisation impossible. No control over variables.	Small sample size which covers a range of healthcare professionals. No linkage between the participant's perceptions and reality or their perceptions in relation to the type of CPE which they had undertaken.

Appendix 2: Ethical Approval -Cardiff School of Nursing and Midwifery Studies, School Research Ethics Committee

Cardiff School of Nursing and Midwifery Studies
Head of School and Dean Professor Sheila Hunt

Ysgol Astudiaethau Nyrsio a Bydwreigiaeth Caerdydd
Pennaeth yr Ysgol a Deon Yr Athrawes Sheila Hunt



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Caerdydd

29 October 2012

Freda Browne
SONMS

Dear Freda

Application for School Research Ethics Committee approval
Reference: 2012/09/01

Thank you for sending the covering letter (dated 23.11.2012) to REC feedback outlining the changes made to your proposal and associated documents.

I can confirm that your project entitled 'Continuous Professional Education, Knowledge Development and Practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland' has been approved by the School of Nursing and Midwifery Studies Research Ethics Committee of Cardiff University and you can now commence the project.

This approval is based on:

1. The research protocol (version 2, dated 23.11.12)
2. The participant information sheet Stage 1 (version 2, dated 23.11.12)
3. The consent form, Stage 1 (version 2, dated 23.11.12)
4. The participant information sheet Stage 2 Observation and Interview (version 2, dated 23.11.12)
5. The consent form, Observation and Interview Stage 2 (version 2, dated 23.11.12)
6. The participant information sheet, Stage 2 Interview (version 2, dated 23.11.12)
7. The consent form, Stage 2, Interview (version 2, dated 23.11.12)

If you make any substantial changes with ethical implications to the project as it progresses you need to inform the SREC about the nature of these changes. Such changes could be: 1) changes in the type of participants recruited (e.g. inclusion of a group potentially vulnerable participants), 2) changes to questionnaires, interview guides etc. (e.g. including new questions on sensitive issues),

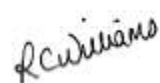


3) changes to the way data are handled (e.g. sharing of non-anonymised data with other researchers).

All ongoing projects will be monitored every 12 months and it is a condition of continued approval that you complete the monitoring form. Please inform the SONMS REC when the project has ended.

Please use the SONMS REC project reference number above in any future correspondence.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ben Hannigan', written in a cursive style.

Pp
Dr Ben Hannigan
Chair of the School of Nursing and Midwifery Studies Research Ethics Committee

Appendix 3: Ethical Approval - Organisation's Research and Ethics Committee

Re: Continuous Professional Education, Knowledge, Development and Practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland. Covering Letter. Protocol vs 4 8/3/13. Application Form PIL/Consents vs 4 8/3/13. CEO approval letter. Poster

Dear Ms Browne,

Thank you for the revised documents and clarifications that were requested at the Ethics and Medical Research Committee meeting held on Wednesday 6th February, 2013 at which the above study was reviewed.

Following review of the revised documents and clarifications, this study is now granted full ethics committee approval.

Yours sincerely,

Appendix 4: Approval- Organisation's Nursing Research and Innovation Committee

Ms. Freda Browne,
[REDACTED]

7th May 2013.

Re: Research Request – Continuous Professional Education, Knowledge Development and practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland.

Dear Ms. Browne,

Your research proposal was discussed at the [REDACTED] Nursing Research and Innovation Committee meeting which took place on 9th April 2013.

The Committee has agreed to grant permission to carry out your research following the approval you received from [REDACTED] and the [REDACTED] Ethics and Medical Research Committee.

I wish you every success with your study and I look forward to receiving a much welcomed copy of your report when available. I will also be inviting you to give a presentation on your subject at the relevant forums in the Hospital.

Yours sincerely,

Appendix 5: Approval- Organisation's Chief Executive

26th February 2013.

Ms. Freda Browne,
RNT/Clinical Educator,

[REDACTED]

Re : Approval to conduct a research study in [REDACTED]

Dear Ms. Browne,

I am in receipt of your e-mail dated 20th February 2012 and have noted your request for approval to conduct a research study in [REDACTED]. I further note you need an approval letter from me as [REDACTED] CEO in order to fulfil one of the criteria from the Ethics & Medical Research Committee.

I am writing to indicate that as Group CEO I have no issues with regard to you carrying out this research in the hospital on the understanding that:

- (i) The Director of Nursing or appropriate person from the Nursing Department oversees same from the perspective of establishing some ground rules around the recruitment of staff nurses for observation of medical administration/data collection as described in your research outline.
- (ii) Full approval from the hospital's Ethics & Medical Research Committee is granted following clarification from you around some issues pertaining to your research study.

With kind regards,

Yours sincerely,

Appendix 6: Approval -Director of Nursing for the use of Nursing Quality Care Metrics

Subject: FW: Research Study progress and application for permission to use Nursing Quality Care Metrics

From: [REDACTED] (Director Of Nursing)
Sent: 29 May 2017 10:50
To: Browne, Freda [REDACTED]
Subject: RE: Research Study progress and application for permission to use Nursing Quality Care Metrics

Freda

With regards to your doctorate you have the necessary permissions from the relevant committees in [REDACTED] and Cardiff University. It would be necessary for you to access the Nursing Quality Care Metrics to complete your Doctorate subject to the same confidentiality and ethical considerations. I Wish you well with your studies.
Kind Regards
[REDACTED]

From: Browne, Freda [REDACTED]
Sent: 29 May 2017 8:18 AM
To: [REDACTED] (Director Of Nursing)
Subject: Research Study progress and application for permission to use Nursing Quality Care Metrics

Dear [REDACTED]

Please find attached a letter detailing the progress of my research study and requesting permission to utilising Nursing Quality Care Metrics on Medication Administration.

Regards,
Freda Browne

Appendix 7: Stage 1- Participant Information Leaflet (PIL) and Consent

Stage 1

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Continuous Professional Education, Knowledge Development and Practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland.

NAME OF PRINCIPAL INVESTIGATOR: Freda Browne

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to explore how knowledge and skills obtained through a Continuous Professional Education programme on Safe Medication Administration are transferred to the clinical care environment. The study will also look at what factors effect this transfer and what outcomes can be related to the programme.

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in the study as you have been identified as key participant in the development of local or national policy in relation to continuous professional education for nursing and/or medication safety.

WHAT WILL HAPPEN IF I VOLUNTEER?

Whilst your contribution to this study is valuable, participation is voluntary. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. You may stop the interview at any time. If you wish me to destroy any interview material collected, please inform me of this.

If you agree to participate you will be contacted by the researcher to arrange a mutually convenient date and time for interview. The interview will take

approximately 30 minutes and will be recorded and transcribed for the purposes of analysis. The interview will take place in a location convenient to you.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information gathered may aid in the development and delivery of future Continuous Professional Education Programmes.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks to participation in this study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Whilst your contribution to this study is valuable, participation is voluntary.

CONFIDENTIALITY

The identity of your organisation or your clinical area will not be known and your identity will be protected. All research data collected will be strictly confidential (no name identification required) and used for the purpose of the completion of the doctorate. No information gathered will be disclosed to any third party.

In accordance with the Data Protection Acts 1988 and 2003 all information about you will be handled in confidence. Audio files will be retained in a locked cupboard and retained for five years. Anonymous transcribed data will be securely stored in a file using a coded identification number and will be destroyed within 5 years of collection.

WHO IS ORGANISING AND FUNDING THIS RESEARCH

This study is being undertaken by a nursing doctoral student at the School of Nursing and Midwifery, University of Cardiff.

There will be no payment for participation in this study.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?
This study has been approved and reviewed by the Research and Ethics Committee of Cardiff University, School of Nursing and Midwifery Studies and by the St. Vincent's Healthcare Group, Ethics and Medical Research Committee.

CONTACT DETAILS

If you require any further information please contact Freda Browne (BrowneF@Cardiff.ac.uk or 089 4969103. If you have a concern about any aspect of this study, you should contact Dr Jane Harden (Research Supervisor) at Cardiff University hardenj@cardiff.ac.uk.

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- | | | |
|---|-----|----|
| • I have read and understood the Participant Information | YES | NO |
| • I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily | YES | NO |
| • I have received enough information about this study | YES | NO |
| • I understand that my participation is voluntary and that I am free to withdraw from the research at any time, without giving a reason and without prejudice | YES | NO |
| • I agree to take part in the study | YES | NO |
| • I agree to take part in an interview and to have the interview audio recorded | YES | NO |

Participant's Signature: _____
Date: _____

Participant's Name in print: _____

Investigator's Signature: _____
Date: _____

Investigator's Name in print: _____

Appendix 8: Stage 1-Sample of Semi -Structured Interview Schedule

Interview Schedule

What works for whom in what circumstances and why?

How are knowledge and skills, obtained through a Continuous Professional Education programme for safe medication administration, transferred to the clinical care environment, and what are the factors that enable or constrain this transfer?

People for Interview

- Medication Safety Officer

Semi-Structured Schedule

Topic	Content
Introduction and explanation of study	<ul style="list-style-type: none">• Can you tell me a little about your role?
Safety in medication administration	<ul style="list-style-type: none">• Can you tell me about the medication safety programme in this organisation?• What is the reporting structure of the medication safety officer?• Can you tell me how the HSE national clinical programme for medicines management and Pharmacotherpaetic intervention has influenced the medication administration safety culture• Tell me about the relationship between medication safety officer/culture and nursing?• Whose role is medication administration safety?
Programme Design (for interviews with curriculum developer's only)	<ul style="list-style-type: none">• What factors need to be considered when designing education to support medication safety
Trainee characteristics (all-specifics will change depending on position of interviewee)	<ul style="list-style-type: none">• What characteristics do you believe the learner needs to have in order to transfer new knowledge into practice?• What about trainee's perception of relevance of the CPE programme?
Transfer into practice	<ul style="list-style-type: none">• How does the organisation support change of practice to support medication safety?• From your experience working in this organization what factors have influenced the transfer of new knowledge into clinical practice
Establishing the	<ul style="list-style-type: none">• Tell me about your organisation, what's it like to work in?

<p>culture of the organisation <i>Values and beliefs of the organisation- define culture in terms of these prevailing values</i></p>	<ul style="list-style-type: none"> • Would you describe this organisation as a learning organisation? • Tell me about team working in this organization? • Can you tell me about how power and authority in this organisation? • Are there any incentives for further education and training/CPD in this organisation?
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Appendix 9: Stage 2- Sample Semi Structured Interview Schedule - Expert

Interview Quality Management -Local Organisation

cCMO 1: Registered nurses, who undertake a safe medication administration education programme in an acute hospital with a positive patient safety culture, may adopt critical thinking skills in medication administration, which may led to reduced patient harm.

Conjectured CMO 1	Looking at my data, I can see that in organisations where a positive patient safety culture exists and where a SMAP programme existed that staff were enabled to think critically and this helped to reduce patient harm caused by medication errors.
	<ul style="list-style-type: none"> • Is this something you have experienced? Can you tell me about it?
	<ul style="list-style-type: none"> • Have you seen others experience this?
	<ul style="list-style-type: none"> • Have you experienced a change of thinking of people who have undertaken education programmes? • Can you tell me about this? • Have you seen this transfer in to practice? • What was necessary for it to transfer?
	<ul style="list-style-type: none"> • Does the organisation need to be .. for the education programme to work? • Have you experiences of this?
	<ul style="list-style-type: none"> • Have you experiences to say that critical thinking in medication administration can lead to an improvement in patient safety

cCMO 2: Registered nurses, who undertake a safe medication administration education programme in an acute hospital which adopts national policy on medication safety, may adopt a quality improvement approach to medication administration, which would may led to reduced patient harm .

Conjectured CMO 2	Looking at my data so far I can see that in organisations which adopt national policies and programmes staff who have undertaken the SMAP programme appear to adopt a quality improvement approach to medication safety in administration
	<ul style="list-style-type: none"> • Is this something you have experience? Can you tell me about it?
	<ul style="list-style-type: none"> • Have you seen others experience this?
	<ul style="list-style-type: none"> • Have you experienced a quality improvement approach in people who have undertaken education programmes? • Can you tell me about this?
	<ul style="list-style-type: none"> • Does the organisation need to adopt the national polices on medication safety in order to enable this process? • Have you experiences of this?
	<ul style="list-style-type: none"> • Can a quality improvement approach in an organisation which adopts national policies on safe medication administration reduce patient harm from medication errors? • Have you experiences of this?

cCMO 3: Registered nurses, who undertake a safe medication administration education programme in an acute hospital where medication safety involves multidisciplinary collaboration, may develop individual receptivity to change, which may lead to reduced patient harm.

Conjectured CMO 3	Looking at my data I can see that receptivity to change in an organisation with a multidisciplinary approach to medication safety may have a positive effect on improving patient safety.
	<ul style="list-style-type: none"> • Is this something you have experience? Can you tell me about it?
	<ul style="list-style-type: none"> • Have you seen others experience this?
	<ul style="list-style-type: none"> • Have you experience of people who have undertaken an education programme become more perceptive to change? • Can you tell me about this? • Have you seen this transfer into practice? • What was necessary for it to transfer?
	<ul style="list-style-type: none"> • Does the organisation need to have any particular characteristics for this receptivity to change to work? • Have you experiences of this?
	<ul style="list-style-type: none"> • Have you experienced to say that critical thinking in medication administration can led to an improvement in patient safety

Appendix 10: Stage 2- Code Book

Code book for Stage 2
Multi-disciplinary collaboration
Incident/near miss reporting
Leadership
Safety focused organisation
Patient safety culture
Professional standards
National initiatives and structure
Change management/ quality improvement
Receptivity to change
Critical thinking
Measuring impact/nursing metrics

Appendix 11: Stage 3- Participant Information Leaflet and Consent- Observation and Interview

Stage 3

OBSERVATION AND INTERVIEW

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Continuous Professional Education, Knowledge Development and Practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland.

NAME OF PRINCIPAL INVESTIGATOR: Freda Browne

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to explore how knowledge and skills obtained through a Continuous Professional Education programme on Safe Medication Administration are transferred to the clinical care environment. The study will also look at what factors effect this transfer and what outcomes can be related to the programme.

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in the study as you have recently completed the e-learning Safe Medication Management Programme.

WHAT WILL HAPPEN IF I VOLUNTEER?

Whilst your contribution to this study is valuable, participation is voluntary. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you agree to participate you will be contacted by the researcher to arrange a time for

If you decided to participate, you would be observed by the researcher in the ward for up to 4 hours over **three** shifts. The observations will be arranged on dates convenient to you. The purpose of the observations is to observe your practice to understand what factors enable or constrain the transfer of what you have learnt on the Safe Medication Administration Programme into practice. Observations do not judge your ability to deliver nursing care. Although, if unsafe/unprofessional practice is observed, the usual professional procedures will be followed.

The interview will take place when the observations have been completed at a time, date and location convenient to you. It will take approximately 30 minutes and will be recorded and transcribed for the purposes of analysis.

You may stop the interview or observation at any time without giving a reason. If you wish me to destroy any interview material collected, please inform me of this.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information gathered may aid in the development and delivery of future Continuous Professional Education Programmes.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks to participation in this study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Whilst your contribution to this study is valuable, participation is voluntary.

CONFIDENTIALITY

The identity of your organisation or your clinical area will not be known and your identity will be protected. All research data collected will be strictly

confidential (no name identification required) and used for the purpose of the completion of the doctorate. No information gathered will be disclosed to any third party.

In accordance with the Data Protection Acts 1988 and 2003 all information about you will be handled in confidence. Audio files will be retained in a locked cupboard and retained for five years. Anonymous transcribed data will be securely stored in a file using a coded identification number and will be destroyed within 5 years of collection.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is being undertaken by a nursing doctoral student at the School of Nursing and Midwifery, University of Cardiff.

There will be no payment for participation in this study.

HAS THIS STUDY BEEN REVIEWED BY AN ETHICS COMMITTEE?

This study has been approved and reviewed by the Research and Ethics Committee of Cardiff University, School of Nursing and Midwifery Studies and by the St. Vincent's Healthcare Group, Ethics and Medical Research Committee.

CONTACT DETAILS

If you require any further information please contact Freda Browne (BrowneF@Cardiff.ac.uk or 089 4969103). If you have a concern about any aspect of this study, you should contact Dr Jane Harden (Research Supervisor) at Cardiff University hardenj@cardiff.ac.uk.

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO ☐
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that my participation is voluntary and that I am free to withdraw from the research at any time, without giving a reason and without prejudice YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐
- I agree to the researcher observing my clinical practice YES ☐ NO ☐
- I agree to take part in an interview and to that interview being audio recorded YES ☐ NO ☐

Participant's Signature: _____
Date: _____

Participant's Name in print: _____

Investigator's Signature: _____
Date: _____

Investigator's Name in print: _____

Appendix 12: Stage 3- Participant Information Leaflet and Consent-Interview CNM's

Stage 3

Managers Interview

PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Continuous Professional Education, Knowledge Development and Practice Improvement: a realistic evaluation of a safe medication administration programme in the Republic of Ireland.

NAME OF PRINCIPAL INVESTIGATOR: Freda Browne

You are being invited to participate in a research study. Thank you for taking time to read this.

WHAT IS THE PURPOSE OF THIS STUDY?

The aim of the study is to explore how knowledge and skills obtained through a Continuous Professional Education programme on Safe Medication Administration are transferred to the clinical care environment. The study will also look at what factors effect this transfer and what outcomes can be related to the programme.

WHY HAVE I BEEN CHOSEN?

You have been invited to participate in the study as member of staff on your ward has attended the Safe Medication Management programme.

WHAT WILL HAPPEN IF I VOLUNTEER?

Whilst your contribution to this study is valuable, participation is voluntary. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. You may stop the interview at any time. If you wish me to destroy any interview material collected, please inform me of this.

If you agree to participate you will be contacted by the researcher to arrange a mutually convenient date and time for interview. The interview will take approximately 30 minutes and will be recorded and transcribed for the purposes of analysis. The interview will take place in a location convenient to you.

ARE THERE ANY BENEFITS FROM MY PARTICIPATION?

You will not benefit directly from taking part in this study but the information gathered may aid in the development and delivery of future Continuous Professional Education Programmes.

ARE THERE ANY RISKS INVOLVED IN PARTICIPATING?

There are no known risks to participation in this study.

WHAT HAPPENS IF I DO NOT AGREE TO PARTICIPATE?

Whilst your contribution to this study is valuable, participation is voluntary.

CONFIDENTIALITY

The identity of your organisation or your clinical area will not be known and your identity will be protected. All research data collected will be strictly confidential (no name identification required) and used for the purpose of the completion of the doctorate. No information gathered will be disclosed to any third party.

In accordance with the Data Protection Acts 1988 and 2003 all information about you will be handled in confidence. Audio files will be retained in a locked cupboard and retained for five years. Anonymous transcribed data will be securely stored in a file using a coded identification number and will be destroyed within 5 years of collection.

WHO IS ORGANISING AND FUNDING THIS RESEARCH

This study is being undertaken by a nursing doctoral student at the School of Nursing and Midwifery, University of Cardiff.

There will be no payment for participation in this study.

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have read and understood the Participant Information YES ☐ NO ☐
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that my participation is voluntary and that I am free to withdraw from the research at any time, without giving a reason and without prejudice YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐
- I agree to the researcher observing my clinical practice YES ☐ NO ☐
- I agree to take part in an interview and to that interview being audio recorded YES ☐ NO ☐

Participant's Signature: _____

Date: _____

Participant's Name in print: _____

Investigator's Signature: _____

Date: _____

Investigator's Name in print: _____

Appendix 13: Situations where I will intervene during observation

The researcher will intervene in patient care only when:

a	A patient is experiencing a life threatening event such as a cardiac or respiratory arrest.
b	Patients' lives are at risk from other patients or fire.
c	No nurse or career is present and a patient is at risk of injury for example a fall.
d	If a potential serious incident were to occur in relation to medication administration.
e	The investigator will deal with any such instances on a case by case basis in accordance with The Code of Professional Conduct for Nurses and Midwives (NMBI 2014) and in accordance with local policy.

Appendix 14: Semi Structured Observation Tool

Section A

	Observation	Spradley framework	Comment
1	Drug storage area	<i>Objects</i>	
2	Single room shared room	<i>Object</i>	
3	Position of drug room	<i>Object</i>	
4	Drug information available- information location	<i>Objects</i>	
5	Staff levels/ patient numbers	<i>Actors</i> <i>Activities</i>	
6	Skill mix	<i>Actors</i>	
7	Ward pharmacist observed	<i>Actors</i>	
8	Manager interactions	<i>Acts</i> <i>Actors</i>	

Spradley framework	Comments
Activities	
Events	
Time	
Goals	
Feelings	

Section B.

Questions	Criteria	Yes	No	N/A	Comments				
1	Did staff use the reduction of interruptions equipment <ul style="list-style-type: none"> Red alert apron Do Not Disturb Signage 								
2	Did staff use hand hygiene before the administration								
3	Did staff prepare drugs for only 1 patient								
4	Did staff open the medication chart and compare it with the medication prior to administration? Where was this done?								
5	Uses an information source Detail source used								
6	The nurse correctly transported the medication								
7	Patients identity be verified by name and medical record number, <ul style="list-style-type: none"> medication record and the patient's identity band verbally with the patient 								
8	Were the five rights of medication administration utilised? If no circle the unmet right								
9	Was an independent second check used for enteral medications and MDA medications?								
10	Special precautions applied for any high alert medications								
11	Did staff document the medication given on the drug administration chart								
12	Did nurse explain to the patient the medication he or she has been given and their use								
13	Did staff provide teaching or answer questions of the patient or family member								
14	Was there distraction or interruption during preparation or administration/ Was this avoidable?								
15	Follow up on any omission or errors noted								
16	Reports any medication errors or near miss								
Date of review		Staff ID							
Clinical area									
Observation number									
Comments									

Appendix 15: Mapping Conjectured CMO Configurations to Data Collection

CMO 1

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 1 – Context- Positive Patient Safety Culture			
Observation Section	Tool	Spradley (1980) Dimension	Observation
Part A-		Acts	Further information sources available example computer with Medecines.ie or hospital formulary, BNF etc.)
Part A-		Space and Objects	Medication storage
Part A		Act and Actors	Leadership style local level –visibility of nurse manager
Part A-		Actors and activities	People entering and leaving the observation field and their activities
Part A-		Events	Recording any significant observed events
Part B-		Acts	Checking name band
Part B-		Acts	Application of policies
Part B-		Acts	Checking the 5 rights

CMO 1 – Mechanism- Reasoning skills			
Observation Section	Tool	Spradley (1980) Dimension	Observation
Part A- Observation		Acts	Seeking out - drug information
Part B- Observation		Acts & time	Withholding medication
Part B- Observation		Acts	Not following process
Part B-Observation		Acts	Seeking out - drug information
Interview			Talk out loud
Interview			Following observation/decision making-withholding medication

CMO 1 – Outcome –reduced patient harm		
Interview-	Self-reports	
Document collection-	Medication Incident reports (MIR's	
Document collection	Metrics	

CMO 2- Registered nurses, who undertake a safe medication administration education programme in an acute hospital which adopts a **safety focused organisation and governance structure**, may adopt a **quality improvement approach** to medication administration, which may lead to **reduced patient harm**.

CMO 2 – Context- Safety Focused Organisation		
Observation Tool Section	Spradley (1980) Dimension	Observation
Part A Observation	Act & Actors	Leadership style local level – visibility of nurse manager
Part A- Observation	Actors and activities	People entering and leaving the observation field and their activities
Part A Observation	Objects	Ward layout
Part A- Observation	Actors	Managers and others
Interview	Managers leadership style	
Interview	Staff /managers leadership style	

CMO 2 – Mechanism –Quality improvement Approach		
Observation Tool Section	Spradley (1980) Dimension	Observation
Part B Observation	Acts	Application of policy
Interview	Clarification of observation	
Interview	staff knowledge of governance and medication safety	

CMO 2 – Outcome –reduced patient harm		
Interview-	Self -reports	
Document collection-	Medication Incident reports (MIR's	
Document collection	Metrics	

CMO 3 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.

CMO 3 – Context- Multi-disciplinary Medication Safety		
Observation Tool Section	Spradley (1980) Dimension	Observation
Part A	Observation Actors & Activities	Interaction with multidisciplinary team
Part B Observation	Activities	Seeking information
Part B-Observation	Activities	Confirmation prescription
Interview	Clarification from observation	

CMO 3 –Mechanism- Individual receptivity to change		
Interview		Observation
Interview	Have you changed?	
CNM interview	Have you seen change?	

CMO 3 – Outcome –reduced patient harm		
Interview-	Self- reports	
Document collection-	Medication Incident reports (MIR's	
Document collection	Metrics	

Appendix 16: Stage 3-Sample Interview Schedule –Following Observation

Interview Schedule- Cathal

Part 1

Can you tell me a little about the ward you work in?

What's it like to work here? - What's the atmosphere like here?

Is it a supportive clinical area?

Is there a culture/focus of patient safety and how do you practice this?

Why did you undertake the safe medication administration education programme?

Do you think any differently after doing the SMAP? Can you explain?

Do you do anything differently after doing the safe medication administration education programme?

Have you ever reported a medication error or omission?

How did you feel about this?

Were you happy with the outcome?

Would you encourage others to report a medication error or omission?

What is the atmosphere or culture on the ward like if a medication error /omission occurs

Are you encouraged or supported in the ward are to think critically about medication administration? Tell me about it?

Do you know who is responsible for medication safety in the hospital?

Have you been involved in any change process in relation to medication management in your clinical area in the last 12 months?

Do you feel that there is a multidisciplinary approach to medication administration/Management in your ward? Can you tell me about it and your experiences?

Part 2- Observation

How do you find administering medication when the patients are in single rooms?

I saw that often when you went with medications to the patients bed side you greeted them by name? Do you always do this?

I noticed that you mostly checked the patients name band- why?

? Looking for meds

I noticed a practice where before you started dispensing medications for a patient you always ran through their prescription and went to get their nutritional supplements first- do you always do this?

On each observation I noticed that you did wear the red apron- do you always wear it?

Do you think it helps?

? No signage

Interruptions – how do you feel about interruptions during the medication round? On one occasion A Doctor came into the treatment room to provide treatment plans in relation to patient care and apologised for interrupting you but continued anyway- would this be a frequent occurrence?

How long are you working on the ward/in the organisation - what support did you receive in relation to medication administration.

I noticed that you did not refer to any information sources for medication information? Why not? How did you learn all about the medications you administer- for example Creon?

Appendix 17: Sample Interview Schedule Stage 3 Manager

Interview Schedule-Manager –Oak Ward

Part 1

Can you tell me a little about the ward you work in?

What's it like to work here? - What's the atmosphere like here?

Is it a supportive clinical area?

Is there a culture/focus of patient safety and how do you practice this?

Why have some of your staff undertaken safe medication administration education programme?

Do you notice they do anything any different following the SMAP? Can you explain?

Have you ever reported a medication error or omission?

How did you feel about this?

Were you happy with the outcome?

Do you encourage your staff to report a medication error or omission?

What is the atmosphere or culture on the ward like if a medication error /omission occurs

How to you create this atmosphere?

Do you encourage the staff in your ward to think critically about medication administration?

Tell me about it?

Do you know who is responsible for medication safety in the hospital?

Have you been involved in any change process in relation to medication management in your clinical area in the last 12 months?

Do you feel that there is a multidisciplinary approach to medication administration/Management in your ward? Can you tell me about it and your experiences?

Part 2- Observation

How do you find it/ or your staff find it administering medication when the patients are in single rooms?

I noticed that when I was observing the staff member was checking name bands- do they always do so?

Looking for meds

I noticed a practice when before the nurse started dispensing medications for a patient she always ran through their prescription and went to get their nutritional supplements first- do all staff do that-do you encourage this?

Interruptions- stocking up/topping up? Who is responsible for this?

On each observation I noticed that the nurse always wore here red apron but others did not what is the general practice on the ward for wearing the apron?

Do you think it helps?

? No signage

Interruptions – how do you feel about interruptions during the medication round?

Generally are there many interruptions?

How do you manage the interruptions?

How do you support new staff in relation to medication safety?

I noticed that you did not refer to any information sources for medication information? Why not? How do staff know about the medications they administer?

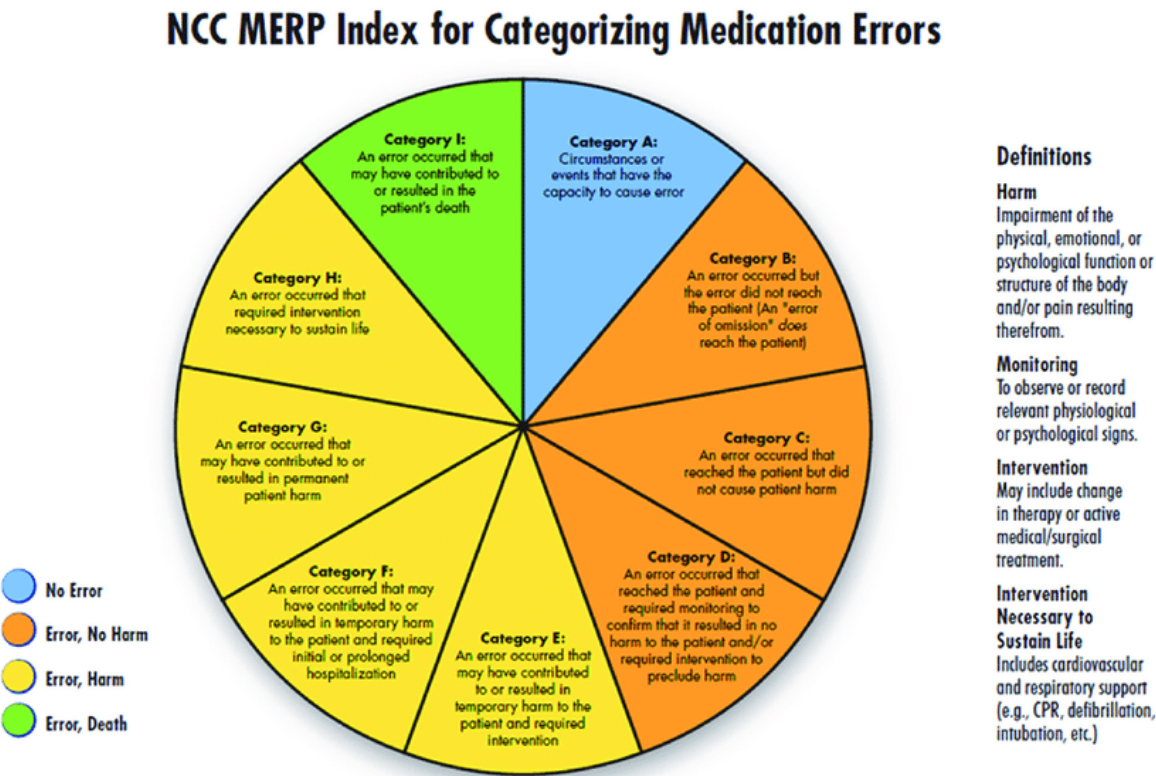
Safety initiatives

Quality boards/

Careful nursing ward

Role of the clinical facilitator

Appendix 18: National Coordinating Council for Medication Error Reporting and Prevention- Categorisation of Medication Errors



Appendix 19: Poster Displayed During Observation

Organisation Branding Goes Here

Research Observation Currently in Progress on Ward

- A researcher is currently undertaking observation of nursing practice in relation to the administration of medication
 - The presence of the researcher presents no known risk to you
 - Only nurses who have agreed to take part in the study are subject to observation however, if you are uncomfortable with the presence of the researcher please inform the researcher and observation can be discontinued while you are on the ward
 - All data collected will remain confidential and the identity of the organisation will not be known
- This study has been approved and reviewed by the Research and Ethics Committee of Cardiff University, School of Nursing and Midwifery Studies and by the St. Vincent's Healthcare Group, Ethics and Medical Research Committee
- If you require any further information please contact Freda Browne (BrowneF@Cardiff.ac.uk or 086 8792067). If you have a concern about any aspect of this study, you should contact Dr Jane Harden (Research Supervisor) at Cardiff University hardenj@cardiff.ac.uk.