DOCTOR OF PHILOSOPHY

Interventions to reduce interruptions to medication administration in a Paediatric Intensive Care Unit
a qualitative study

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Interventions to reduce interruptions to medication administration in a Paediatric Intensive Care Unit: a qualitative study

By

Rachel Ann Bower

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A thesis submitted in partial fulfilment of the University's requirements for the Degree of Doctor of Philosophy

Ethical approvals

Stage 1 - Realist Review (Coventry University)

Certificate of Ethical Approval

Applicant:

Rachel Bower

Project Title:

Interventions to reduce interruptions to medication administration: a realist review

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Low Risk

Date of approval:

04 April 2017

Project Reference Number:

P46289

Stage 2 (Part a and b) – Survey of Practice and Interviews (Coventry University)

Certificate of Ethical Approval

Applicant:

Rachel Bower

Project Title:

A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as High Risk

Date of approval:

08 August 2017

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P58021

Stage 3 – Parent/carer interviews – (Coventry University)

Certificate of Ethical Approval

Applicant:

Rachel Bower

Project Title:

An exploration of parental views of interventions to reduce interruptions to medication administration within Paediatric Intensive Care

This is to certify that the above named applicant has completed the Coventry University Ethical Approval process and their project has been confirmed and approved as Medium Risk

Date of approval:

15 January 2018

Project Reference Number:

P62123

NHS ethics

NHS
Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

23 March 2018

Dr Joseph C Manning
Clinical-Academic Senior Research Fellow in Children, Young People and Families
Nursing Faculty of Health and Life Sciences

Coventry University

Priory Street, Coventry

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Dear Dr Manning,

Study title:	**An exploration of parental views of interventions to reduced interruptions to medication administration within Paediatric Intensive Care**
REC reference:	**18/EM/0042**
Protocol number:	**P62123**
IRAS project ID:	**237172**

Thank you for your letter of 07 March 2018, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice Chair and another member of the committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [poster]	1	18 October 2017
Covering letter on headed paper	1	16 January 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		15 January 2018
Interview schedules or topic guides for participants	2	16 January 2018
IRAS Application Form [IRAS_Form_07032018]		07 March 2018
Letter from funder		08 June 2017
Letter from sponsor		15 January 2018
Letters of invitation to participant [poster to be given as leaflet]	1	18 October 2017
Other [response to NHS ethic review 18/EM/0042]	1	06 March 2018
Participant consent form [consent]	5	27 February 2018
Participant information sheet (PIS) [PIS]	4	27 February 2018
Referee's report or other scientific critique report		15 January 2018
Research protocol or project proposal	4	27 February 2018
Summary CV for Chief Investigator (CI)		16 January 2018
Summary CV for student		16 January 2018
Summary CV for supervisor (student research)		16 January 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language		16 January 2018

18/EM/0042 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely,

This item has been removed due to third party copyright. The unabridged version

Professor Cris Constantinescu Vice Chair

Email:NRESCommittee.EastMidlands-Nottingham1@nhs.net

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Abstract

Background: Globally safe prescribing and medication practices are vital as they are one of the most widely used interventions in healthcare (Elliott et al., 2021) and are associated with an increased risk of errors (Cousins et al., 2007). Interruptions are cited as a leading cause of medication error, with numerous interventions being implemented that aim to reduce their frequency, although evidence of their effectiveness is limited(Raban and Westbrook, 2014). Increased medication error rates in Paediatric Intensive Care Units (PICU) were highlighted by Alghamdi et al. (2019) due to the unpredictable physiology, complex routines and frequent use of high-risk medications. However, there are limited studies that have assessed the effectiveness of these interventions within PICU and have failed to understand their impact on the wider multidisciplinary team (MDT) and parents/carers.

Aim: The aim of this study was to understand how, when and in which context interventions to reduce interruptions to medication administration in the PICU were effective.

Methods: The design of this qualitative study included four stages: [i] a Realist Review of current literature (n=25); [ii] Survey of Practice (n=11) and MDT interviews (n=14); [iii] interviews with parents/carers (n=19); and [iv] a synthesis of findings. The realist review identified and explored the contexts and mechanisms that were associated with the effectiveness of interventions to reduce interruptions to the medication administration process. The data from Stage 2 and 3 was initially analysed using a thematic approach. Following this, a Realist lens was applied to identify the specific contexts and mechanisms in PICU that affect the effectiveness of interventions to reduce interruptions to medication administration. Finally, the synthesis critically explored the data to understand the relationships and influences between the three datasets. Concluding the synthesis was the formation of context, mechanism and outcome configuration (CMOC) illuminating the interactions within the overall picture.

Findings: The Realist Review findings identified contexts, including leadership and culture, education and engagement, and the need to understand interruptions, that triggering mechanisms that included needing to isolate the task, empowerment and trust within the team. Whilst the MDT findings revealed key contexts such as the patient and PICU environment, these were noted to trigger mechanisms that stimulated feelings, as well as the balance between focus and risk . Whereas the parent/carer findings explored contexts concerning parental knowledge and experience which stimulated mechanisms such as feeling safe and protecting their child. The overall synthesis of these findings identified the importance that interventions to reduce interruptions to medication administration comprehend the impact of maintaining patient safety in PICU, understand the medication workload, the challenge of isolating the administration process and the requirement to deliver a consistent process.

Conclusion:This thesis has illuminated the complex, interrelated, and key contexts and mechanisms that affect the effectiveness of interventions to reduce interruptions to medication administration in PICU. Furthermore, novel findings concerning the conflict and challenges that may be generated when these interventions are implemented have been identified. Collectively this study/thesis makes a novel and contemporary contribution to understanding of this phenomena which can inform future development of effective interventions to reduce interruptions to medication administration in PICU.

Glossary

Caring around the clock: a process where patients are reviewed/checked within set timeframes

Context: The backdrop or background structures that influence behavioural or emotional responses (mechanisms) to the intervention. These are not explicit or formally identified parts of the intervention (Jagosh et al., 2011)

CMOC's (Context-Mechanism-Outcome Configuration): A CMOC is a working construct (complex idea formed from simpler elements) that generates causative explanations about the data. A lens of generative causation is applied to identify the relationships between context, mechanisms and outcomes. These can relate to the whole intervention or elements of the intervention (Jagosh et al., 2011)

Demi-regularities: Semi-predictable patterns (Jagosh et al., 2011)

Extubation: Removal of endo-tracheal tube (breathing tube) from airway

Intentional rounding: a systemic process where Nurses deliver regular checks to their patients

Intubation: Insertion of endo-tracheal tube (breathing tube) into airway

Just culture: a culture where there is a balance between accountability and safe systems and processes

Float Nurse: an additional nurse who does not have caring responsibilities for a specific patient but whose role is to assist others with the delivery of care

Middle range theory: A testable theory that can be implicit or explicit that can be used to assess programmes and interventions (Jagosh et al., 2011)

Mechanism: A generative force that leads to outcomes. They are often behavioural or emotional responses that are triggered by the insertion of an intervention (Jagosh et al., 2011)

Outcome: The intended or unintended impact of the intervention (Jagosh et al., 2011)

Productive ward: a system that focuses on efficiency freeing time to deliver care

Programme theory: A description of how the theory should work and in what setting. This is informed by research, knowledge, experience and the assumptions of the intervention designers (Jagosh et al., 2011)

Retroductive strategies: the researcher identifies the circumstances which need to be present for the concept or mechanism needs to exist (Meyer and Lunnay, 2013)

Safety Two: approaching safety management by reviewing practice when things go right

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Chapter 1 Introduction

1.1 Preface – personal insights and motivations

I have now been a Registered Children's Nurse for 25 years and during this time I relished the challenge of working in Paediatric Intensive Care (PICU) for 20 years. More recently, I have moved into the field of Quality, Risk and Safety which has allowed me to have a continued interest in the safety of medication administration across the whole of Nottingham Children's Hospital (NCH), in the East Midlands region, United Kingdom (U.K.).

As a senior nurse and manager on the Paediatric Intensive Care Unit (PICU) in NCH, I was involved in the administration of multiple medications to significant numbers of critically ill children. The provision of medication to critically ill patients is a fundamental part of their treatment as they contribute to their recovery or support the systems of the body whilst healing occurs. My personal experience includes the administration of extremely complex medications which can require difficult calculations and the consequence of an error could be catastrophic.

Whilst working in PICU, I have also experienced the heart stopping moment when you realised that a mistake has been made. Additionally, I have managed the process when other professionals have made an error. The formal reporting and investigation which occurs at these times encourages reflection and further education but may still have a significant impact on the individual as they lose confidence in their skills. It was these experiences that led me to realise that as practitioners we need researchers to explore and understand how errors can be prevented in the first place, for both the patient and the nurse's well-being.

My studies prior to this thesis have always aimed to combine current clinical practice and research to ensure the findings are relevant to the real world of nursing. Previous academic work includes a narrative literature review (Bower et al., 2015) and an exploratory empirical study examining nurse decision making when interruptions in medication administration occurred (Bower et al., 2017), which formed part of a fully funded 'Master's in Clinical Research'. This work identified that managing such interruptions in PICU was complex due to

the large multi-professional health teams involved and the need to support parents/carers and that current intervention strategies were not consistent and effective across the United Kingdom (U.K.). This enabled a platform for further study to explore this more comprehensively.

Consequently, this prior research provided a good foundation of knowledge about interruptions in medication administration. But this thesis takes one step further in illuminating how, when, why and for whom interventions are effective in terms of medication administration. It is the desire to understand how interventions work within clinical practice which remained my constant passion in the journey to understand current PICU practice in context. Completing this research within a doctoral programme has enabled me to examine philosophical beliefs in detail which led me to the paradigm of Critical Realism as a platform to explore from. In particular, the work of Pawson and Tilley (1997) who explored the impact of context and underlying hidden mechanisms that can facilitate or hinder the implementation and use of interventions. Through the understanding of these relationships, it is possible to illuminate previously unseen elements which are essential for an intervention to work. Throughout this thesis, my study has focused on understanding interruptions to medication administration and interventions that seek to reduce their frequency in Paediatric Intensive Care Units (PICU). In particular, my thoughts have centred on the families and health professionals with whom I 'interacted' whilst undertaking this PhD. Whilst I do not use my own voice to narrate the thesis, I do include some reflective pieces set into tables. This was important because it is without doubt because of the children, young people and their families that my interest in this area and journey began. It is because of that interest and drive that I am beginning this thesis by including some personal information to set the scene.

Within this preface, it is important to recognise that the empirical element of this study was completed prior to the start of the COVID-19 pandemic. Whilst the findings presented relate to the observations and experiences of healthcare professionals and parents/carers prior to COVID-19, the discussion/conclusion will examine changes in practice that may relate to the effectiveness of interventions to reduce interruptions to the medication administration process.

1.2 Global overview

Safe prescribing and medication practices in healthcare are vital as they are one of the most widely used interventions worldwide (Elliott et al., 2021). Alongside frequency of use, medication safety is essential due to the associated increased risk of errors (Cousins et al., 2007). The process is complex and errors may occur at any stage, as indicated in the definition provided by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 2021):

> *"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."* (NCCMERP, 2021)

The global overview provided by the World Health Organisation (WHO) indicates that one death occurs each day as a result of a medication error (World Health Organisation, 2017). Exploring the international literature illuminates a varied prevalence of medication errors in healthcare. In Australia, Evans (2009) found that two percent of inpatient admissions were involved in an error. Whereas in South East Asia, Salmasi et al. (2015) reported in their review that administration error rates varied from 15.2% to 88.6% and prescribing from 7% to 35.4%. In the Middle East, a review completed by Alsulami et al. (2013) of 45 studies found that error rates for prescribing varied from 7.1 % to 90.5 % and from 9.4 % to 80 % for administration. However, overall the systematic review of 91 international studies conducted by Keers et al. (2013b) identified a median error rate of 19.6%, demonstrating a significant issue within the delivery of healthcare globally.

1.2.1 Global overview of medication errors in children

Moving on to explore the literature for children, an international systematic review by Miller et al. (2007) reported error rates of 3-37% for prescribing and between 72-75% for administration. Closer examination of different countries demonstrates significant variation in the numbers of medication errors reported.

Studies in North America show a significant number of medication errors. Ghaleb et al. (2006) found that the administration error rate in the United States (US) was 14.7 per 100 admissions, whereas, Kirkendall et al. (2012) identified an overall rate of 36.7 per 100 admissions. Furthermore, in their prospective study, Kaushal et al. (2001) found that of 10 778 prescriptions, six percent were incorrect and concluded that children were three times more at risk of potential harm than adults.

An examination of studies in Australia showed the error rate in children was reported to be lower. Hibbert et al. (2020) reviewed 6 689 prescriptions and identified an error rate of three and a half percent. Of the 232 errors, 83% caused low harm and 48% of them were related to intravenous fluids. Whereas, in a smaller South African study, Gokhul et al. (2016) found that in 117 prescriptions 95% included an error of which 89% were due to prescribing mistakes and three percent resulted in harm for the child.

Collectively the findings from these international studies highlight children are at increased risk of potential harm. This is due to significant numbers of administration errors, particularly with intravenous fluids.

1.2.2 Impact of medication errors

The literature within this field suggests a strong association between mortality and morbidity with medication errors. The significance of this has been recognised by WHO and as a response have aimed to reduce their frequency by 50%, by 2022 (Donaldson et al., 2017). Coupled with these mortality rates, is the cost of harm from medication errors, which is estimated to be one percent of global health expenditure (World Health Organisation, 2017). Focusing on the cost, McCarthy Jr et al. (2017) estimate that the average total hospital costs per person who experience a medication error average $19,444. Dalton and Byrne (2017) estimate that medication errors add an additional two days to the average length of stay and account for six percent of hospital admissions. Moreover, it is suggested in the literature that medication errors cause unintended injury and disability (Rodziewicz and Hipskind, 2018). It is evident from these studies that medication errors are costly, contribute to an increased

length of stay and risk of harm, thus indicating a need for future studies to focus on strategies for their reduction.

In addition to the harm and financial costs for patients from medication errors, there is an impact on healthcare professionals. It has been highlighted by Wittich et al. (2014) that medication errors are in the top ten reasons for malpractice in Texas leading to regulatory review. Furthermore, Rodziewicz and Hipskind (2018) suggest that medication errors may tarnish reputations, decrease confidence and lower morale resulting in less effective working. Furthermore, Choi et al. (2020) found an association between patient safety incidents and post-traumatic stress disorder in nurses. These studies demonstrate another important reason for there to be robust research into the reduction of medication errors. If healthcare professionals are not able to work in an environment where processes support the safe delivery of medications, Treiber and Jones (2018) and Robertson and Long (2018) both suggest there may be a negative impact on wellbeing and ultimately retention.

This brief overview of the global impact of medication errors has demonstrated that they continue to be a patient safety concern. The studies included illuminate the frequency of errors and the harm, to patients and staff, associated with them, thus indicating the need for further research to identify strategies to help reduce their frequency. Moreover, in children the risk of potential harm is significantly higher than in adults and that they are at risk of errors with intravenous medications. Both issues are especially pertinent to medication administration in PICU. Having provided a global overview, these issues will now be examined within a national context.

1.3 National (U.K.) overview

As in all healthcare settings medication management in PICU is governed by U.K. law, predominantly by The Medicines Act (1968), with more recent amendments made within The Human Medicines Regulations (Department of Health, 2012). In 2019 the guidance from regulatory bodies decreased as the Nursing and Midwifery Council (NMC) withdrew their medication governance document. Their rationale for this decision was that it was no longer within their remit as regulator to provide this practice guidance. The NMC now refer nurses

to a document written by The Royal Pharmaceutical Society (RPS) and Royal College of Nursing (RCN) (RPS and RCN, 2019). This guidance offers overarching directives but devolves the detailed responsibility to organisational governance processes and individual accountability for practice (RPS and RCN, 2019).

The medication administration process is reported to involve five distinct steps; prescribing, checking of prescription, preparation of medication, second check of preparation and administration to the patient (Bower et al., 2015). Furthermore, within these stages it is estimated that 50-100 steps are taken (Kliger, 2010) and the nurse can be required to perform multiple calculations, solve problems and decide if, how and when a medication should be given. The administration process involves a multidisciplinary team of medical, pharmacy and nursing teams. Ultimately, the final check rests with the nurses administering the medication (Bower et al., 2015), therefore, it is essential that contemporary practice includes robust systems and processes to minimise the risk of errors.

In their recent review of the literature, Elliott et al. (2021) estimate that the prevalence of medication errors, across the NHS in England, to be 237 million events per year. Although, 72% of these errors are thought to result in little or no harm. Notably Elliott et al. (2018) identified that from their data including adults and children, 66 million medication errors were thought to be clinically significant for the patient. These errors occurred throughout the medication process but significantly, 54% occurred during the administration phase. Although this data includes primary care, secondary facilities and care homes, it demonstrates the frequency at which errors occur. Additional costs are associated with adverse medication reactions resulting in longer hospital stays costing £14.8 million, causing 85 deaths and contributing to 1,081 deaths (Elliott et al., 2018). Furthermore, medication errors have been linked with admission to intensive care and a need for increased resources after discharge (Elliott et al., 2021). In children, Raine (2011) found that one of the most common reasons for litigation was harm associated with medication errors, with estimates of £52-£96 million pounds being associated with the costs of these cases (Walsh et al., 2017, McCullagh and Slattery, 2019).

Medication error rates are noted to be higher within paediatric departments (McDowell et al., 2009), in the U.K. it has been reported to be between 0.15 and 17.2 per 100 admissions (Ghaleb et al., 2006, Davis et al., 2005, Gill et al., 2012). It is noted within the literature that children are most at risk of serious and fatal medication errors, with children under the age of four experiencing 10% of medication errors (Cousins et al., 2007). However, the error rate within paediatrics is variable and lower than reality, as it is acknowledged that errors are underreported in practice (Alomari et al., 2015).

A recent systematic review by Sutherland et al. (2020) estimated that there were 101 errors per 1000 doses of intravenous medications in children, of which a third were administration errors. This finding is significant as mistakes with intravenous medication are more likely to be harmful (Kaushal et al., 2001, Neuspiel and Taylor, 2013). Furthermore, the frequency and increased levels of harm is particularly pertinent to PICU where the administration of intravenous medication is prevalent (Alghamdi et al., 2021). It is suggested that increased error rates are seen within paediatrics due to the complexity of dosing due to large weight ranges, the adaption of adult based, age appropriate dosing and interchanging dosage units from milligrams to micrograms to nanograms (Dickinson et al., 2012, Cousins et al., 2007, Sears et al., 2013).

To summarise, this section has illuminated the national challenge of medication errors. It has provided context surrounding the morbidity, mortality, cost and harm associated with medication errors. Furthermore, when exploring the literature concerning children, it highlights an increase rate of medication errors particularly during the administration of intravenous medications which is especially relevant to PICU.

1.4 Introduction to medication administration in PICU

This thesis focuses on medication administration in the PICU environment. The first PICU within the U.K. was opened at Great Ormond Street Hospital in 1961 (Levin et al., 2013), it was noted by Goldstein and Nadel (2013) that service provision did not develop a robust centralised structure until 1997. It is this regionalised service that continues to deliver increasingly complex medical and nursing care to critically ill children in the U.K. (Paediatric Intensive Care

Society, 2015). Recent data released from the national audit (Paediatric Intensive Care Audit Network, 2020) demonstrates that there are 20 000 admissions to PICU and 140 000 bed days are delivered per year.

Alongside the 20 000 children who are admitted to PICU in the UK, are parents/carers. A previous study (Bower, 2016) highlighted the influence of parents/carers within PICU. It is perhaps not surprising that when this study was conducted, parents/carers had open access to PICU to allow them to be present at their child's bedside. However, in the current literature concerning medication administration in PICU the parent/carer voice is hardly recognised. Recently (Manias et al., 2019) have identified that the involvement of parents/carers can result in increased numbers of medication errors being identified. However, the impact of their role in medication administration safety in PICU is not known.

The complexities of medication administration in children have already been identified as well as the higher risk of error. This is further exacerbated within intensive care unit setting where errors are more common (Alghamdi et al., 2019). Increased error rates in PICU were highlighted by Wilson et al. (1998) and Alghamdi et al. (2019) who attribute this to the unpredictable physiology, complex routines and frequent use of high-risk medications. Children in PICU have an increased risk of harm from medication errors due to them being a child and having a critically illness or injury, therefore it is essential that medication administration systems are designed to maintain their safety. However, it is important to understand the contributory factors that can affect medication safety.

Within the delivery of critical care for children there is a requirement to provide enhanced observation, monitoring and interventions such as ventilation and haemofiltration, to enable the child to recover from a life-threatening illness or injury (Paediatric Intensive Care Society, 2015, Levin et al., 2013). Alongside these challenging interventions, such as ventilation or haemofiltration, is the administration of medications, which arguably, is one of the most complex roles that nurses perform. They are required to consider decision-making issues such as weight related dosing, physiological instability and interactions between medications (Alghamdi et al., 2019, Dickinson et al., 2012). Within the PICU

environment the complexity increases as the time critical nature of urgent medication administration only serves to increase the pressure (Sears et al., 2013, Anthony et al., 2010). In addition to the complexities within medication administration, the Paediatric Intensive Care Audit Network (2020) highlight that only a quarter of U.K. PICU's meet the standards for nurse staffing, thus suggesting an additional pressure in the delivery of safe medication practice, as the literature suggests that medication error rates may be affected by staffing levels (Härkänen et al., 2018).

Recent studies by Alghamdi et al. (2021) and Alghamdi et al. (2019) have highlighted an increased prevalence of medication errors within PICU. In their systematic review Alghamdi et al. (2019) concluded that within PICU there was an error rate of 14.6 per 100 medication prescriptions. Like data presented in sections 1.2 and 1.3, administration errors were one of the most frequently reported. More recently, their mixed methods review of national safety incidents (Alghamdi et al., 2021) revealed that over 50% of errors occurred during the administration phase and involved infants or neonates. The national audit of PICU admissions (Paediatric Intensive Care Audit Network, 2020) demonstrates that 45% of admissions to PICU are aged under one year. Thus, demonstrating the significance of the findings from Alghamdi et al. (2021) as approaching half of the PICU population are at higher risk of being involved in a medication error, and furthermore these were more likely to cause significant harm.

Within his book about 'Just Culture', Dekker (2018) acknowledges many factors both individual and system based, that contribute to the prevalence of errors. Within the literature concerning medication errors factors such as fatigue, experience, competence, staffing levels and interruptions are identified (Björkstén et al., 2016, Kaliyaperumal et al., 2017, Hall et al., 2010). In their qualitative review of medication errors Björkstén et al. (2016) found that role overload contributed to 36% of errors, 30% each for communication and lack of guidance. Furthermore, experience significantly impacted on the actions taken. They found that less experienced nurses had a lack of knowledge and were less likely to follow protocols. Whereas nurses with more experience were more likely to practice beyond their scope. In their empirical study, Kaliyaperumal et

al. (2017) explored the impact of sleep deprivation and illuminated that cognitive function decreased with 32% making more mathematical errors at night. This is an important factor for PICU as medication administration occurs throughout the 24-hour clock. Arguably, one of the most frequently cited contributing factors to medication errors is that of interruptions (Altmann et al., 2014, Bower et al., 2015, Colligan and Bass, 2012, Davis, 1994, Grundgeiger and Sanderson, 2009, Hayes et al., 2015a, Sasangohar et al., 2012), which is the focus of this thesis and will be discussed briefly in the next section and in detail in Chapter 2.

In summary, this section has illuminated the key influencing factors that affect medication administration in PICU, such as the environment, requirements of the patient, needs of parents/carers and complexity of calculations. All these factors contribute to a significantly higher risk of medication errors, thus creating a need for further research to understand how practice can be improved to increase patient safety.

1.5 Interruptions in medication administration

The prevalence of medication errors in children and the complexities of the PICU environment identified in the previous two sections has highlighted a need for safe medication practice. As noted in section 1.3, one reason suggested in the literature (Donaldson et al., 2000, Grundgeiger and Sanderson, 2009) as being a cause of medication errors is that of interruptions. Although there is limited literature regarding interruption rates to medication administration in PICU, Bower et al. (2017) acknowledged in their empirical study that interruptions were noted to impact on concentration and affect clinical decision-making. In addition to this study, small quality improvement projects by Osman et al. (2015) and Hewitt et al. (2017) suggest that interruptions are perceived to be a problem within PICU in the U.K. and that some interventions such as red aprons and ‘No interruption zones’ (NIZ) have been implemented in order to reduce their frequency. Neither study was able to provide conclusive evidence of effectiveness, as Hewitt et al. (2017) concluded that medication errors rose after implementation and Osman et al. (2015) was unable to effectively measure the impact of the intervention.

The phenomena of interruptions may be defined as *'a break in continuity of complete focus on the task of preparing medication'* (Anthony et al., 2010:24). Over the last 20 years there has been debate within the health literature regarding the impact of interruptions on the medication process and their link to patient harm. There is a body of evidence which suggests that constant interruptions have a negative impact on patient safety (Hall et al., 2010, Anthony et al., 2010, Biron et al., 2009). Furthermore, Westbrook et al. (2010) found an associated increase in procedure and clinical errors when staff were interrupted. Conversely, there are researchers who suggest that there is limited empirical evidence which clearly supports a link between interruptions and harm from medication errors (Hopkinson and Jennings, 2013). Furthermore, more recently the results from Sasangohar et al. (2015) demonstrated that not all interruptions were detrimental to nursing care as they may include team communication which is vital to patient safety. This research suggests that understanding interruptions from a Multi-disciplinary Team (MDT) point of view may illuminate a wider comprehension of the impact and need for interruptions to occur.

In PICU, the requirement of the nurse to be continually present at the patients' side encourages administration of medication to subsequently occur at the bedside. A previous study (Bower et al., 2017) highlighted that bedside preparation was required because critically ill children require continual observation. This requirement of continual observation and the increased medication workload contribute to an increased the risk of interruptions due to the need to respond to deterioration and ensure continual care is delivered.

Interruptions to medication administration have been identified as an issue within healthcare, despite a lack of robust evidence which demonstrates a link between them and increased error rates (Hopkinson and Jennings, 2013). The identification of this issue has resulted in a plethora of studies which seek to implement an intervention to reduce interruptions to medication administration (Westbrook et al., 2017, Anthony et al., 2010, Relihan et al., 2010, Pape, 2003, Pape et al., 2005, Palese et al., 2015, Colligan et al., 2012, Verweij et al., 2014). Nevertheless, the evidence base continues to demonstrate mixed results concerning the effectiveness of interventions to reduce interruptions to

medication administration (Raban and Westbrook, 2014, Rafferty and Franklin, 2017).

The common interventions implemented seek to differentiate the medication process from the delivery of nursing care, either by making the task stand out (tabards, aprons, sashes or lighted lanyards) or by placing it behind a barrier (no interruption zones). These interventions have frequently been informed by aviation industry safety practices (Pape, 2003). There is a paucity of literature which seeks to understand the complexity of interruptions in healthcare and the impact that interventions to reduce interruptions has on patient safety (Rafferty and Franklin, 2017).

Collectively, the current status of contemporary literature in the field of medication administration and interruptions within a PICU setting indicates that there are several areas where knowledge is lacking:

- How do interventions to reduce interruptions to medication administration work and what affects their effectiveness?
- What interventions have been implemented within PICU in the UK to reduce interruptions to medication administration and are they effective?
- What impact do these interventions have on the wider MDT?
- What do parents/carers experience when medications are administered within PICU?

In addition to these gaps in the literature there is a growing body of literature that questions the effectiveness of current interventions that aim to reduce interruptions to medication administration.

In summary, the previous three sections have illuminated a significant issue with medication within safety within healthcare, which has financial implications as well as associated harm, morbidity and mortality. Interruptions have been identified as a contributing factor in medication errors, but little is known about the interventions used within PICU that help reduce them. Therefore, with

reference to these issues, the following research question, aim and objectives were constructed.

1.6 Research question, aim and objectives

1.6.1 Research question

How do interventions to reduce interruptions to medication administration work, for whom and under which circumstances within the Paediatric Intensive Care Unit?

1.6.2 Aim

To understand how, when and in which context interventions to reduce interruptions to medication administration in the PICU are effective.

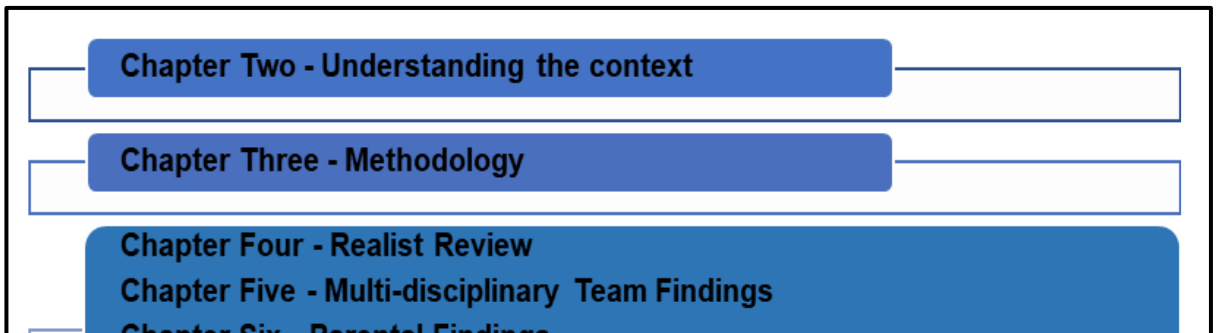
1.6.3 Objectives

1. Critically review the contemporary existing research to understand how, when and in what circumstances interventions work in the PICU context
2. Investigate what interventions are used in clinical practice across PICUs in England
3. Explore perceptions and experiences of the multidisciplinary team in the medication process and interventions to reduce interruptions in PICU
4. Explore perceptions and experiences of parents/carers in the medication process and interventions to reduce interruptions in PICU
5. Synthesise these multiple perspectives to develop understanding of the context, mechanisms and outcomes in relation to interventions to reduce interruptions for medication administration within the PICU setting.

1.7 Outline of thesis

The previous section has illuminated the research question and aim that will be answered within this thesis, whilst the following diagram (Figure 1) and narrative will outline the structure of the thesis.

Figure 1 - Outline of thesis



Following this introduction, Chapter Two will explore the context of medication administration and interruptions, as well as examining current interventions to reduce interruptions, whilst exploring theories that support their use. The methodology and methods for the Realist Review and empirical studies that will aim to address the research question, will be outlined in Chapter Three. The findings from the Realist Review will be incorporated with those from the empirical studies to allow it to contribute to the generation of theory which is promoted within realist methods. Afterwards, a synthesis of the finding's chapters will suggest an overall theory which will then be critically resituated within the existing theory and wider literature in a discussion chapter (Chapter Eight). This thesis will conclude by outlining the implications for policy, practice and future research.

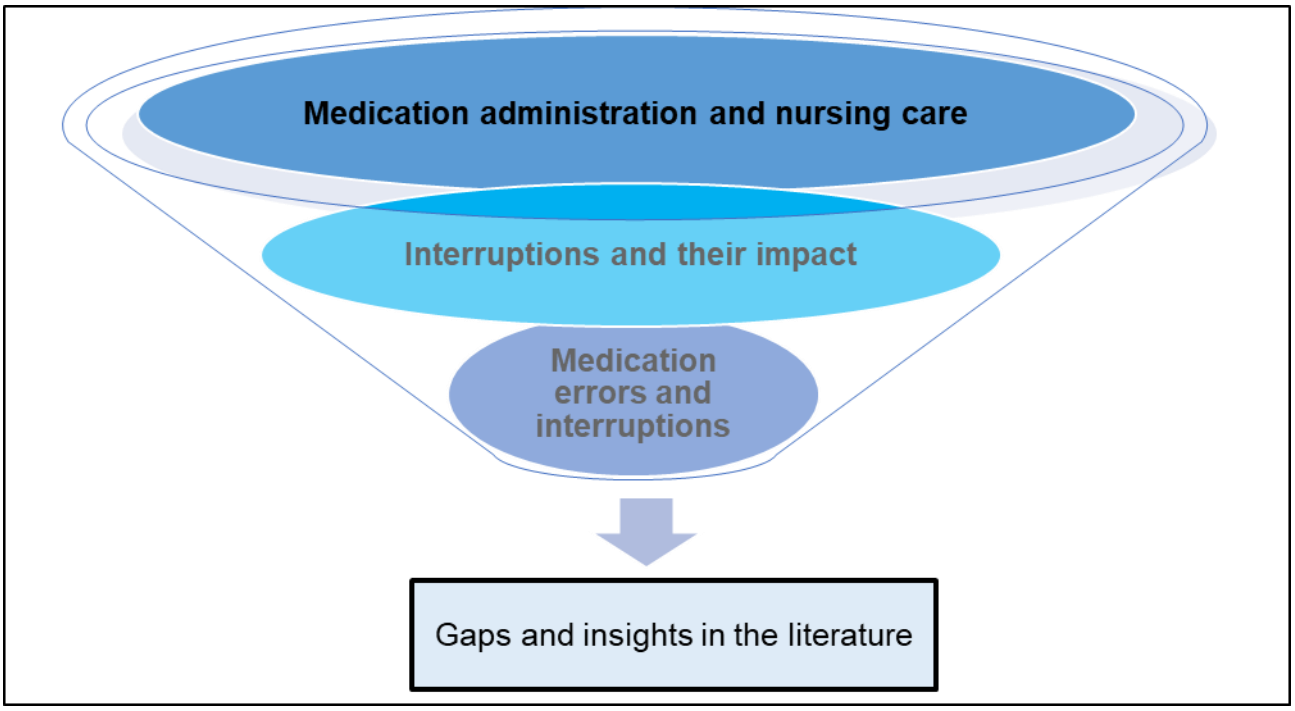
Chapter 2 – Understanding the context

2.1 Introduction

> *"Interruptions are likely to be a natural by-product of an experienced nurse's role in supervising, communicating and coordinating the process of care."* (Rafferty and Franklin, 2017:1).

This extract from Rafferty and Franklin (2017) is used here to set the scene of this chapter which will present a narrative review that uses a funnel structure (Figure 2) to narrow the focus before expanding to identify the insights and gaps in the current evidence base. This is an important process to undertake as Rafferty and Franklin (2017) clearly state in their discussion the complexities within nursing care, of which medication administration is one element.

Figure 2 – Narrative review structure



The chapter will also include an exploration of medication administration and nursing, followed by an examination of the phenomena of interruptions. There has been frequent discussion concerning interruptions in the delivery of health care within literature (Brixey et al., 2004, Brixey et al., 2007, Grundgeiger et al., 2016, Biron et al., 2009, Hopkinson and Jennings, 2013, Kalisch and Aebersold, 2010, Potter et al., 2005). High profile reports in the United States, such as The Institute of Medicine report 'To err is human' (Donaldson et al.,

2000) and an evidence report from the Agency for Health Care Research and Quality (Hickam et al., 2003) documented a possible link between interruptions and error. Moving on, the chapter will critically discuss different types of interventions and theoretical frameworks that have been used to reduce interruptions to medication administration. Following on, the concluding discussion will explore the limitations of the current literature to provide a rationale for the following study.

2.1.1 Literature scope and search terms

In order to provide a comprehensive, critical and objective analysis of the topic, the aims of this broad narrative review were to explore:

- the medication process within PICU
- interruptions and their impact
- the relationship between interruptions and medication errors

To achieve these aims a wide-ranging search of electronic databases (CINHAL, MEDLINE, EMBASE, PsychINFO, and the British Nursing Index) was completed in January 2017 and updated in March 2021.

The terms of this search included:

- Medication OR medicine OR drug administration AND children OR paediatrics OR pediatrics AND critical care OR intensive care
- Interruptions OR distractions AND effect OR impact OR management
- Errors OR mistakes OR adverse event OR procedural error/failure
- Interventions AND reduce OR reduction AND interruptions

The search was restricted to papers published between 1970 and March 2021. The publication of ‘To Err is Human’ (Donaldson et al., 2000) was released in 2000 which was the seminal book that suggested a link between medication errors and interruptions within healthcare. The search preceded this publication

date by searching back to 1970, in order to understand how interruptions were perceived and managed prior to this suggestion by Donaldson et al. (2000). Ferrari (2015) suggests that narrative reviews should appraise the key concepts identified within the literature. In this review the identified key concepts were understanding the medication administration process, exploring the impact of interruptions and their relationship with errors. The funnel structure enabled the review to begin with a broad overview of the medication process and its location within nursing care, before narrowing the focus to interruptions and their impact.

2.2 The Medication administration process

There is an overwhelming amount of literature written about the medication process within healthcare up to March 2021, with searches of electronic databases showing approximately three million citations. One of the dominant reasons for this extensive evidence base is that the association between the medication administration process and harm either to patient (Walsh et al., 2017, Leufer and Cleary-Holdforth, 2013, Donaldson et al., 2017, Anderson and Abrahamson, 2017) or professional (Treiber and Jones, 2010, Hewitt, 2010, Cadwell and Hohenhaus, 2011, Cabilan and Kynoch, 2017). Indeed, Anderson and Webster (2001) suggest that medication administration is one of the highest risk processes that a nurse will be involved in. As well as the association with harm, medication administration is noted to be time-consuming, frequent, complex and merges with the delivery of other elements of nursing care (Jennings et al., 2011, Sitterding et al., 2014, Martyn et al., 2019). At the end of their Appreciative Inquiry, observational study of 20 nurses performing medication administration Martyn et al. (2019) summarised the complexity and skill required for the process:

> *'Routine medication administration was not a simple task as suggested by the rights framework; instead, it was observed to be a complicated, convoluted and time-consuming activity requiring cooperative teamwork, diplomatic lobbying and patient-centered strategies.'* (Martyn et al., 2019:13)

As outlined in Chapter 1, medication administration processes in England are guided and tightly regulated by the law. Moreover, The Rights Framework (See (Table 1) with the aim of improving medication administration safety has as an

intervention been very influential nationally and internationally (Martyn et al., 2019, Elliott and Liu, 2010, Edwards and Axe, 2015).

Table 1 – Five Rights of Medication Administration

Number	R	Information
1	Right patient	Ensure medications are administered to the correct patient by checking positive patient identification
2	Right drug	The prescription of the drug should be clear and legible. The generic name, and not the trade name, should be used (unless appropriate). Highlight any medication allergies on a wristband and on drug chart.
3	Right dosage	Check the name of the drug against the dosage of the medication to be administered
4	Right time	A drug needs to be administered at appropriate time(s) to ensure an effective outcome
5	Right route	Some medications cannot be administered by the oral route (GTN or insulin, for example). Others must be administered IV for 100% bioavailability.

Adapted from Edwards and Axe (2015)

However, throughout the last two decades the usefulness of the Rights Framework as an intervention has been questioned (Institute for Safe Medication Practices, 2007, Elliott and Liu, 2010, Martyn et al., 2019, Jones and Treiber, 2010) primarily because it focuses on individual actions rather than the systems in which nurses work. Other studies have suggested additional 'rights' to the framework to change the number to seven (Smeulers et al., 2015) and nine (Elliott and Liu, 2010) in order to attempt to address the complexity within the process. Despite this continued debate, the practice is described within the international literature with no apparent alternative. These attempts to adjust the Rights Framework could be suggestive of the difficulties of attempting to implement simple interventions that do not comprehend the complexity of the process; therefore, it is important that the medication administration process is examined within the context of the delivery of nursing care.

2.2.1 Situating medication administration in the delivery of nursing care

Having set the scene of medication administration systems in Section 2.2 one aspect that evolved in the narrative review was that they have historically been designed to be a standalone process with a defined beginning and end. This

standalone system is supported within the law, regulatory standards and hospital policies. However, empirical studies identify medication administration as often woven in with other elements of nursing care (Martyn et al., 2019, Jennings et al., 2011). This context was developed further by Jennings et al. (2011) who concluded from their ethnographic study that medication administration was not a separate entity, it was entwined within nursing care and interruptions could not be counted as there was no beginning or end to the process.

When additional elements of care interact with the medication process nurses were described as multi-tasking, this occurs when concurrent thoughts or tasks are performed simultaneously (Hayes et al., 2015a, Jennings et al., 2011). Findings conveyed from observational studies of the medication process (Sitterding et al., 2014, Magalhães et al., 2019, Bucknall et al., 2019) illuminate several situations such as maintaining situational awareness, effective communication, delivering personal care and recognising patient deterioration that commonly interact with the medication process. Furthermore, a mixed methods study by McLeod et al. (2015), that included the observation of 56 medication rounds, found two types of nursing behaviour. Some involved individuals who were task focused following a streamlined approach, compared with others who interacted with patients and completed non-medication tasks at the same time as administering medication. Unsurprisingly McLeod et al. (2015) concluded that nurses who interacted with patients during medication administration were more likely to be interrupted. What was not clear from this study was whether this difference in behaviour was due to culture (data was collected from three different wards), personality type or individual behaviour. This may suggest that in some circumstances interventions that isolate the medication process into a separate task may be successful, but more work is required to understand when this is possible.

Historically, nursing care was delivered differently to contemporary nursing in terms of in that it was focused on task delivery (Lindstrom, 1975). Holistic care evolved during the 1990's and is defined by (Zamanzadeh et al., 2015) as the provision of care to meet the needs of the person as a whole. It requires the delivery of care to meet the biological, social, psychological and spiritual needs

as an integrated thinking. It is perhaps the introduction of holistic patient care that increased the need for interruption management as this development in practice encouraged nurses to deliver the care that met all the needs of their patient rather than purely focusing on one task at one time (Hayes et al., 2018, Jennings et al., 2011). This could result in different elements of care being delivered at the same time and nurses feeling central to the delivery of care and needing to be involved in all conversations about their patient to keep up to date about all aspects of care (Sasangohar et al., 2015, Nelms et al., 2011).

The studies discussed so far within this section have used data collected within clinical areas that care for adults. However, the focus of this thesis is medication administration and interruptions in PICU, therefore these issues need to be explored within this setting. The medication administration process within PICU is often completed at the bedside and this may amplify the impact of the issues discussed in this section.

2.2.2 The Medication administration process in PICU

The medication workload in PICU is described in the literature as large and frequent. However, it is difficult to precisely quantify this workload. Johnston (2015) estimated in her small observational study that at 90% occupancy there were 30.6 medications administered per patient per day in PICU. This is suggestive of a significant workload, particularly as 50% were intravenous medications. Douglas et al. (2013) explored the differences in workload between an Adult Intensive Care Unit (AICU), Cardiac Intensive Care Unit (CICU), PICU and Neonatal Intensive Care Unit (NICU). They found that in PICU and NICU nurses spent more time on direct physical care, 23% and 17% respectively, which included medication administration, compared with 14%in AICU and CICU. However, of note is that this study was conducted in the United States of America where medications are delivered to the clinical area pre-prepared therefore reducing the time needed for administration, in comparison to England where this is completed on PICU by the nursing team. These two studies are suggestive of a medication process that consumes a significant amount of nursing time within PICU. However, there are other reasons, both physiological and process, which contribute to complex medication administration in PICU.

It is evident within the literature (Alghamdi et al., 2019, Dickinson et al., 2012, Douglas et al., 2013) that there are several reasons specific to PICU that make medication administration more difficult such as physiological instability, weight base dosing and off-license administration which can contribute to a high rate of medication errors. In their systematic review Alghamdi et al. (2019) found that there were between six and nine errors per 1000 bed days. Of these prescribing and administration errors were the most frequently reported within PICU. Furthermore, preventable error rates were thought to be 21-29 per 1000 bed days, the level of harm attributed to these incidents was low. The commonest types of medications involved in the errors were anti-infective and cardiovascular agents. This review by (Alghamdi et al., 2019) acknowledged issues with heterogeneity due to different processes, research methods and measurement rates. This is the only systematic review of medication errors rates within PICU, in the wider inpatient population numbers have been suggested between five and 24 per 100 prescriptions (Maaskant et al., 2018, Kaushal et al., 2001), suggesting that this is a significant issue for the whole team.

It is also important to understand the role of the wider Multidisciplinary Team (MDT) in medication administration in PICU. The medical and ANP team are responsible for the prescription of medications, this may be by computerised system or paper (Alghamdi et al., 2019). Prescriptions are reviewed daily by the specialist pharmacist which has been demonstrated to improve medication safety (Maaskant et al., 2018, Cope et al., 2019). The preparation and administration is then completed by the nursing team, involving a check of the prescription (Bower et al., 2015). This collaborative working within the MDT demonstrates the need for medication safety interventions to involve the whole team in the development as it is possible changes in practice will impact on them and their engagement will be required.

The experience of parents/carers with medication administration in PICU is absent in the literature. Ames et al. (2011) and Hill et al. (2019) found in their qualitative studies with parents/carers in PICU, that they wanted to work in partnership with the MDT team. In the current literature this working in

partnership has not been explored within the field of medication administration in PICU.

In conclusion, this section has explored the structure of the medication administration process, how it interacts with other elements of nursing care and the complexity of its use within PICU. This review of the literature has identified the challenges faced when implementing interventions into the complex medication administration process and the importance of involving the wider team. Whilst there are large amounts of literature concerning medication administration in general, this decreases when exploring it within PICU. The review has also illuminated a lack of involvement of parents/carers in the literature concerning medication administration in PICU.

2.3 Interruptions

Interruptions to nursing practice and their impact have been highlighted within the literature since the late 1980's (Fuqua and Stevens, 1988). Early discussions identified an association between errors and interruptions, particularly in relation to medication administration (Davis, 1994). The following section will explore the phenomena of interruptions. It will begin with a discussion regarding the multiple definitions used within interruption research. This will be followed by an examination of the impact of interruptions on cognition. Finally, the section will conclude by exploring the literature that researches interruption management.

2.3.1 Definition of interruptions

> *'An interruption is a secondary activity that requires one's attention and stops interaction with the primary task.'* (Li et al., 2012:6)

Within recent literature, Couffe and Michael (2017) highlight that interruptions are known to divert the focus of an individual's attention, as it forces them to consider distracting events which are often unanticipated and may have an impact on performance and speed. Whereas other researchers (Clapp and Gazzaley, 2012, Jett and George, 2003) break it down into four different types:

- Discrepancy – inconsistencies that are perceived between knowledge and expectations and the observations they make that are relevant to the task they are performing

- Distraction - psychological reaction to an external stimuli or secondary task

- Intrusion – an unexpected encounter by someone else that interrupt flow and continuity bringing it to a halt

- Break – planned or spontaneous recesses that interrupt flow and continuity

(Jett and George, 2003)

Within the literature concerning interruptions in healthcare these different definitions are used interchangeably (Biron et al., 2009, Hopkinson and Jennings, 2013). However, in their mixed methods, observational study Hall et al. (2010) reported significant levels of distractions and intrusions but very few discrepancies or breaks. The cause of these distractions and intrusions were individuals such as other healthcare professionals or patients and technical systems such as alarms or telephones. Li et al. (2012) established in their systematic review of 63 studies that clinical tasks can be split into three types: procedural, problem-solving or clinical decision making. The combination of the type of interruption, type of task, position in task and choice of handling strategy can all affect the impact of the task.

This section has explored the definition of interruptions by illuminating the literature that explores the different types. Understanding the different types of interruptions and providing a clear rationale for the one used is important in this field as it can affect the impact.

2.3.2 Cognitive impact of interruptions

In their systematic review (Li et al., 2012) identified three frameworks that were relevant to understanding the impact of interruptions; the activation goal memory model, the prospective memory model and multiple resource theory.

i. **Activation goal memory model** relates to automatic procedural type process where one step leads to another. If an interruption occurs during

the procedural task routine actions may stimulate the individual to re-focus.

ii. **Prospective memory** pertains to the individual's ability to remember to return and complete a task. This reminder is intrinsic and has no explicit prompt.

iii. **Multiple resource theory** links with the multi-tasking action; where two tasks compete for attention, and which may hamper performance. This may result in one task being abandoned.

One of the dominant psychological theories that attempts to understand the impact of interruptions is that of prospective memory (Grundgeiger and Sanderson, 2009, Grundgeiger et al., 2016). Where interruptions can cause the individuals to forget where they are in the process and/or what their next step should be Prospective memory performance is affected by the individual's ability to recall a future plan or intention without being reminded (Grundgeiger and Sanderson, 2009:299, Altmann et al., 2014, Dodhia and Dismukes, 2009). They note that it is relevant for the delivery of nursing care, due to there being a requirement to prioritise and adjust plans dependent on patients' condition and care needs. Furthermore, Grundgeiger and Sanderson (2009) highlighted that it is dependent on the individual either monitoring the environment for cues to aid their memory or there being an automatic association between the cue and action required. However, other factors can also influence interruptions such as workload and environmental factors (Hughes and Blegen, 2008). These factors are present within clinical settings exerting additional pressures on the working memory of nurses (Shackman et al., 2006).

It is possible that it is not only interruptions that impact on the working memory of nurses but that other reasons may increase levels of fatigue and have a detrimental effect. One key element that may affect fatigue in nursing is the use of 12-hour shifts. Recently researchers have also questioned the impact of twelve-hour shifts on fatigue and patient safety. In their systematic review Banakhar (2017) reported that there was limited evidence to suggest that 12-hour shifts had a negative effect on fatigue. However, it was noted by Ball et al. (2015) that the use of 12-hour shifts increased fatigue and poor quality of care.

Furthermore, Stimpfel et al. (2013) found that paediatric nurses working 12-hour shifts reported more adverse events and lower quality standards.

In contrast to prospective memory, Parker and Coiera (2000) focused on a the working memory, that can be identified as the state of attention. The working memory collates a small amount of information required to perform tasks, such as mental calculations, but, it may be limited by factors such as stress, hunger or tiredness (Blasiman and Was, 2018). Interruptions can easily interfere with the information stored in the working memory, causing it to be impaired. Parker and Coiera (2000) state that accurate memory lasts for a maximum of 20 seconds and items in the middle of the list are more at risk of being forgotten due to longer term objectives and more recent additions being more accurately recalled. In addition, Grundgeiger and Sanderson (2009) note that a delay of 10 seconds on the working memory can also have a detrimental effect on prospective memory performance. Ultimately, within healthcare and in particular medication administration, interruptions can be detrimental to the nurse's memory, leading to a potential impact on patient safety.

This section has explored the cognitive impact of interruptions, paying particular attention to the prospective and working memory. However, it has also identified alternate factors that could have detrimental impact on memory indicating that it is not only interruptions that could lead to error and harm.

2.3.3 Interruption management in nursing

Interruptions can lead to a capture error which was noted by Leape et al. (1995) to occur when the sequences from two actions overlap, which can lead to error. Often models of interruption management focus on the switching from primary to secondary tasks (Colligan and Bass, 2012). However, Clark (1996) described four reactions to interruptions; full compliance, accept with alteration, decline or withdraw.

Colligan and Bass (2012) in their qualitative study of interruption management in paediatric medication administration, suggest that not all interruptions stimulate the same response. They propose, that after an interruption, the

individual could select a handling strategy and they propose a four-level taxonomy (see Table 2). Three levels allow the interruption to occur and the fourth to block it. When applied to medication administration they found that nurses dynamically assessed both the primary task and the interruption. This assessment included a measurement of risk and efficiency but was influenced by experience.

Table 2 - Handling strategies

Handling strategy	Definition
Engage	Interruption is high priority and primary task is suspended
Multi-task	Interruption and primary task have equal priority and attention is divided
Mediation	An action is taken to support the individual remember where in the

	process they were (supports prospective memory). Or the interruption is delegated
Blocking	The primary task is high priority, and the interruption is blocked

In conclusion, section 2.3 has explored the complex phenomenon of interruptions, their impact on cognitive ability and how they are responded to. The literature explored has suggested that there are alternative factors that could influence prospective and working memory in addition to interruptions that could lead to errors. Furthermore, individuals have a choice in how they respond to interruptions and the small amount of literature available suggests that experienced nurses are skilled at managing this complex phenomenon.

2.4 Interruptions and errors

Previously this chapter has explored the medication administration process and the theory that underpins knowledge of interruptions and their management. Developing this further, this section will explore the impact of interruptions on the medication administration process and the relationship with errors.

2.4.1 Impact of Interruptions on medication administration and errors

The impact of interruptions on work activity has been demonstrated in empirical studies (Bailey and Konstan, 2006, Eyrolle and Cellier, 2000) with them establishing a negative impact on performance and increase in errors. In alternative safety critical industries, such as aviation, a strong link has been established between interruptions and error, after several accident investigations cited interruptions as the cause (Iani and Wickens, 2007, Roelen and Klompstra, 2012, Gordon et al., 2012, Reason, 1990, Reason, 2000). Since the turn of the century this knowledge has been applied to healthcare resulting in the development of interventions within many different areas of healthcare, such as anaesthesia, emergency medicine and medication administration (Powell-Dunford et al., 2017, Kapur et al., 2015, Reason, 2000, Green et al., 2017a, Green et al., 2017b).

There is a significant amount of evidence (Brixey et al., 2005, Brixey et al., 2008, Chisholm et al., 2000, Hall et al., 2010, Potter et al., 2005) that demonstrate significant interruption rates in healthcare. For instance, Hall et al. (2010) completed 2880 hours of observation of nursing care and recorded 13 025 interruptions, suggesting an interruption rate of 4.5 per hour. Of the 13 025 interruptions 25% occurred during medication preparation and administration. However, in an Adult Intensive Care Unit Sasangohar et al. (2014) completed 48 hours of observation and noted 1007 interruptions, creating a rate of 21 interruptions per hour. The results of that study suggested a significant increase in interruption rates within the intensive care environment. The examination of studies that focus on medication administration (Biron et al., 2009, Palese et al., 2009, Kreckler et al., 2008) demonstrate significant interruption rates. Biron et al. (2009) suggested in their evidence review that there was an interruption rate to 6.7 per hour when medication administration studies were analysed. However, this study is limited due to it not being a systematic review and not including a meta-analysis. Furthermore, in his ethnographic study Potter et al. (2005) reported 1.2 interruptions per hour in the medication room when a human factors expert completed the observation. This may suggest that interruptions to medication administration are lower when the process is completed within a medication room.

Moving on from the cognitive effects of interruptions and their impact on the medication administration process it is important to explore their link with errors, as the literature often indicates that there is limited clinical evidence to support this and assumptions are made (Sanderson et al., 2019, Grundgeiger and Sanderson, 2009). Interruption rates have been measured frequently within the literature (Biron et al., 2009, Hall et al., 2010) and researchers have demonstrated high levels. An external human factors researcher in an ethnographic study by Potter et al. (2005) measured overall interruption rates at 5.9/hr although during medication administration this reduced to 1.3/hr. Alternatively, Kalisch and Aebersold (2010) demonstrated that interruption rates were found to be 10/hour and Brixey et al. (2005) concluded that 11.86% of tasks completed by a registered nurse were interrupted. Yoder et al. (2015) reviewed 12 studies and found both systematic and individual factors that caused medication errors. Such as work patterns, staffing levels, illegible

prescriptions, fatigue and lack of knowledge. They also indicated from this review that 45-50% of errors were linked to distractions or interruptions. In contrast, Potter et al. (2005) found that 24% of interruptions preceded a change in cognitive task, but no association with any errors. Likewise, Kalisch and Aebersold (2010) completed an observational study of 36 nurses, they reported that there was no significant association between interruptions, multitasking and errors. Furthermore, although there were higher rates of interruptions in AICU, there were no differences in error rates. However, both studies included observation of all nursing care not only medication administration.

Interruptions have been frequently noted as occurring within the medication administration process (Potter et al., 2005, Brixey et al., 2004, Sasangohar et al., 2015) and have been cited as a contributory factor in causing medication errors (Anthony et al., 2010, Colligan et al., 2012, Sasangohar et al., 2015, Keers et al., 2013a). When Blignaut et al. (2017) focused on medication administration (1847 episodes) in adult medical and surgical units, their cross-sectional observational study identified that interruptions were significantly associated with wrong dose errors. Johnson et al. (2017) reported in their non-participant study that 3.6% of the 56 medication episodes observed resulted in a clinical error. Moreover, Westbrook et al. (2010) identified in their observational study of 4271 medication administration episodes and reported that when interruptions occurred they were associated with a 12% increase in procedural failures and clinical errors. Furthermore, when interruptions were frequent the error severity increased. Each of these studies employed the method of observation which is always at risk of the 'Hawthorne effect' (Bryman, 2016), that is the presence of the observer may influence the behaviour displayed and this should be considered a limitation. Although these studies (Blignaut et al., 2017, Johnson et al., 2017, Westbrook et al., 2010) suggest an association between interruptions and errors, what is not evident is whether these errors would have occurred even if an interruption had not been present. Coupled with this lack of knowledge is not knowing the reason for the interruption after all, Hall et al. (2010) suggest that 10% of interruptions occur for positive reasons such as sharing clinical information, and may prevent further patient safety issues.

Within this section the relationship between interruptions and errors has been explored. Initially looking at this association within the delivery of nursing care followed by the links between interruptions and errors in the medication administration process. Ultimately it is difficult to prove a direct causal link between the interruption and error, but their presence is suggestive of a higher risk of mistakes being made or procedures not being followed.

2.4.2 Interventions to reduce interruptions to medication administration

Interventions to reduce interruptions during medication administration were first tested in adult healthcare practice over 15 years ago. The seminal study tested protocols and tabards (Pape, 2003) with the aim of isolating the task of medicine administration and preventing interruptions. This study by Pape (2003) was informed by the application of practices from the aviation field.

In 2009, to inform the intervention literature, Shrivastava et al (2009) linked this phenomenon with aviation safety under the High Reliability Theory. This was developed through the study of organisations that aimed to be failure or error free, such as air traffic control and the nuclear industry. Through this study of high reliability, concepts that deliver zero errors were felt to be useful in being implemented in other areas that delivered high risk services. Consequently, high reliability principles have been used in healthcare to address problems that in turn contribute to increases in patient safety (Sutcliffe et al., 2017). Pronovost et al. (2015) found that the implementation of a high reliability system demonstrated significant improvements in both performance and governance structures.

Critics of High Reliability Theory note a lack of empirical research demonstrating a cause-and-effect relationship with safety outcomes (Lekkha, 2011). The organisational ability to remain error free indicates that they can predict and anticipate problems and plan for their occurrence. However, organisations such as healthcare are unpredictable and therefore unable to anticipate all future problems. This is relevant to interruptions to medication where events such as patient deterioration cannot always be predicted in advance.

Within aviation safety the framework developed by Roelen and Klompstra (2012), included the development of policy, risk assessment, assurance and safety promotion. Within aviation safety, distractions and interruptions were noted to contribute to errors, with Flight Safety (2012) stating that they had the potential to disrupt focus and reduce situational awareness. To try to reduce interruptions and their impact in aviation the sterile cockpit ruling was introduced. Lewis et al. (2011) state that the sterile cockpit ruling means that during critical tasks within the flight such as taxiing, take-off and landing (flying below 10 000 feet) the crew must not engage in non-essential activities or conversations. Historically, flight accident investigators identified that these activities frequently contributed to fatal accidents (Lewis et al., 2011, Baron, 1997). Although, Baron (1997), Flight Safety (2012) and Wiener (1993) highlighted that the introduction of the sterile cockpit alone created problems as flight attendants were unsure when and how to interrupt the pilots when safety issues arose. This resulted in the additional Crew Resource Management training which addressed these problems by focusing on teamwork and communication. Although the practice has been highlighted by Wiener (1993) as a controversial intervention, as it invades the cockpit atmosphere and restricts self-expression it remains embedded within aviation (Lewis et al., 2011).

Gordon et al. (2012:10) identify three theories that have supported the development of aviation safety processes: emotional intelligence; team intelligence; and distributed cognition. Within aviation safety, emotional intelligence is the focus as attributes such as leadership are important elements within safety practices in aviation. Emotional intelligence acknowledges the individual's ability to identify and monitor both feelings and emotions and use this information to guide thoughts and actions (Salovey and Mayer, 1990:189). Furthermore, Stubbs Koman and Wolff (2008) summarise the definition of emotional intelligence as the ability to recognise and regulate emotions. Strong emotional intelligence is thought to be an important skill to be able to demonstrate strong leadership (Gordon et al., 2012) and requires four skills: self-awareness, self-management, social awareness and relationship management. However, Cherniss (2010) highlights two limitations of emotional intelligence theory, firstly the wide range of definitions and models available and

secondly the limited validation of measurement instruments. These limitations may restrict the ability of individuals to develop their skills in emotional intelligence.

Gordon et al. (2012) were also critical of the theory because it was too focused on self-regulation and monitoring and does not increase awareness of the impact of individual behaviour within the team. Furthermore, emotional intelligence does not recognise the importance of social awareness and relationship management, that are important within a team but has been identified as a potential pre-requisite for team intelligence. It has been noted that high functioning teams have been demonstrated to have collectively high emotional intelligence levels (Gordon et al., 2012, Stubbs Koman and Wolff, 2008, Cherniss, 2010). Emotional intelligence is particularly relevant for team leaders, they are required to understand all four domains and be responsible for their own emotions and those of others. Stubbs Koman and Wolff (2008) suggest that an emotionally intelligent leader can enhance the abilities of others. Team intelligence theory has developed this further, although there is little written about it (Runsten, 2017). Gordon et al. (2012) as define it as effective action and interaction from and between team members. It differs from individual emotional intellect due to the social and communicative skills required (Runsten, 2017) and an intelligent team will have a shared mission with associated goals.

Gordon et al. (2012:11) identify four elements required in team intelligence:

i) Shared team identity – the articulation of shared mental model, language and assumptions which allow them to achieve the team goal.

ii) The ability to share information, cross monitor, coach, request input and listen to the response regardless of the members position in the organisational hierarchy.

iii) Members must understand different roles within the organisation and how they work together to achieve goals.

iv) There must be a collective ability to help and support each other so that jobs can be done effectively and efficiently.

In contrast, (Runsten, 2017) argues that there is very little research that examines the intelligence, emotions and personality traits at group level. He acknowledges that there needs to be greater understanding about the relationship between individual and team intelligence. Furthermore, greater understanding is required about the factors that influence individual intelligence and their impact on the team. Each team will be formed from unique members with individual emotional intelligence, and it is difficult to comprehend how every team will work together in the same way.

Associated with team intelligence is the theory of distributed cognition, this is defined by Gordon et al. (2012) as the ability to think about tasks and roles and how they impact on other members of the team. Nardi (1996) offers further explanation of distributed cognition, an activity such as flying a plane should be thought of as a system, that would not be comprehensively understood if roles or tasks are examined individually. The theory of cognitive distribution suggests that all tasks, roles, interactions and coordination of these elements must be examined in unity, as they are all required for the successful completion of the activity. Limitations of the theory have been highlighted in studies (Rajkomar and Blandford, 2012, Halverson and Clifford, 2006) where distributed cognition theory has been used to further understand systems and how they work, although limitations have been identified. Rajkomar and Blandford (2012) discovered that the use of distributed cognition within their study of infusion administration in the intensive care unit was limited due to its inability to analyse dynamic properties within the environment. Furthermore, Halverson and Clifford (2006) discovered that the theory was unable to comprehend the motivational factors that encouraged or restricted the implementation of interventions aiming to change practice. Understanding the limitations of each theory is an important element of comprehending how they relate to the interventions used in practice

Since the initial study by Pape (2003) multiple studies have tested different interventions such as, visible clothing, no interruption zones, visible signs and

medication administration training programmes in order to reduce interruptions. A review of the research associated with interruptions by McCurdie et al. (2017) categorised studies into four main types; epidemiology, quality improvement, cognitive systems engineering and finally applied cognitive psychology. This review has been developed further in Table 3 to display the relationship between these research traditions and interventions to reduce interruptions to medication administration as well as the underpinning theory. It is evident from Table 3 that despite much published research on the topic, there are few studies that are linked to behavioural or cognitive psychology theories to interruption interventions. However, studies where interventions to reduce interruptions to medication administration are implemented the main research methods used were epidemiology methods or quality improvement. Furthermore, the most common theory used to inform the development of intervention was aviation safety. Within this theory the primary focus is the development of standard procedures and teamwork.

Table 3 - Summary of Interventional Studies

Research category	Primary Research	Associated theories	Participants
Epidemiology (Observational fieldwork and quantitative analysis to determine the burden and eradicate the problem)	Anthony et al (2010)	High reliability theory Sterile cockpit/aviation	Registered Nurse (RN)
	Choo et al (2013)		RN
	Craig et al (2014)		RN
	Kreckler (2008)		RN
	Nelms and Trieber (2011)	Watson's Caritas Model	RN
	Pape (2003)	Aviation theory	RN
	Relihan (2010)		Patients
	Verweiji et al (2014)		RN
	Westbrook et al (2017)		RN
	Yoder et al (2012/15)	Aviation theory	RN
Quality Improvement (Rapid change to improve safety; observational fieldwork and evaluation of intervention)	Capasso and Johnson (2012)		RN Student Nurses Patients
	Conrad et al (2010)	Critical thinking and judgement	Nurses
	Federwisch et al (2014)		RN
	Flynn et al (2016)		RN Support workers
	Fore et al (2013)	Sterile cockpit/aviation Crew Resource management	RN
	Freeman et al (2012)		RN
	Nguyen et al (2010)		RN
	Pape et al (2005)	Aviation theory	RN
	Pape et al (2013)	Aviation theory	RN
	Rochman et al (2012)		Healthcare professional graduates
	Scott et al (2010)		RN

			Other staff Patients
	Williams et al (2014)		RN
Cognitive systems engineering (understand purpose of interruptions and system-based re-design; naturalistic studies and simulation)	Campbell (2013)	Self-efficacy	Undergraduate Nurses
	Colligan et al (212)	Human factors Situational awareness	RN
	Thomas et al (2014)		Undergraduate Nurses
Applied cognitive psychology (Understand how interruptions disrupt cognitive processes in order to protect them; controlled laboratory studies)	Krautschied et al (2011)		Undergraduate Nurses

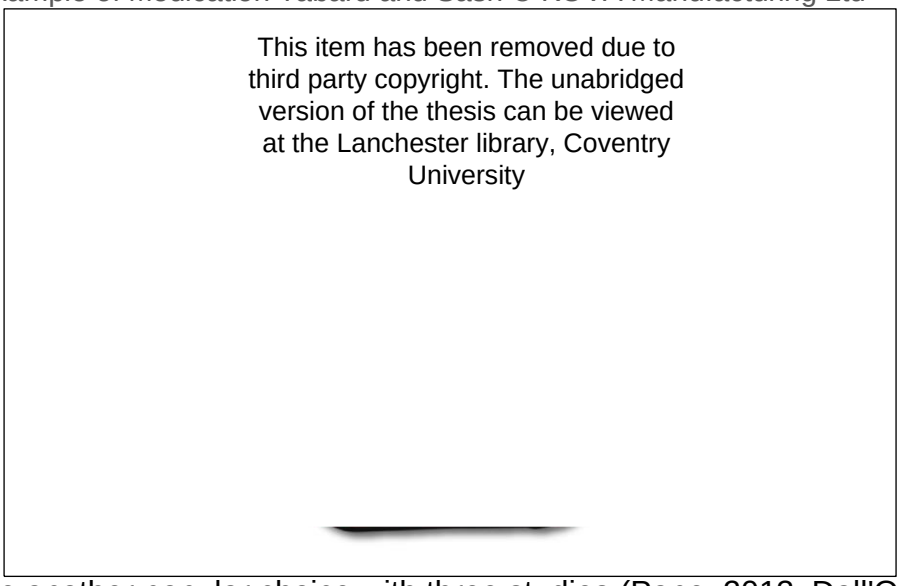
(Adapted from (McCurdie et al., 2017)

The information presented in Table 3 indicates the most used single interventions that includes distinctive clothing; protocols; NIZ's; visible signs; and education. Eleven studies used a combination of multiple interventions which were called 'bundles' (Dall'Oglio et al., 2017, Nelms et al., 2011, Relihan et al., 2010, Westbrook et al., 2017, Conrad et al., 2010, Federwisch et al., 2014, Fore et al., 2013, Freeman et al., 2013, Pape, 2013, Williams et al., 2014, Yoder et al., 2015). The following sections will now describe the intervention examine their effectiveness and explore the theoretical frameworks that are associated with them.

2.4.3 The use of distinctive clothing

The use of distinctive clothing (vests, tabards, lanyards, sashes, apron) is a frequently chosen intervention (see Figure 3 for pictures) , either as a single item (Choo et al., 2013, Craig et al., 2014, Pape, 2003, Scott et al., 2010, Verweij et al., 2014) or as part of a bundle (Dall'Oglio et al., 2017, Nelms et al., 2011, Relihan et al., 2010, Westbrook et al., 2017, Fore et al., 2013, Freeman et al., 2013, Williams et al., 2014, Pape, 2013)The terms tabard and vest are used within the literature to describe a short apron that has full front and back panels (see Figure 3 for an example), often they will have a 'do not disturb' message placed on both sides. Palese et al. (2019) interviewed 104 patients to ask their view of tabards, they indicated that the message may increase the risk of them not interrupting even for emergency issues. This indicates that patient/family involvement within the design of an intervention is important. Within the literature tabards were often coloured red (Scott et al., 2010, Pape, 2003, Westbrook et al., 2017, Williams et al., 2014) and less commonly yellow (Verweij et al., 2014), white (Craig et al., 2014) or orange (Fore et al., 2013). Only one study (Relihan et al., 2010) used a red plastic apron, these had no writing on them and would mainly be visible from the front.

Figure 3 - Example of Medication Tabard and Sash © KOVA Manufacturing Ltd



Sashes were another popular choice with three studies (Pape, 2013, Dall'Oglio et al., 2017, Nelms et al., 2011) selecting this item of distinctive clothing (see Figure 3 for an example). The sashes used were either fluorescent or yellow in colour. Finally, Freeman et al. (2013) used a lighted lanyard which was a red necklace that was switched on to flash during medication administration. Although this review has highlighted a variety of different distinctive clothing items, they all have the same rationale for use; to highlight to others that the wearer is involved in the medication administration process (Verweij et al., 2014).

When distinctive clothing items were implemented as an intervention, either on their own or as part of a bundle interruption rates were often shown to decrease. For example, Westbrook et al. (2017) found in their cluster randomised controlled feasibility study that non-medication interruptions decreased from 50/100 administration episodes to 34/100 which was statistically significant. Verweij et al. (2014) noted their observational study a 75% reduction in interruptions but not from patients as well as a 66% reduction in medication errors. Pape (2003) completed a quasi-experiment to test two interventions (protocol and tabard). She identified that the use of a tabard had a significant impact on interruption rates. The analysis involved a one-way analysis of variance (ANOVA) which demonstrated that the group wearing the vest received less interruptions than either the control group or the group with a focused protocol. However, when using an ANOVA test there is an assumption that the variances in the groups are equal (Field, 2013), and require the completion of a homogeneity of variance test. Pape (2003) did not complete this test for the number

of medications administered which may affect the analysis as incorrect assumptions may have been drawn, creating a limitation flaw in the analysis of the data.

In their Delphi study, Laustsen and Brahe (2015) achieved an expert consensus stating that tabards are useful in the reduction of interruptions during medication administration, although, limited rationale for this assumption is provided which may add a bias to the study. Conversely, Craig et al. (2014) conducted a quasi-experiment where a white vest with associated protocols and education for support staff were implemented to reduce interruptions. Analysis identified that the length of interruptions increased with the introduction of the intervention, that could not be accounted for. It showed reduced interruption rates in all areas, including reasons such as missing equipment that the use of clothing should have limited impact upon. This may suggest that it is not only the intervention of a tabard that reduces interruptions but the associated increased awareness of the issue. The maintenance of this awareness can be difficult resulting in the intervention having limited impact in the long term. Additional studies such as (Verweij et al., 2014, Williams et al., 2014, Yoder et al., 2015, Nelms et al., 2011) found issues with compliance. Further investigation highlighted issues with the colour, feeling hot, negative feedback or feeling they were unfriendly for patients. The identification of these issues suggests that there are circumstances that would influence engagement and compliance with the use of distinctive clothing as an intervention.

In addition to the use of aviation safety theory to underpin the use of distinctive clothing Nelms et al. (2011) used Watson's Theory of Human Caring to support the implementation of sashes. As the sash was put in place the individual nurse was expected to take a moment to reflect and focus their attention on the medication process. This theory was developed by Jean Watson between 1975 and 1979 having been influenced by a combination of her own views of nursing and her studies within educational, clinical and social psychology (Watson, 2015, Clark, 2016). Watson (2015) identified a common meaning (caring) that transcended settings, population and specialty whilst expanding beyond the physical world view which dominated medicine, by seeking to understand the lived experiences of patients. Therefore, seeking to balance curative medicine with the philosophy of human healing using transpersonal relationships.

Clark (2016) identified that transpersonal healing-caring experiences were a core element of this theory as they require the nurse and patient to meet as equal partners. This partnership allowed them to share their lived experiences, be fully present in the moment and connect so that a relationship could develop that expanded beyond the individual. To help the nurse achieve this Watson (2015) identified ten processes that support the nurse in the delivery of individualised, holistic nursing care (see Table 4). This theory allows the use of technology within nursing and is also congruent with clinical research, such as the study completed by Nelms et al. (2011). The processes highlighted in blue are the ones selected by Nelms et al. (2011) to inform the development of their intervention to reduce interruptions to medication administration. These were selected as they were particularly relevant to the task of medication administration. Practicing with equanimity supports the nurse to be calm under stress, being authentically present ensures focus on the process and medication administration forms part of the trusting relationship between nurse and patient, therefore safe practice is essential (Nelms et al., 2011).

Table 4 - Watson's Ten Caritas Processes

(Watson, 2015)

Criticisms of the theory include a need for philosophical underpinnings to be more consistent with clear and operational definitions alongside the validation of the Caritas processes and outcomes of transpersonal caring (Sourial, 1996). This would enable the theory to be translated consistently into every day, clinical practice, particularly in the development of building caring relationships between nurse and patient. Furthermore, research studies are beginning to demonstrate the benefits and the validation of using Watson's theory as a framework for interventions.

This section has explored the use of distinctive clothing as an intervention to reduce interruptions to medication administration. It has provided a clear definition of the intervention and the associated theoretical frameworks that support their development. Whilst the empirical research included within the review demonstrates success in reducing interruption errors there are identified issues that will influence engagement and compliance with these interventions.

2.4.4 The use of protocols to reduce interruptions

The use of protocols to reduce interruptions to medication administration has been influenced by aviation safety (see Section 2.4.3), where pilots are expected to follow a standard operating procedure that coordinates their actions. Contained within these protocols are clear lines of authority and communication strategies that the team is expected to adhere to (Pape, 2003, Hohenhaus and Powell, 2008).

Within medication administration, five studies have included the use of a protocol (Pape, 2003, Pape et al., 2005, Conrad et al., 2010, Pape, 2013, Flynn, 2016). The

original study by Pape (2003) used a 12-step nursing protocol for the whole process of medication administration and this was more effective when combined with a red tabard. Whereas in the 2005 study the protocol had been reduced to seven steps (Pape et al., 2005). In their quality improvement study, Pape et al. (2005) added visible signs to the protocol, that informed staff and visitors that medication administration was in progress. Adherence to this protocol was assessed by observers and the findings indicated increased focus and standardisation in the medication process. However, data was only collected after the implementation of the protocol, so improvement is only anecdotal not empirical. The limitation of this study was that they were unable to demonstrate improvement as only have post intervention data. Pape (2013) used this protocol within a bundle of interventions (visible signs, NIZ, yellow sash and teamwork) and reported 84% less interruptions within the intervention group when compared to the control. Conrad et al. (2010) indicated that interruptions reduced from a median of four interruptions per medication administration to one, but this was not assessed for statistical significance. All the protocols in these studies referenced or were influenced by the 'Rights Framework' that was discussed in Section 2.2, where it was noted that the framework may be too simplistic and not comprehend the complexity of the medication process. The use of this framework within interventions to reduce interruptions may also affect compliance in practice.

In contrast, Flynn (2006) developed the use of protocols by implementing a set of guidelines that promoted communication, coordination of care and teamwork during medication administration. The analysis focused on reducing interruptions and assessing the impact of this change on medication error rates. This was a pilot study that was tested on two cardiac units with a third acting as a control unit. The pilot occurred over an 18-month period, but it is not clear when the post-intervention data was collected in relation to the implementation date. When the guidelines were introduced, the whole team received instruction regarding the implementation, communication and managing workload. Observation was the method used to collect the data; interrater reliability was assessed as 96%. The implementation of these guidelines provided mixed results with a reduction in interruptions in unit one from 23% to 4% but in unit two there was minimal change and in the third unit interruptions increased. It would have been useful to note whether the guidelines were successfully implemented in unit two and to understand possible differences within the baseline cultures of each unit. Interestingly, further analysis illuminated that units one and two

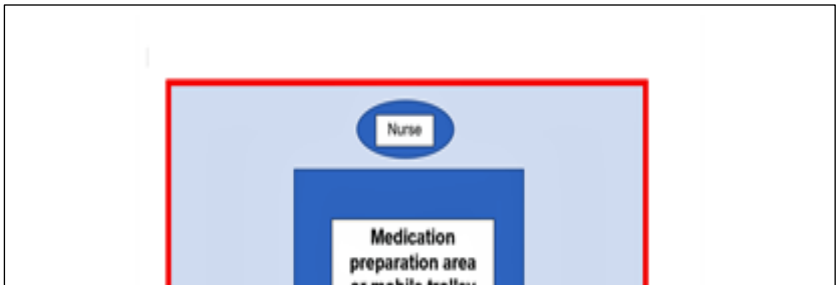
had been successful in reducing avoidable interruptions (unavoidable interruptions had increased in unit two to result in minimal overall change). Surprisingly, medication errors were seen to decrease in all three units, except only unit one and three had a high enough level of medication errors at baseline to perform statistical analysis.

The results of these studies raise the question whether it is the reduction of interruptions that decreases errors or the focus on improving medication safety. The reduction in avoidable errors in both intervention units suggests that this intervention may contribute to reducing errors, but they may not work on their own. Nevertheless, the content of this intervention is suggesting that the improvement of teamwork may to contribute to the reduction of errors in some clinical settings, suggesting it may be context dependent.

2.4.5 The use of a No Interruption Zone (NIZ)

A 'No Interruption Zone' (NIZ) has been the primary intervention in seven studies (Anthony et al., 2010, Dall'Oglio et al., 2017, Yoder et al., 2015, Freeman et al., 2013, Pape, 2013, Williams et al., 2014, Colligan et al., 2012). Two of these studies implemented a NIZ alone(Anthony et al., 2010, Colligan et al., 2012), whilst the remaining ones included it as part of a bundle. Five zones (Anthony et al., 2010, Dall'Oglio et al., 2017, Yoder et al., 2015, Pape, 2013, Williams et al., 2014) were marked with tape of which red and yellow were the colours of choice (see Figure 4). Colligan et al. (2012) created a centralised area with glass screens, whilst Freeman et al. (2013) used a medication room. All studies had similar rules that once nurses were in this zone preparing medications they should then not be interrupted.

Figure 4 - 'No Interruption Zone'



Each of the studies relate the theoretical underpinning of the NIZ intervention to the aviation industry and its use of a ‘sterile cockpit’ (see Section 2.4 for explanation of this theory). Within healthcare, the sterile cockpit rule has been transformed into a ‘No Interruption Zone’ (NIZ) and is recommended by the Institute for Safe Medication Practices (2012). Anthony et al. (2010) describe two methods of achieving this environment, by creating a physical area that is marked and signposted or by wearing a piece of visible clothing such as a brightly coloured tabard. Both methods require the professionals both within and outside of the zone to engage with the rule of no interruptions. As within aviation, these zones may be supported using checklists or protocols.

The use of a NIZ was first tested by (Anthony et al., 2010) in AICU. Nurses involved in the study were blinded to the intervention, but they did receive education about the no interruption zone, so it is difficult to imagine how they remained blind in the study. The pre-intervention data showed 76 interruptions during 218 episodes of medication administration and post-intervention 37 interruptions during 179 episodes. The analysis showed that the percentage of interrupted episodes reduced from 31.8% to 18.8%. This data demonstrates a reduction in interruptions, but due to the pilot nature of the study that resulted in a single site and small sample the analysis will be underpowered and not generalisable.

In their paediatric study Colligan et al. (2012) used human factors approach to facilitate the design of a central medication station. The results of this study demonstrated that the mean interruption rate per minute of medication administration was reduced from

1.4 to 0.27 post-intervention which was statistically significant (<0.01) . As with (Anthony et al., 2010) only one time point post-intervention was measured, questioning the sustainability of the impact. Furthermore, observers were not blinded to the intervention so this could have introduced researcher bias into the study. Interestingly, nurses did not perceive that the new medication area made medication administration any safer. Although, this may be an indication that the team were resistant to change rather than a failure in the intervention.

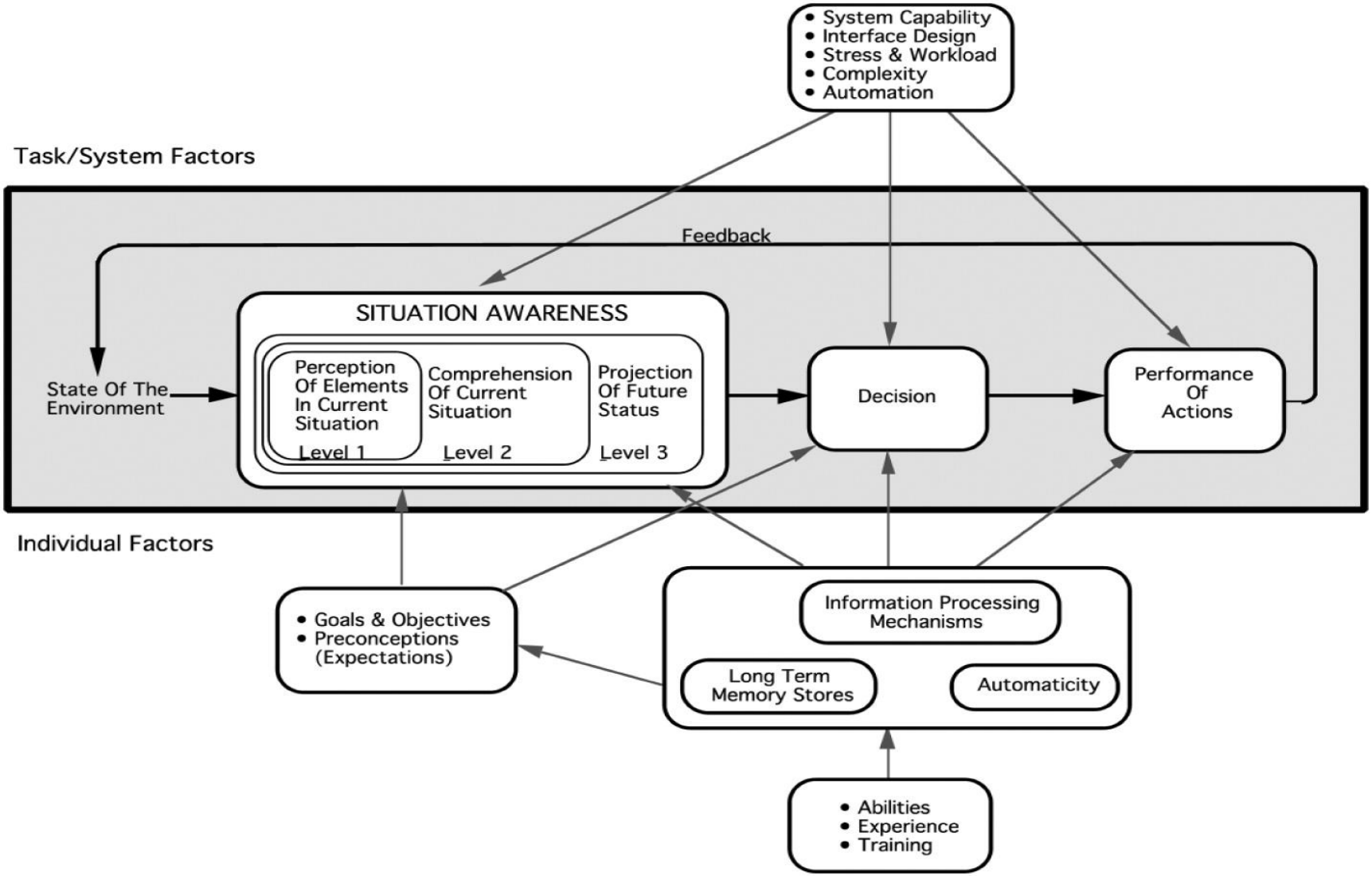
Human factors theory is a recent development in healthcare safety, having been implemented in the last twenty years (Catchpole, 2013). This theory combines disciplines such as psychology, engineering and physics with the Health and Safety Executive defining human factors as *'environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety'* (HSE, 1999). It is particularly helpful in healthcare as it focuses on the cognitive workload of professionals whilst promoting patient safety (Russ et al., 2013), which is similar to medication administration research. Within healthcare, the two goals of human factors theory are:

i) to support the cognitive and physical work of professionals

ii) prevent accidental harm to patients.

Within this theory communication, situational awareness and decision making are essential components. Situational awareness is simply defined by Endsley and Garland (2000) as the ability to comprehend what is going on around you. Situational awareness can be influenced by multiple factors, Endsley and Garland (2000) describe a model that includes individual factors such as memory, automaticity, goals, expectations and attention (see Figure 5). Although additional individual factors will be influenced by environmental structures such as workload, automation, complexity and stress.

Figure 5 - Situational Awareness



Situational awareness is important within healthcare where complex situations with multiple personnel require the leader to have an overall awareness rather than focusing on a single element. Despite the popularity of the information processing model, Salmon et al. (2008) list several criticisms of the theory. These criticisms include a lack of empirical evidence to support the model, it is based on poorly defined constructs, and it is unable to respond to the dynamic nature of situational awareness. In addition, Salmon et al. (2008) highlight that situational awareness theories cannot be validated as the concept of situational awareness is difficult to observe. In the reflection in section 2.2 the need for situational awareness whilst preparing medication was illuminated, therefore understanding this concept will be important within this study, as there is no observation within the study design findings will be dependent on participant perception of the concept.

Colligan et al. (2012) created a definitive zone but its design allowed families/patients to see where nurses were located and minimising concerns that staff would become 'unavailable' which was a concern. Similarly, Federwisch et al. (2014) question the usefulness of the 'sterile cockpit' concept. They introduced a medication quiet time rather than a static zone, in addition to bedside rounding, education and visible signs. This study used nurse's perceptions of reductions in interruptions and despite a prolonged use of these interventions the nursing team did not perceive that the rate of interruptions reduced significantly. The study was abandoned due to the workload increasing for other team members whilst nurses were uninterrupted during medication administration. These last two studies (Federwisch et al., 2014, Colligan et al., 2012) have illuminated the importance of nurses engaging with and perceiving benefit when any intervention to reduce interruptions is implemented.

In summary, this section has provided clarity concerning the different types of NIZ's used in healthcare. Whilst the studies provide evidence that NIZ's can reduce interruptions, nurses identified issues with their use that affected engagement with the intervention. Understanding the circumstances that impacted on engagement in more detail is required.

2.4.6 The use of visible signage

An alternative intervention implemented to reduce interruptions is the use of visible signs (see Figure 6 for an example). Historically visible signs have been used to direct behaviour, in particular and are associated with warnings of danger (Pape et al., 2005). The signs may have a visual design like those used on roads or may include written text. Similarly, in healthcare, visible signs are commonly used to signal danger or the need for caution, such as indicating when x-rays are in progress. Signs were seen to increase awareness of important situations but a concern that is linked with them is that of habituation; the sign no longer being seen (Pape et al., 2005). Federwisch et al. (2014) (see section 2.4.6 for details of study methods) attempted to negate this by making the signs removable but signs are likely to be overlooked if the consequences of the action are deemed acceptable (Pape et al., 2005).

Figure 6 - Example of a Visible Sign(Federwisch et al., 2014) © Wolters Kluwer

Pape et al. (2005) combined visible signs with a seven-step protocol. The signs were added in after the implementation of the protocol and analysis showed that the signs had greatest impact on interruptions caused by other nurses. Nevertheless, it is important to note that these interruptions were recorded by a validated self-report instrument. Thus, this data may be limited by the nurses' recollection of events that occurred resulting in the possible over or under reporting of interruptions. However,

this study by Pape et al. (2005) illuminates how different interventions may influence different types of interruptions.

2.4.7 The use of intervention bundles

In the narrative review, eleven studies (Dall'Oglio et al., 2017, Nelms et al., 2011, Relihan et al., 2010, Westbrook et al., 2017, Conrad et al., 2010, Federwisch et al., 2014, Fore et al., 2013, Freeman et al., 2013, Pape, 2013, Williams et al., 2014, Yoder et al., 2015) combine different interventions together into a bundle. The design of these studies often involves a combination of interventions (see Table 3 in section 2.4 for examples of different bundles) allowing different areas to be targeted such as behaviour, cognition and culture. Addressing these different areas suggests that studies are increasingly understanding that the medication administration process is complex.

Ten of the studies that included the implementation of a bundle demonstrated a decrease in interruption rates. Williams et al. (2014) found a statistically significant reduction in interruption rates from a mean of 7.94 per medication round to 2.13 per medication round. Similarly, Relihan et al. (2010) and Dall'Oglio et al. (2017) demonstrated statistically significant reductions in interruptions errors, with Fore et al. (2013) presenting a 42% reduction in medication errors. In contrast, Federwisch et al. (2014) abandoned their study due to a lack of engagement which was attributed to the additional workload placed on colleagues within the MDT that was associated with the intervention bundle. Furthermore, Yoder et al. (2015) found that RN's were not compliant with the bundle in 50-70% of administration episodes and that interruption rates increased. The increased rates were statistically significant where interruptions were caused by physicians, noises or family. In addition, medication error rates increased from 1.74 to 2.88 per 1000 bed days. It is important to recognise the variability in these results and to consider the importance of understanding why this has occurred.

Interestingly, Yoder et al. (2015) were one of the few studies to collect data from patients and they found an increase in patient satisfaction scores post-intervention, wither their perceptions about quality and safety increasing by 40%. Dall'Oglio et al. (2017) report that parents learned to delay their interruptions but did not collect any data from them to understand how and why these behaviours changed. Ultimately,

this review suggests that there is very limited engagement with either patients or parents/carers within this body of literature.

In summary, this section has explored the effectiveness of intervention bundles and their impact on reducing interruption rates and medication errors. It is possible that the implementation of a bundle that achieves results due to the different elements addressing the complexity of the phenomenon, however, it has been shown that these bundles are not 100% effective.

2.4.8 Education, training and interventions

A number of studies drawn for the narrative review (Capasso and Johnson, 2012, Conrad et al., 2010, Craig et al., 2014, Federwisch et al., 2014, Freeman et al., 2013, Pape et al., 2005, Relihan et al., 2010, Williams et al., 2014, Yoder et al., 2015) included training within their intervention for Registered Nurses working in the area where the intervention was implemented. Conrad et al. (2010) aimed to create a standard medication process that would enhance efficiency and patient safety with a training plan that formed a significant part of the intervention. The programme focused on clinical practice, concentrating on policy, technology and creating a safe environment. Results showed that the median rates of interruptions reduced from four to one per medication administration episode. Furthermore, the median duration of each medication episode reduced from 15 minutes to ten minutes. Over a period of three years' medication errors had reduced by 53%. This study appears to have achieved and sustained its aim to deliver a medication process that is efficient and safe. It may be argued that this study attempted to increase knowledge with its education programme rather than focusing on strategies purely attempting to change behaviour. This strategy of addressing cognitive processes may account for the sustained improvement in rates over a three-year period, but the interventions were not tested individually to prove or disprove this theory.

In contrast, four studies focused specific groups such as nursing students or newly qualified nurses (Krautscheid et al., 2011, Campbell, 2013, Rochman et al., 2012, Thomas et al., 2014). The programmes for student or newly qualified nurses are important to acknowledge as Pape et al. (2005) noted that distractions would affect the new nurse or newly employed nurse more frequently. These studies attempted to use laboratory and simulation settings to address training and medication

administration. They attempted to address the theory/practice gap between the classroom and clinical practice. Krautscheid et al. (2011) increased the practical teaching regarding medication administration with student nurses within a laboratory setting. Although, the qualitative, in-depth evaluation of this programme identified that this method did not prepare nurses for the interruptions/distractions experienced within the real clinical world. They recommended that programmes should teach communication and conflict management strategies to help nurses learn how to reduce or eliminate distractions.

The simulation study by (Rochman et al., 2012) recruited interdisciplinary graduate students. The aim of this study was to increase non-nurse awareness of the impact of interruptions on nurses. Medication administration formed part of all four scenarios tested. The evaluation indicated that the simulations allowed participants to increase their understanding of the impact of interruptions on nurses in their attempt to administer safe care.

Campbell (2013) used a theory of self-efficacy to underpin a more formal educational programme. It was felt to be an appropriate theory due to the complexity of the medication task that required both cognitive and psychomotor skills. A simulation programme was designed to improve medication administration skills. Volunteer students were randomised into either the simulation programme or the control group of traditional learning. This study demonstrated that students felt that they obtained the required knowledge from the simulation. However, when they were graded in clinical practice more students in the control group met the requirements for safety issues such as patient identification and dosage assessment. This indicates that simulated knowledge does not always easily transfer into the real world.

The theory of self-efficacy originates from the writing of psychologist Albert Bandura. Self-efficacy is associated with an individual's ability to succeed in the delivery of a task. Furthermore, the greater an individuals' belief in their self-efficacy the more likely they are to complete a task even if it is difficult. Bandura (1977) outlines four areas that can affect self-efficacy

i) performance accomplishment – repeated success will improve confidence and override occasional negative experiences

ii) vicarious experience – being able to safely observe others complete a task

iii) verbal persuasion – reinforcement of learning through repeated teaching

iv) emotional arousal - ensuring stressful situations are kept to a minimum

These areas link by allowing the individual to initially be receive teaching and observe the safe completion of a task, before being enabled to practice the task repeatedly in a non-threatening or stressful environment. In turn this increasing exposure, allowing the student to experience increasing responsibility for the task, increases their confidence. This increased confidence enables the individual to manage situations when the process may not run to plan, increased resilience can enable individuals to recover from negative experiences.

Researchers have critiqued the self-efficacy theory, with Williams (2015) questioning how much it can help identifying factors that influence motivation. Additionally, Phillips and Gully (1997) also question how much ability influences the constructs within the self-efficacy theory. They highlight that ability affects self-efficacy and can be modified in some circumstances, yet researchers have failed to control this factor when researching the theory. Furthermore, Phillips and Gully (1997) query how self-efficacy is developed and the impact factors such as individual learning have.

Another element that impacts on the delivery of a task is that of cognitive decision-making. Within the literature (Wang and Ruhe, 2007, Kinsey et al., 2019) cognitive decision making is thought to be a dual process theory as two interacting systems within the brain influence cognitive processing. One system is automatic where decisions are made non-consciously with no use of the working memory. This type of decision-making is quick and often based on inclinations, impressions and feelings. It is also thought that there are occasions where these reactions can be trained. Whilst the other is a reflective process that takes longer and uses conscious thought and is limited by the working memory. It is likely that this second process will be used during unfamiliar situations or during problem solving. Kinsey et al. (2019) also acknowledges the role of heuristics, sometimes referred to as the rule of thumb, where associations between events and reactions are developed. This process alongside the automatic system can contribute to quick decisions that are good enough and avoid error in the

most situations. Moreover, the quality of these decisions may be influenced by the how experienced the individual is and the context in which they are working.

In contrast Thomas et al. (2014) focused their simulation on the role that distractions may play on potential medication errors. The simulation required students to prepare 10 prescribed medications whilst listening to eight minutes of clinically common noises in via headphones. Examination of their prepared medications identified errors such as, incorrect solutions, lack of awareness of allergies to antibiotics. Participants reported that conversations were extremely distracting as they attempted to listen to them. The students also felt they were extremely competent at multitasking; but this was disproved by the errors that were seen.

Collectively, the existing literature reviewed identified that there are many interventions that have been tested to reduce interruptions during medication administration within healthcare settings. However, there appears no consensus regarding which to use, variation in acceptability and feasibility, and effect on reducing interruptions.

2.5 Insights and gaps in the literature

This narrative review has comprehensively explored the phenomena of interruptions to the medication process and interventions that have been employed to reduce them. The discussion within the review illuminated the complexities of the medication administration process and the challenges faced within healthcare when the process needs to be isolated. Moreover, it was suggested that interventions need to comprehend this complexity but that there is a conflict between the current design of interventions and how medication administration is conceptualised within nursing care. Therefore, this suggests that interventions to reduce interruptions to medication administration need to comprehend how the process is delivered within the real world of contemporary healthcare.

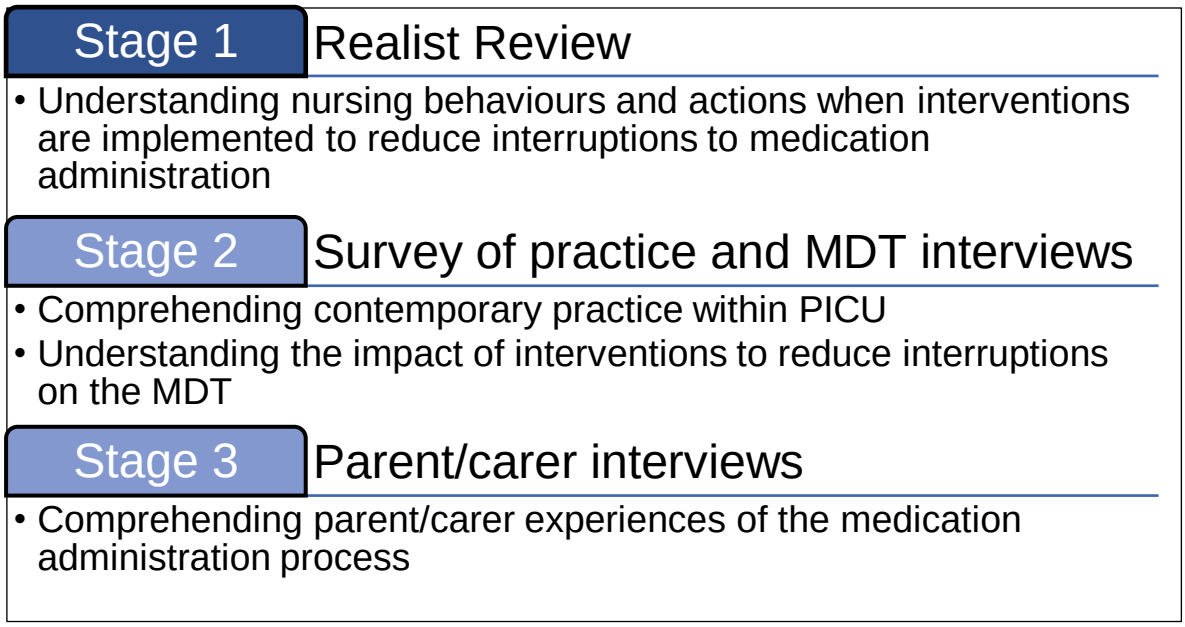
Following on from the complexities of the medication process the review highlighted that nursing behaviours and actions need to be understood and influence intervention design. In addition, these interventions require the input of the wider MDT team to understand their rationale for use and to proactively follow the rules of engagement. However, there were very few researchers (see Table 3) that included participants other than Registered Nurses within their sample.

The narrative review indicated that only two studies were conducted within paediatric settings and neither included PICU. Therefore, the current literature base has not explored this phenomenon within PICU and there is little evidence base to suggest which interventions have been implemented or evaluated their effectiveness. In addition, there was no reference to the management of interruptions such as patient deterioration that are essential and how they were managed. Within PICU the stability of the patient is unpredictable and being responsive to these changes is essential in the delivery of safe patient care. It is important that interventions comprehend this instability and do not solve one problem but increase a risk to patient safety in another area. The recognition of instability is important within the PICU environment as children can deteriorate very quickly when unwell and nurses need to be able to identify this as early as possible (Gawronski et al., 2018).

Finally, neither study had included parents/carers in their design. Therefore, it was important to understand parent/carer views and experiences of the medication process, interruptions and interventions to reduce them. In addition it has been highlighted in a previous study (Bower et al., 2017) that the presence of parents/carers within the PICU environment is an important influence in nurse decision making during medication administration.

The gaps identified within this narrative review have informed the study design for this thesis and they have been summarised in Figure 7. It was anticipated that the Realist Review would critically analyse current literature to explore how these interventions work, for whom and in which circumstances. The outcome of stage two will be to increase the knowledge base about contemporary practice in PICU, by understanding which interventions have been implemented and exploring their impact. Followed by increased comprehension of the impact of interventions on the MDT in PICU. Finally, the emphasis in stage three is understanding the parent/carer view of medication administration in PICU, which is currently absent. These findings from all three stages will then be discussed in a synthesis to understand how they relate and interact.

Figure 7 - Linking gaps in literature with study design



In conclusion Section 2.5 has identified the insights and gaps from the literature concerning the medication administration process, interventions to reduce interruptions and PICU. The gaps in the literature have been summarised in Figure 7 and linked to the design of the study. A comprehensive review of the selection of the methods in these stages will be provided in Chapter 3.

2.6 Conclusion

The narrative review followed a funnel shaped structure and began with an exploration of the medication administration process, its regulation and place within the delivery of nursing care. The key elements identified were:

- The complexities woven into the medication administration process
- The cognitive impact of interruptions and their association with error
- The common interventions used to reduce interruptions to the medication administration process and their effectiveness
- The key theories associated with the development of these interventions and their limitations

It was an important step in the development of this thesis as it has provided a contextual background for the study and contributed to the identification of gaps in the

current literature base. Following on from this narrative review, Chapter 3 will detail the methodology and methods used in the collection of empirical data in this thesis.

Chapter 3 Methodology

3.1 Introduction

The chapter will present the methodology for this study in terms of philosophy and design. The chapter will commence with the presentation of the aim and objectives of the study. The design of the study is then explored including both the philosophical paradigm and conceptual framework. Each stage (Realist Review and empirical study) will be critically discussed in turn. Specifically, the sampling, recruitment, consent, data collection and analysis methods supported by relevant literature. Integral to methodological decisions will also be ethics, quality and rigour of methods chosen. These are all vital considerations in any study in order to answer the posed research questions (Bryman, 2012).

3.2 Overarching research question, aim and objectives

The research question, aim and objectives have been presented earlier in Chapter 1 (sections 1.6.1, 1.6.2 and 1.6.3) but have been included here as a reminder.

Research question

How do interventions to reduce interruptions to medication administration work, for whom and under which circumstances within the Paediatric Intensive Care Unit?

Aim

To understand how, when and in which context interventions to reduce interruptions to medication administration in the PICU are effective.

Objectives

- Critically review the contemporary existing research to understand how, when and in what circumstances interventions work.
- Investigate what interventions are used in clinical practice across PICUs in England
- Explore perceptions and experiences of the multidisciplinary team in the medication process and interventions to reduce interruptions in PICU

- Explore perceptions and experiences of parents/carers in the medication process and interventions to reduce interruptions in PICU

- Synthesise these multiple perspectives to develop understanding of the Context mechanisms and outcomes in relation to interventions to reduce interruptions for medication administration within the PICU setting.

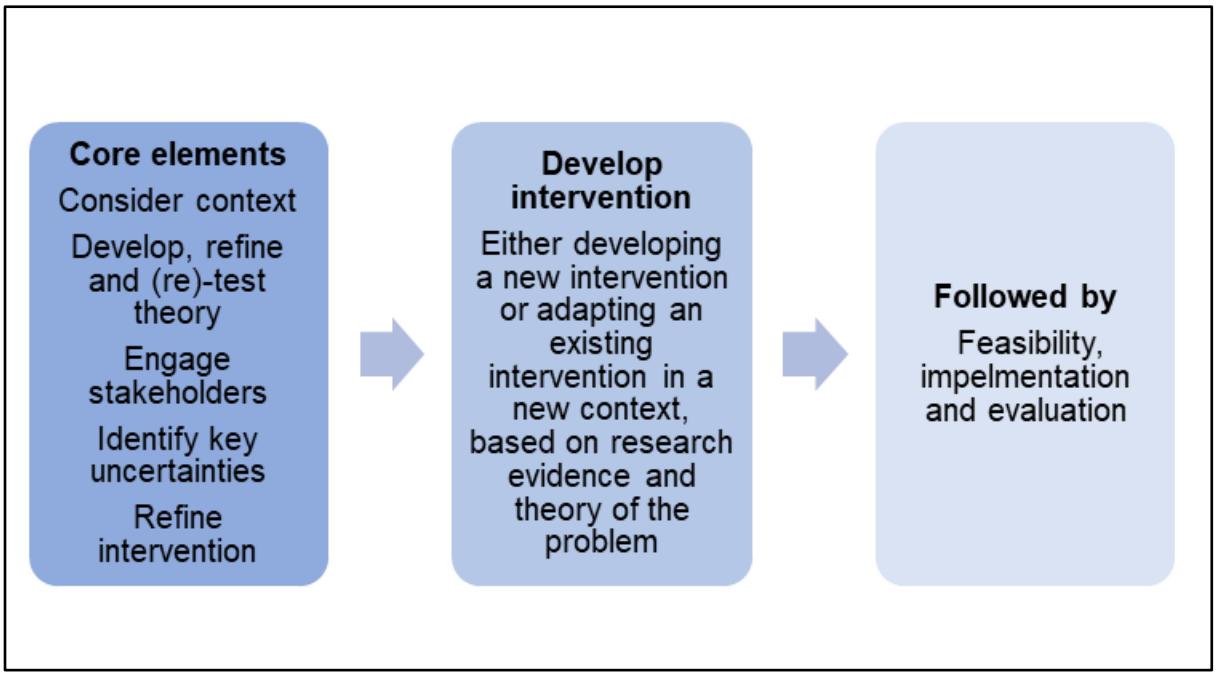
3.3 Overall study

In order to achieve the aim and objectives listed in section 3.2, the design of this study was supported by the Medical Research Council (MRC) Framework for the development of complex interventions (Skivington et al., 2021). The following section will explore how this framework was used and critically discuss its limitations.

3.3.1 Medical Research Council's Framework for the Development of Complex Interventions

The MRC Framework includes a four-staged approach to the development of a complex intervention, this has been summarised in Figure 8. This framework includes a development phase which seeks to understand which interventions work and in what contexts. This preparation is thought to be vital in the design of effective interventions (Skivington et al., 2021). This study purely focused on the development phase, as the aim of this study was to understand how current interventions work through the identification of theoretical frameworks and exploring their relevance to the intensive care environment. However, the MRC Framework does suggest that interventions should be tested in feasibility or pilot studies which incorporate rigorous evaluation before being implemented in practice. The process also encourages ongoing evaluation to ensure that the intervention is effective and does not negatively impact in other areas of practice.

Figure 8 - MRC Framework adapted from Skivington et al. (2021)



An intervention is classed as complex by Craig et al. (2008) when it has several interacting components. Lewin et al. (2017) extend this definition further to include the intervention having components which act dependently and independently and have active ingredients which are difficult to define. In addition, the intervention operates at individual, organisational or population level and targets patients through the use of healthcare workers or systems. Clark (2013) suggests that the power lies with the participants using the intervention rather than the tool itself and the understanding of mechanisms which influence their actions. Applying this framework to the development of an intervention attempts to ensure that the intervention comprehends the complexity of these underlying influences.

Historically the MRC Framework was criticised as researchers (Fletcher et al., 2016, Blackwood et al., 2010, Rycroft-Malone and Burton, 2010, Wilkinson, 2011) identified that the framework was flawed in its ontological and epistemological beliefs. The ontological and epistemological tenets within the MRC Framework were mixed, as a positivist ontology which was aligned with an interpretivist epistemology. The framework supported the use of qualitative methods within the developmental phase to explore the influence context had on the intervention before testing with a Randomised Controlled Trial (RCT). However, a recently published review of the MRC Framework (Skivington et al., 2021) presents an updated version that no longer

focuses purely on estimates of effectiveness but seeks to evaluate how interventions contribute to change and interact with the contexts in which they are implemented.

In order to address the knowledge deficits outlined in Chapter 2, and to address the aim and objectives of this thesis, a four-stage sequential exploratory design (outlined in Table 5) was developed. Each stage of the study was designed to meet the objectives listed in section 3.2. To meet the first objective, Stage 1 involved a Realist Review of contemporary international literature to understand how interventions to reduce interruptions to medication administration work within healthcare settings. This review was developed using the quality standards developed by Wong et al. (2014) and reported in Chapter 4 using Realist and Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES) (Wong et al., 2013). These quality standards were developed by Wong et al. (2014) and Wong et al. (2013) to ensure realist studies are robustly designed and reported. A Realist Review has not been completed in this field prior to this study, therefore the using this method new knowledge about these interventions was generated.

Meeting objective two was achieved through the use of a telephone survey that aimed to identify which PICU's within England had implemented interventions to reduce interruptions to medication administration. In addition, it was anticipated that the survey would identify when these interventions had been successful and how this had been measured.

The qualitative methodology used within Stage 2 (Part b) and Stage 3 aimed to understand individual perceptions and experiences of using existing interventions thus completing objectives three and four. These perceptions and experiences were obtained from a variety of professionals who delivered care to critically ill children to explain the context and mechanisms which influence the impact of such interventions. Therefore, their perceptions and experiences will also inform the development of an intervention to reduce interruptions to medication administration in PICU. The inclusion of the wider MDT and parents/carers was unique to this study as the literature predominantly captures data from the nursing team.

The final objective of exploring the multiple perspectives to develop understanding of the context, mechanisms and outcomes in relation to interventions to reduce interruptions for medication administration within the PICU setting was achieved by

the completion of a synthesis (Chapter 7). This synthesis aimed to critically explore the relationships and influences between the different perspectives to create an overarching explanation of how, when and for whom interventions to reduce interruptions to medication administration in PICU work.

Table 5 - Overall study design

Stage 1 - Realist review of the literature (May-December 2017)	Stage 2a – National survey of practice in English PICU's (October 2017-March 2018)	Stage 2b - Semi-structured interviews MDT team (October 2017-March 2018)	Stage 3 – Semi-structured interviews parents (March 2018-July 2018)
Rationale for inclusion • Contribute to identification of evidence base and gaps in knowledge • Identification of theoretical frameworks • To search for the contexts and mechanisms which influence the impact of interventions	**Rationale for inclusion** • Contribute to identification of evidence base • What interventions are being used and have they been measured for effectiveness? • Thematic analysis was conducted to identify any factors that influenced behaviours and actions when medications were administered within PICU	**Rationale for inclusion** • Address gaps in knowledge raised by realist review of literature • Use stakeholder experience to influence design of intervention • Explore barriers and facilitators to acceptability of intervention to aid process modelling and increase likelihood that future intervention would be successful • Thematic analysis of data to identify any factors that influenced behaviours and actions when medications were administered within the PICU	**Rationale for inclusion** • Address gaps in knowledge raised by realist review of the literature • Use parental experience to influence design of intervention • Explore barriers and facilitators to the acceptability of interventions to aid process modelling and increase likelihood that future intervention would be successful • Thematic analysis of data to identify themes that parents describe as being important when medicines were administered to their child
Stage 4 – Synthesis of findings **Rationale for inclusion** • To identify the overarching Context, Mechanism and outcome Configuration (CMOC)			

In summary, this section has illustrated how this study was designed to meet the aim and objectives presented at the beginning of the chapter. Moreover, it has demonstrated how the study aligns with the MRC Framework for the development of complex interventions. Whilst the section has illuminated the limitations of the MRC Framework, it has also conveyed the benefit of using Critical Realism in this situation.

3.4 Philosophical Underpinnings

The different methods of collecting data within research are associated with contrasting ontological (truth) and epistemological (knowledge) considerations (Bryman, 2012). Grix (2002:177) and Crotty (1998) consider ontology to be 'the starting point' of research as it concerns reality and how people perceive it. One view of ontology is that of objectivism which notes that reality is external to and uncontrolled by the population under examination. Conversely, constructivism refers to a process where social phenomena are continually adapted by the population (Bryman, 2012, Grix, 2002, Mustafa, 2011). Whilst ontology refers to what we may know, it is also important to consider epistemological viewpoints which relate to how individuals know about social reality.

Epistemology is acknowledged by Boyd et al. (1991) to examine the origins, scope, nature and limitations of knowledge. It is described by Crotty (1998:3) as the theory of knowledge and Blaikie (2000b:8) expands this description to include the methods, validation and ways of gaining knowledge of social reality. These processes of gathering knowledge are in a constant state of flux as they contribute to the development of new theories and models (Grix, 2002:177). Key contrasting epistemological views are those of positivism and interpretivism (Grix, 2002:178). Firstly, positivism relates to the application of natural science to the study of reality, which includes the use of testable hypotheses to explain irrefutable facts which contribute to the generation of knowledge through laws (Bryman, 2016:24). The contrasting view of interpretivism acknowledges that there are differences between people and objects of the natural sciences and requires the researcher to understand the meaning of social action (Bryman, 2016:26). Combining ontological and epistemological views then leads to the selection of a relevant methodology.

Furthermore, there are paradigms, or 'world views' that align to specific philosophical tenets in relation to knowledge and truths. Creswell (2011:38) notes that these paradigms inform the researchers' theoretical stance, which then inform the choice of methodology, methods and analysis within the study. Commonly used paradigms are positivism, constructivism and interpretivism. The positivist paradigm aims to test a priori hypotheses, the results of which can be calculated using statistical testing and demonstrate causal relationships (Mustafa, 2011). Conversely, the paradigm of interpretivism adheres to the beliefs that the social world is understood through the understanding and interpretation of those taking part in the action being investigated (Mustafa, 2011). In contrast, Bhaskar and other theorists such as Archer and Sayer developed critical realism to offer an alternative philosophy to structural functionalism, positivism, interpretivism and postmodernism which were popular at the time but they perceived to have shortcomings (Fleetwood, 2014). Within the development phase of this study other methodologies were explored, but the research question was seeking to understand how, why, when and for whom interventions to reduce interruptions to medication administration work, that provided a strong reason to select Critical Realism. Moreover, it was anticipated that the stratified layers within Critical Realism lens would help to explore hidden mechanisms that may affect how the interventions were used and why. Thus, creating a unifying philosophy that ensured that the philosophy, framework and methods involved in design, data collection and analysis were linked by the same epistemological and ontological beliefs.

In his writing, Bhaskar (1978) developed a combined theory to create a meta-theory for social science in general. The philosophy was firmly rooted in ontology and studied the way the world was (Fleetwood, 2014). Critical realism philosophy seeks to understand the entities, relationships and processes that affect the way the world is, defining this within a stratified model. The Critical Realism model includes three layers that Walsh and Evans (2014) described as:

I. Empirical - observable experiences

II. Actual – what is known but cannot be seen

III. Real – hidden structures and mechanisms that are needed to generate events

It was anticipated within this thesis, that this stratification would help to comprehend what influenced the success or failure of interventions to reduce interruptions to the medication process in the real world of PICU. The researchers personal experience and prior research suggested that the context of PICU may significantly affect the effectiveness of interventions to reduce interruptions to medication administration.

Critics of critical realism highlight that realist philosophers remain divided when defining the elements within the philosophy and that the ontological principles that guide it, are not required within social sciences (Magill, 1994). Furthermore, it is noted that there are differing views concerning epistemology within the field of critical realism, as realist ontology can be associated with both interpretive and constructionist epistemologies. Maxwell (2012:5) argues that knowledge of the world may be based on interpretation rather than representation. In relation to this study, there was an assumption that participants would report their construction of reality rather than an interpretation of events. Thus the ontological perspective in this study, was that a real world existed independently of perceptions, theories and constructions, with an associated constructivist epistemology as the understanding was a construction from individual viewpoints (Maxwell, 2012). A key tenet of critical realism is that regular patterns between variables cannot be evidenced by observation alone (Dalkin et al., 2015). Therefore, using a critical realist lens within research seeks to explain the relationships which link the inputs and outputs within a system, as well as identifying what factors influence them (Dalkin et al., 2015). This philosophy aligns particularly well with this study as is aims to understand participants' perceptions of reality in which interventions to reduce interruptions work and which elements of reality do not produce robust, sustainable changes on outcome

3.4 Stage 1 Realist Review

3.4.1 Rationale for review

The narrative review in Chapter 2 illuminated many studies where interventions to reduce interruptions to medication administration have been implemented. The systematic literature review completed by (Raban and Westbrook, 2014) concluded that there was limited evidence to suggest that these interventions were effective in practice. Consequently, it was felt that what was really needed in this thesis was to complete a deeper literature dive and thus aim to fully explore the phenomenon including what structures, agents or organisational requirements facilitate or prevent these interventions working as this knowledge will be important in the developments in the future. Hence a realistic review approach was used (see Table 5).

3.4.2 Objectives and focus of the Realist Review

The aim of the Realist Review was to identify situations, actions and reactions that influence the effectiveness interventions to reduce interruptions to medication administration. This was achieved by identifying the contexts that triggered underlying or hidden mechanisms that generated the outcomes linked to the intervention. To help achieve this the research question presented in section 3.2 was reviewed and split into sub-questions that were designed to contributed to the realist analysis (see Table 6). Furthermore, the findings from the Realist Review would also contribute to the development of the evidence base and supporting theory that was required within the Medical Research Council's (MRC) Framework for the Development of Complex Interventions (Skivington et al., 2021).

Table 6 - Research questions

Overarching research question
• How do interventions to reduce interruptions to medication administration work, for whom and under which circumstances within the paediatric intensive care environment?
Realist Review questions
• What are the important contexts in which interventions to reduce interruptions during medication administration result in their intended outcome? • What are the mechanisms generated by interventions to reduce interruptions during medication administration? • What outcomes are measured when interventions to reduce interruptions to medication administration are implemented? • In which circumstances are interventions to reduce interruptions to medication administration most effective?

3.4.3 Changes in process

In the Realist Review protocol (see Appendix 1) the search strategy proposed a search for testing the theory. Ultimately this search was not completed as it was decided that each stage of the study would conclude with the identification of the individual contexts, mechanisms and outcomes (CMO) for each set of data. This change was made as it was felt by the researcher and agreed by her supervisory team that the synthesis chapter (7) would critically explore the identified CMO's from each data set. That chapter would conclude with the CMO configurations that illustrate the key elements that affect the effectiveness of interventions to reduce interruptions to medication administration in PICU.

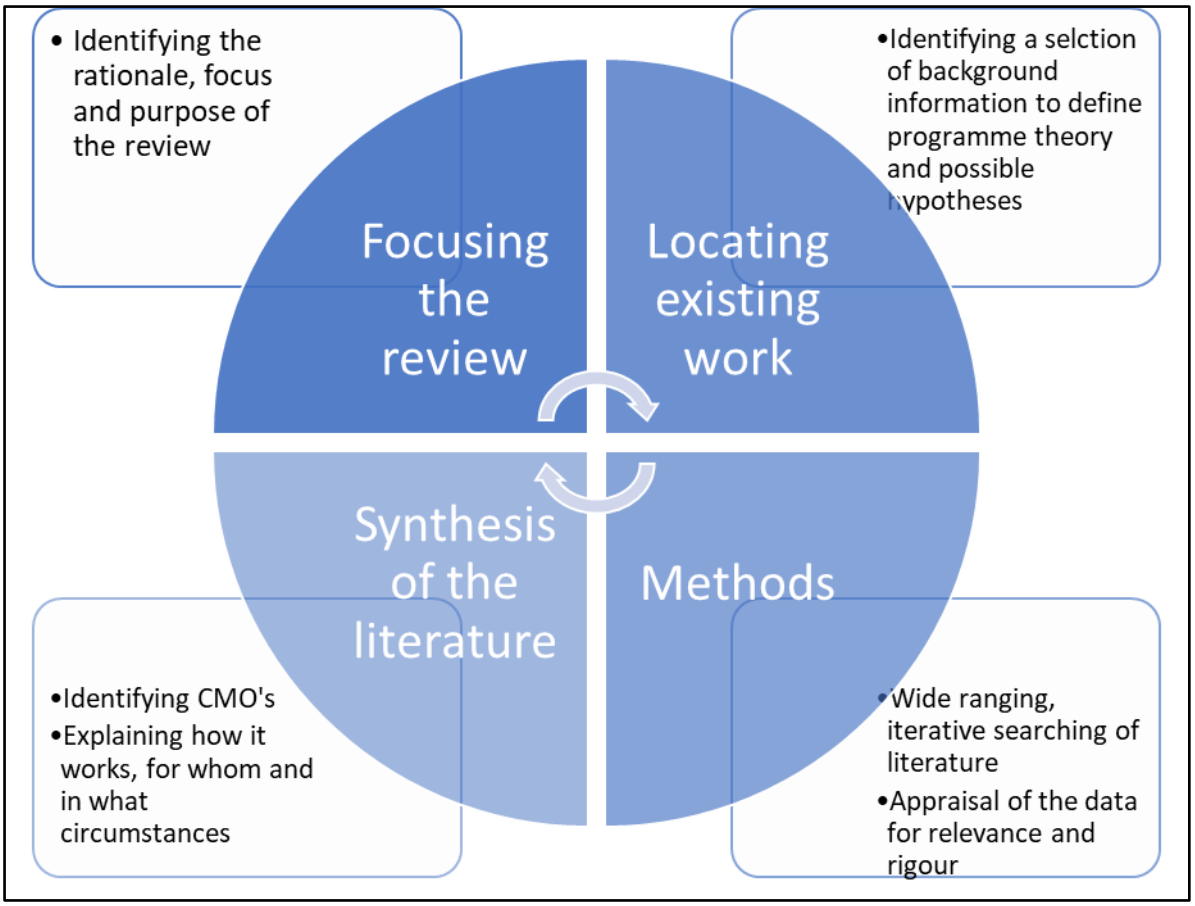
3.4.4 Rationale for realist synthesis

Realist reviews and synthesis are advocated for building explanatory understanding of how and when complex interventions work (Pawson et al., 2005, Dalkin et al., 2015, Rycroft-Malone et al., 2012). With the explanatory nature of a Realist Review requiring the researcher to seek to understand 'what works for whom, and in what circumstances and why?' (Pawson and Manzano-Santaella, 2012:177). Moreover, realist methodology aims to synthesise the primary research included within the

review and explain the factors that influence the success or failure of an intervention (Pawson and Manzano-Santaella, 2012:178), that may both visible or hidden (Jagosh et al., 2014:133).

As conveyed in Chapter 2, interventions to reduce interruptions during medication administration have not been explored using a realist lens, limiting the understanding of how these interventions work. It is repeatedly identified by realist researchers (Jagosh et al., 2014, Pawson, 2006, Rycroft-Malone et al., 2012, Greenhalgh et al., 2009) that this methodology uses iterative synthesis processes to provide strong explanatory rationale for how complex interventions work. Within this study the Realist Review was undertaken using a four-phase process adapted from Williams et al. (2016) (see Figure 9).

Figure 9 - Realist Review process



Adapted from (Williams et al., 2016)

A realist lens assumes that the intervention does not work in isolation, but that it is affected by both observable contexts and hidden mechanisms. This perspective

allows the researcher to move on from the investigation questioning whether an intervention works or not, to explaining why. This explanatory nature of the Realist Review is achieved through the identification of context, mechanism and outcome (CMO) constructs (for an explanation of these terms see glossary on page 9). The CMO's aim to unpick the relationships between context and mechanisms that influence the outcome of the intervention (Jagosh et al., 2011). Furthermore, this analysis identifies demi-regularities that suggest that in certain contexts individuals are likely to make the same choices (Rycroft-Malone et al., 2012). This has not been achieved in current published systematic reviews (Raban and Westbrook, 2014, Hayes et al., 2015b) as they have explored whether interventions work but have not sought to understand how or when.

In contrast to the Realist Review method, that allows for influencing contexts and mechanisms to be identified, systematic reviews seek to remove variance (Terese and Wong, 2016). They seek to remove variance by being clearly focused, with rigorous explicit appraisal methods resulting in the collection and analysis of data, that are classified as original empirical research (ten Ham-Baloyi and Jordan, 2016). Furthermore, Ferrari (2015) identifies that the key objective of a systematic review is to ask a well-defined question and answer it with either quantitative and qualitative data analysis, sometimes including a meta-analysis.

Within healthcare, particularly medicine, systematic reviews are highly valued, this is demonstrated by the hierarchy of evidence that situates this method at the pinnacle, as the 'gold standard' (ten Ham-Baloyi and Jordan, 2016). In addition, Gough et al. (2012) discuss within their clarification of review methods, that the field of systematic reviews has been dominated with the use of meta-analysis of controlled trials to assess the effectiveness of interventions. Although systematic reviews purely focus on the effectiveness of an intervention they do not aim to explain how or why an intervention works or not. Therefore, with an intervention to reduce interruptions to medication administration where context and individual behaviours are important it is less likely a systematic review would provide useful data, as demonstrated by (Raban and Westbrook, 2014).

The information contained in Table 7 outlines the significant differences between a systematic and Realist Review. A systematic review includes a clearly defined

search process at the start of the study, whilst the Realist Review is iterative in its design. The selection of studies will include a variety of study designs within their inclusion criteria, whereas Akobeng (2005) and Network (2017) highlight that systematic reviews will limit theirs to controlled studies. Whilst realist researchers see the broader criteria as a strength as it enables the review to have an explanatory power. Terese and Wong (2016:285) note that systematic reviewers may view it as a limitation of the method as weaker designs will be included reducing the generalisability of the results.

Table 7 - Key differences in review processes

	Systematic (Meta-analysis)	Realist
Underlying philosophy	Positivism	Critical realism
Purpose	To summarise the results of controlled trials to assess the effectiveness of an intervention (Network, 2017). The process should be explicit, transparent and replicable(ePPI-Centre, 2016)	To produce a synthesis that seeks to provide an explanatory rather than judgemental focus (Pawson et al., 2005)
Research question	Uses a PICO format to design a focused question (Network, 2017)	The question should seek to explain what it is about the intervention that works for whom in what circumstances (Pawson et al., 2005)
Review protocol	Identified in detail before the process begins (ePPI-Centre, 2016)	Identified in detail before the analysis begins
Scope of literature	Exhaustive searching of literature occurs to ensure all relevant sources are included therefore ensuring that the review is not biased by only selecting easily accessible studies. Clear inclusion/exclusion criteria stated (ePPI-Centre, 2016)	The literature included within a realist review uses Purposive sampling methods that will be used to answer specific questions or test theories.

Search process	Detailed reporting of methods and databases used to identify relevant literature	An iterative process that develops as the review progresses and theories are identified. Searching will stop when saturation has been achieved (Pawson et al., 2005)
Data appraisal	Quality of studies is assessed by use of appraisal checklists that are identified in the protocol. Literature is weighted depending on this appraisal and is associated with the hierarchy of evidence, weak literature may be excluded. (ePPI-Centre, 2016)	Realist reviews reject the hierarchy of evidence as this multiple methods are required to provide a rich explanation (Pawson et al., 2005)
Data extraction	Data is extracted from each study for example authors, publication year, number of participants, age range, study design, outcomes, included/excluded (Uman, 2011)	Realist reviews collect data by note taking and annotation as data extraction is not uniformly collected. Data requirements depend on whether the literature is being used to support theory development or testing the theory (Pawson et al., 2005)
Analysis process	Synthesis of results of included studies occurs. May include a meta-analysis (ePPI-Centre, 2016)	Realist synthesis is viewed as a refinement of theory (Pawson et al., 2005)
Presentation of results/findings	Results are presented as narrative, tables or statistical combinations (ePPI-Centre, 2016)	The findings of the realist review demonstrate the links between context, mechanisms and outcomes identified within the analysis (Pawson et al., 2005)

The aim of this Realist Review was to explore whether there were any contexts or mechanisms that influenced how, why and when interventions to reduce interruptions to medication administration were effective. Realist researchers (Pawson, 2006, Rycroft-Malone and Burton, 2010, Wong et al., 2016) have identified three elements that support the rationale for the selection of realist synthesis methodology:

I. The complexity of the process and intervention,

II. Inconsistency of results produced by empirical studies

III. Heterogeneity within research design.

Realist researchers have consistently emphasised that realist review is an approach that is suitable for the evaluation of complex interventions (Pawson et al., 2005, Pawson et al., 2004, Rycroft-Malone et al., 2012). Medication administration within health care is a challenging and complex process (Sears et al., 2013, Jennings et al., 2011). Bower et al. (2015) identified that it can involve pharmacology knowledge and skill, teamwork, interprofessional communication and explanations to patients, parents or families. This process has additional complexities in PICU, due to the frequency and nature of the medication administered, this was highlighted by Bower (2016:64) *'The episodes involved the preparation of multiple, complex medications, some of which maintained the cardiovascular stability of the patient.'* The insertion of interventions to this challenging process adds another layer to a complex process. In addition, Terese and Wong (2016) highlight that the effectiveness of complex health interventions is influenced by multiple interconnecting elements, such as organisational structure and policy, individual behaviours and the response of those receiving healthcare. Within the process of medication administration many healthcare professionals are involved in its delivery, such as nurses, doctors, pharmacists and hospital management teams (Bower et al., 2015). Any intervention that seeks to change practice when medication administration is interrupted, will require organisational support (such as leadership, culture and finance) as well as seeking to influence the behaviours of these professionals and those in immediate contact with the process. Complex interventions are expected to initiate change and systematic reviews assess the effectiveness of that change. However, complex interventions do not always work in the same way in all situations. Therefore, it is important to

understand what contexts that they operate in, influences their use. In addition, it was important to understand what contexts stimulate the mechanisms that change behaviour when the intervention was implemented. Therefore, a synthesis method was required that understood the influence of context (Terese and Wong, 2016).

The second element that supported the choice of a realist rationale was the inconsistency of results within primary research. Primary studies examined multiple outcomes such as interruption rates, medication errors and the timing of medication administration episodes. Several reviews of the existing literature base (Hayes et al., 2015a, Bower et al., 2015, Raban and Westbrook, 2014) conclude that empirical studies that tested interventions to reduce interruptions to medication administration have limited impact and sustainability within practice. Therefore, a literature review that aimed to understand and explain these inconsistencies would provide valuable information for future intervention development. The realist lens would achieve this through the identification and exploration of the influential situations, actions and reactions that determine its success or failure.

Finally, Rycroft-Malone et al. (2012) and Greenhalgh et al, (2011) note that when heterogeneity in research design is associated with the literature surrounding a complex intervention, methodology is required that will allow the inclusion of different types of research design. The impact of including differing types of research design is that it requires a process that allows the different methods and data to be understood. Prior knowledge of this evidence base indicated that there were multiple studies that had tested interventions to reduce interruptions (Pape, 2003, Pape et al., 2005, Anthony et al., 2010, Federwisch et al., 2014, Verweij et al., 2014, Relihan et al., 2010, Flynn, 2016). The data produced by these studies was both quantitative and qualitative. Critically analysing this mix of data using a realist lens, would provide explanatory knowledge about the context and mechanisms that influence the outcomes of interventions to reduce interruptions to medication administration.

In summary, this section has provided a comprehensive rationale for the decision to complete a Realist Review within this study. The aim of this study was to understand how, when and for whom interventions to reduce interruptions to the medication administration process in PICU work. Essentially this review has identified and

explored the CMO's within the current literature base that contribute to the effectiveness of these interventions.

3.4.5 Scoping the literature

The purpose of a scoping search is a preparatory phase noted by Booth et al. (2018) to allow the researcher to explore the quality and quantity of the literature as well as defining the boundaries. Prior research within this area as well as writing the narrative review (Chapter 2) had exposed the author of this study to a significant proportion of the literature in this field. This allowed them to have a comprehensive understanding of the quality and quantity of the research and allowed her to set the boundaries of the search.

In addition, Booth et al. (2018) highlight that the scoping search may also allow for the identification of immediate programme theory. A programme theory is described by Wong et al. (2014:21) as 'an abstracted description and/or diagram that lays out what a programme compromises and how it is expected to work.' The theory should identify the key components of the programme, the outcomes and the components that affect these outcomes (Wong et al., 2014:21). This can be informed by working with stakeholders, examining policy documentation or examining a portion of literature about the intervention. On this occasion, the final option was selected because a significant portion of the literature had already been identified in previous work. In this study the literature was searched for explanations of how the interventions should work. Any citations used to evidence this explanation were then used to explore any theory that was linked to the proposal. These theories have been explored and discussed within Chapter 2.

3.4.6 Literature Searching

Five online bibliographic databases, British Nursing Index (BNI), Cumulative Index of Nursing and Allied Health Literature (CINHAL), EMBASE, Medline, and PsycINFO were searched during June 2017 and refreshed in September 2019. The search included literature from 2003 onwards as this was when the first interventional study was published. These databases were selected to allow relevant literature from the fields of nursing, medicine, pharmacy and psychology to be identified evidencing a well-developed strategy. Extensive reading of the literature for other studies allowed the researcher to be familiar with the literature and identify the relevant search terms.

Wong et al. (2013) note that within a realist review the initial search is used to build an understanding of the topic. Therefore, a Google Scholar search was performed with the initial exploration of the evidence. The addition of a Google Scholar search allowed the exploration of evidence to include grey literature as well as published academic data (Haddaway et al., 2015). The initial search terms for this review are outlined in Table 8.

Table 8 - Initial keyword search

Keyword search
Interruptions AND reductions AND medication administration

The literature search included within a realist review focuses on providing primary studies that will question the explanatory model. Therefore, this determines the need for broad inclusion/exclusion criteria as it seeks to provide a body of evidence that will support theory development (Pawson, 2006). Table 9 details the inclusion criteria for this review.

Table 9 - Inclusion criteria

Study design Randomised Controlled Trial (RCT), cluster RCT's, quasi-experimental studies, pre-post intervention, observational studies, systematic review, quality improvement and non-interventional qualitative studies will be included within the search.
Participants Studies including healthcare professionals (Registered Nurses, Medical Professional, Allied Health Professionals (AHPs), Support Teams) and families will be included within the search.
Study Focus Studies with interventions that attempt to reduce interruptions to medication administration will be included. Non-intervention studies will be included if they can contribute to the explanation of context and mechanisms that influence the impact of interventions to reduce interruptions to medication administration.
Outcome measures The review will include all studies that aim to reduce interruptions to medication administration with the associated aim of reducing the length of medication time and/or medication errors.

Realist review searches are concluded when the author(s) feels that theoretical saturation is complete (Pawson, 2006:86). This search involved a four-stage approach; background search, a theoretical search, testing the theory search and a final search once synthesis is complete (Pawson et al, 2005). The literature searching was completed by RB, however, theoretical saturation was discussed at supervision and agreed by two of the team members (JM and JC).

3.4.7 Selection and appraisal of documents

As with a systematic review the realist review uses transparency to ensure that its findings are valid, reliable and verifiable (Wong et al., 2013). However, realist reviews do not use a hierarchical approach to evidence because it is felt that access to different types of literature help researchers comprehend a more detailed set of data (Pawson et al., 2005). The selection of data within a realist review is driven by:

- relevance (does it address the theory under testing?)
- rigour (does it make a credible contribution to the theory being tested?) (Rycroft-Malone et al., 2012).

Relevance was initially driven by topic as theory is developed and further searches aimed to locate literature to test the theories generated from the background search. The databases in the background search were from inception to current date to enable the development of the interventions to be explored. All empirical studies and quality improvement projects were selected for inclusion, titles and abstracts were imported into EndNote. Only studies that were published in English were included due to a lack of access to translation. Studies were excluded if the interventions to reduce interruptions are related to other healthcare activities for example the delivery of general nursing care. The rationale for this decision was that medication administration is a unique, complex task that requires specifically designed interventions (Campbell, 2013).

Although the selection of studies in a realist review is not based purely on critical appraisal, it is important to have an awareness of methodological limitations during the synthesis phase (Wiese et al., 2017). Therefore, CASP (Critical Appraisal Skills Programme, 2017) or JBI (Joanna Briggs Institute, 2014) method appropriate checklists were used to facilitate this critical appraisal ensuring the evidence is good and relevant enough as required by realist methodology (Pawson and Tilley, 1997).

3.4.8 Data extraction

Initially data was entered on to a Microsoft Word document noting authors, year, department and geographical area, intervention, outcome measured, methods, associated theory, limitations and links to theory (see Appendix 1). Pawson et al. (2005) discusses the use of data extraction forms within a realist review, noting that

data extraction will differ for each piece of data due to the multiple sources used. Despite this constraint, a data extraction form was created to collect contextual data from each interventional study.

3.4.9 Analysis and synthesis process

The aim of the synthesis was to identify the situations or structures (context) that influence behavioural or emotional responses (mechanisms) to the interventions (Rycroft-Malone et al., 2012, Jagosh et al., 2011). Furthermore, the Realist Review also aimed to identify the outcomes expected and unexpected within the literature. At the end of the coding process, contexts mechanisms and outcomes were identified and debated with the supervision team. Tables were constructed to evidence the studies that contributed to each one.

The results and discussion sections of the selected papers were coded manually line by line to identify context, mechanism and outcomes (Wiese et al., 2017). These were then verified by a member of the supervision team (JM or JC). Any differences in coding were discussed at supervision and until an agreement within the team was reached. An inductive process of coding was undertaken, allowing the data to drive the codes (Mitchell et al., 2019a). The process was guided by four questions that were developed from a realist search for information:

I. Does the section of text tell you about the medication process?

II. Does the section of text tell you about an intervention that aimed to reduce interruptions to the medication administration?

III. Does the section of text identify any reaction or behavioural response triggered by medication administration or an intervention?

IV. Does the section of text identify any outcomes associated with interventions to reduce interruptions to medication administration?

3.4.10 Quality and Rigour

Although realist reviews do not follow the traditional systematic review structured approach, quality and rigour are no less important (Emmel et al., 2018). Realist researchers have identified a five stage approach that should be followed to ensure

quality (Wong et al., 2013). These five stages include the identification of an initial programme theory with a clearly defined review purpose, a detailed iterative search, selection of articles based on their relevance, the extraction of data with the final synthesis of the data. Each of these stages were clearly defined in the review protocol (see Appendix 1). The five staged approach outlined by (Pawson et al., 2004, Wong et al., 2013) has informed the development of the quality assessment criteria included within Table 10.

The information captured within Table 10 indicates how the review was designed to meet the quality standards required. It was essential that the subject was suitable for realist analysis and that the data was captured and analysed using the correct methods. In addition to the quality of the methods used within the review, the relevance and rigour of the primary study is also important (Pawson, 2006). The questions asked is the primary study relevant to the research questions within the review and is it trustworthy? The relevance of primary studies included within this review was assisted by the clear definition of inclusion criteria. In addition, included studies were discussed at supervision as all were reviewed by the wider team. In realist research, trustworthiness relates to how well the data supports the secondary inference being made (Pawson, 2006). Again, any debates about trustworthiness of studies were captured in supervision sessions. The supervisory team initially verified the studies included within the review and questioned the researcher about study and the inferences being made. This was then captured within a reflective diary as suggested by Rycroft-Malone et al. (2012).

Table 10 - Quality criteria

Quality criteria	How the criteria were fulfilled
The research topic is appropriate for a realist review	Medication administration is embedded in healthcare delivery. There is a large body of literature concerning interruptions to medication administration and interventions to reduce these. These interventions are complex, and their success is influenced by both healthcare professionals and patients. The aim of the overall study is to identify how, when and for whom these interventions work.
The research question is constructed in such a way as to be suitable for realist analysis, and is sufficiently and appropriately focused	The research questions are constructed so that the situations that influence the interventions to succeed or fail. Furthermore, the questions also seek to identify the behaviours and reactions that are trigged by the intervention in these situations.
The review demonstrates understanding and application of a realist philosophy and realist logic that underpins a realist analysis	The review followed the realist processes identified by (Pawson et al., 2004) and (Wong et al., 2013) that underpin the design of the RAMESES standards for realist reviews. The realist analysis focused on the identification of context, mechanisms and outcomes within the data.

An initial realist programme theory is identified and developed	An initial programme theory was identified by detailed exploration of the theories underpinning the design of the interventions.
The search process is such that it would identify data to enable the programme theory to be developed, refined and tested	The search process was iterative. It began with a broad search and then increased its focus. Multiple data sources were used, and the review was conducted over six months with an update two years later.
The selection and appraisal process ensures that sources relevant to the view containing material of sufficient rigour is identified.	Systematic reviews and primary research were included rather than editorials and opinion pieces to ensure rigorous data was used.
The data extraction process captures the necessary data to enable a realist review	Line by line coding occurred identifying contexts, mechanisms and outcomes were identified within the data. This was verified by the supervisory team.
The realist synthesis is reported using the items listed in the RAMESES reporting standard for realist syntheses.	The RAMESES reporting standards were used to inform the methods within the review and in its reporting structure.

(Table adapted from (Wong et al., 2013, Pawson et al., 2005, Mitchell et al., 2019a)

3.4.11 Stage 1 – Realist Review summary

This section has explored, justified and critically discussed the rationale for completing the Realist Review within this thesis and it being novel in the terms of the phenomenon being explored. Moreover, using a realist approach has outlined a clear and robust process that was used to undertake the realist review of empirical studies that implemented or reviewed interventions to reduce interruptions to the medication administration process. The completion of this has enabled the researcher to critically review the contemporary existing research to understand how, when and in what circumstances these interventions work.

3.5 Stage 2 (Part a and Part b) – Survey of Practice and PICU MDT interviews

3.5.1 – Introduction to Stage 2 (Part a and Part b)

Stage 2 of this thesis aimed to address the absences in the contemporary evidence relating to interventions being employed in clinical practice in PICU setting and the perspectives of MDT that used them (see Table 5). Therefore, this involved a survey of practice in England (Part a) and the semi-structured interviews with the MDT (Part b). This section will present the rationales for the sample size, the recruitment pathway, consent procedures, data collection and analysis processes.

3.5.2 Part a - Survey of Practice in England

The main aim of the Survey of Practice was to investigate what interventions are used in clinical practice across PICUs in England. Surveys are often used within quantitative or mixed design designs to collate data from large populations (Creswell, 2011), often via online methods. However, within this survey the maximum sample size would be 23 so the sample size did not dictate the need for a large-scale online survey. A disadvantage of online survey's noted by Safdar et al. (2016) is that often open- ended questions that may provide rationale for decisions are not included due to the length of the survey tool. When considering the possible methods that may be used to collect this unit data, a telephone survey was chosen due to the maximum sample size and the improved data collection possibilities. The researcher felt that having the ability to probe responses with follow up questions would add depth to the data being collected. The ability to ask additional follow up questions was useful in all the telephone surveys as it allowed information to be clarified and discussed, adding depth to the data that would have been missed otherwise.

It is noted within the literature (Lavrakas, 2009, Safdar et al., 2016) that telephone surveys have several advantages; improved data collection quality, cost efficiency and flexibility. Although, Lavrakas (2009) also highlights that the primary disadvantage of this method as time limitation as participants are unlikely to converse on the phone for longer than 20 minutes. Therefore, the survey was designed to last between 10 – 15 minutes and was arranged at a convenient time for the participant. All surveys were conducted at a time suggested by the participant and the average time of the survey was 15 minutes.

3.5.3 Aim

To conduct a telephone survey of PICU's in England exploring current medication practice and identifying which interventions to reduce interruptions were in use and how their effectiveness was measured.

3.5.4 Sampling

A purposive sample of National Health Service (NHS) PICU's in England (n=23) as identified by NHS England as a designated PICU were selected (see Table 11). A pragmatic decision was taken not to include the whole of the United Kingdom. This was due to time constraints, as approval from Health Research Authorities in each devolved country would be required. This would then only provide access to a further four PICU's.

Due to the maximum size of the sample (n=23), all units were included and not a cross section as this would provide comprehensive understanding of practice within England. This sampling method was selected as the researcher was not seeking a random selection of participants to generalise from but a sample which was able to provide relevant data to answer the research questions (Bryman, 2012).

Inclusion criteria:

- All designated NHS PICU's within England

Exclusion criteria:

- Non-NHS PICU's
- NHS wards and units not providing intensive care to critically ill children

Table 11 - Designated PICU's in England

Included PICUs
Barts and the London NHS Trust; Birmingham Children's Hospital; Cambridge University Hospitals NHS Foundation Trust; Central Manchester University Hospitals NHS Foundation Trust; Great Ormond Street Hospital for Children NHS Trust; Guy's & St. Thomas' NHS Foundation Trust; Imperial College Healthcare NHS Trust; King's College Hospital NHS Trust; Leeds Teaching Hospitals NHS Trust; Liverpool Alder Hey Children's NHS Foundation Trust; Great North Children's Hospital & Newcastle Freeman Hospital; Nottingham Children's Hospital; Oxford University Hospitals NHS Trust; Royal Brompton & Harefield NHS Foundation Trust; Sheffield Children's Hospital; South Tees Hospitals NHS Foundation Trust; St. George's Healthcare NHS Trust; University Hospital of North Staffordshire NHS Trust,; Southampton Children's Hospital; Bristol Royal Hospital for Children; Leicester Royal Infirmary; Leicester Glenfield Hospital. (Paediatric Intensive Care Audit Network, 2020)

3.5.5 Recruitment

'Cold calling' participants via the telephone is not recommended practice in healthcare research. Instead, it is advocated that they should be invited in person, by poster or letter (Ray et al, 2016:128). Therefore, all PICU's within England were invited to participate within the study via email. The recruitment process began by the Paediatric Intensive Care Society (PICS) contacting the medical and nursing Clinical Leads from all Paediatric Intensive Care Units within the England via email.

PICS is a multidisciplinary forum which represents the United Kingdom paediatric intensive care community at a national level. Permission for the PICS administrator to send the study information to their email contacts was granted by the Chair. The email invitations were sent by the PICS Administrator to ensure Data Protection principles of confidentiality were adhered to. It is noted within social science research literature (Bryman, 2012) that it can be difficult to gain access to respondents. By contacting both medical and nursing clinical leads (Tume et al., 2017) it was anticipated that the response rate would increase. Furthermore, it would ensure that the participant could answer questions about contemporary PICU practice within the NHS. The email (see Appendix 2) contained a brief outline of the study and estimated length of the survey. In addition, to allow a convenient time for the survey to be conducted the email

requested contact details for a member of the PICU management team (medical or nursing) who could describe current practice and interventions to reduce interruptions to medication administration and describe how the impact of these interventions were measured. The invitation to participate in the study was made via email. This invitation was circulated prior to the national PICU conference that the researcher was attending, this allowed for informal conversations to promote the study. A follow up email from the PICS administrator occurred two weeks after the initial request. As part 2b of the study was running at the same time participants were asked if they could promote the interviews with the leadership team in their PICU. The survey was conducted between 28th September 2017 and 28th March 2018.

3.5.6 Informed consent

There are three different types of consent recognised by regulatory bodies within healthcare; implied, verbal and written (National Institute of Health Research, 2013). Within research the gold standard for consent is written, unless there are outstanding circumstances such as emergency care studies where ethical review bodies may permit research without consent (Manti and Licari, 2018).

When contact was made with the nominated professional an electronic Participant Information Sheet (PIS) and consent form was sent prior to the telephone survey (see Appendix 2). An appointment convenient to the participant was made to ring back to complete the survey. Consent forms were returned before the interview was conducted and consent was clarified verbally at the beginning of the interview. It was clear within the PIS and consent form that all data would be anonymised by allocating each participant an individual number. Care was taken to ensure units were not identifiable in the findings due to the small amount of PICU's in England. This required some information to be removed about the conditions treated within some PICU's as it would have allowed them to be identified.

3.5.7 Data collection

As outlined in the introduction the survey was completed using a telephone interview, as this method has been reported to allow for rapid collection of data (Novick, 2008). Telephone surveys are quick to administer, allow access to a wide geographical area and enable the respondent to remain in their own environment which may encourage them to answer questions more in depth (Novick, 2008). Furthermore, they allow the

interviewer to explore the responses given by the participant and ask additional questions which would not be possible within the administration of a questionnaire (Carr and Worth, 2001). In addition, telephone interviews are likely to obtain higher response rates than written questionnaires (Carr and Worth, 2001).

A key disadvantage of telephone interviews is initiating the call at an inconvenient time placing the participant in an uncomfortable position (Carr and Worth, 2001). Attempts to minimise this potential issue have been implemented by sending an introductory email and making an appointment for the interview. In addition, the literature notes that it is difficult to build a rapport within a telephone interview, but this may be helped by having a scripted opening statement to outline the rationale of the study (Novick, 2008).

The design of a telephone interview may be structured or semi structured (Carr and Worth, 2001). On this occasion a semi-structured approach was selected including both open-ended and closed questions (see Appendix 2 for schedule outline). The closed questions ensured that the survey remained focused on the topic of interventions to reduce interruptions to medication administration. In addition, the inclusion of open-ended questions allowed the interviewer to probe responses for further clarification. This method was demonstrated to be successful, with a response rate of 78% of hospital trusts (Berry et al., 2017) in their audit of bereavement care in intensive care. In this study, it enabled the participant to describe the interventions and any evaluation completed in more detail.

An important consideration for the researcher to be aware of was that this telephone survey was collecting data from clinically based health professionals. If the participant was required to end the call early due to a clinical requirement, data collected up to that point would be included within the analysis and an appointment would be made to complete the rest of the survey. In this study, one call needed to be rearranged due to an unexpected clinical commitment and another was stopped for an hour at the participants request. A further two had brief interruptions where the researcher was placed on hold. This flexibility within the scheduling of the telephone calls was especially important as the survey was conducted over the winter period when clinical commitments are at their busiest.

3.5.8 Data analysis

The initial design of the study anticipated that the data collected within the telephone survey would include both quantitative and qualitative elements. However, the data collected from participants included rich, detailed qualitative data, rather than the quantitative information that would allow for statistical analysis. The reflection in Table 12 offers the researchers' suggestions for the lack of statistical data within the survey. Therefore, after discussion with the supervision team a thematic analysis method was selected. Initially the methods of data analysis qualitative content analysis linked with realist Context, Mechanism, Outcome Configuration (CMOC) were used. The use of both methods in this initial analysis stage appeared to 'force' the findings and not allow the researcher to inductively analyse the data. Therefore, an alternative approach was required that enabled the researcher to complete an inductive analysis of the data.

Table 12 - Reflective diary entry

Reflective diary excerpt
Feedback from the supervisory team in October 2017 indicated that my questioning in the initial two surveys did not probe the participant responses enough. Since then, I have added questions such as 'can you explain that further?' and 'why do you think that?'. This has increased the detail about the interventions implemented within the different units, but I seem to have lost the statistical data. I was initially concerned that my additional questioning had reduced my access to this data, however, after further immersion in the data I think my data reflects current practice in the real world. It appears that interventions to reduce interruptions are routinely implemented in the clinical environment of PICU but rarely measured to demonstrate impact. This has resulted in me only being able to present how many units have used an intervention and which type but unable to indicate and numerical result for impact. Reflective Diary, October 2018

Inductive thematic analysis was selected, Braun and Clarke (2006:79) as it is a method that identifies, analyses and reports patterns within data. Using an inductive approach in this study allowed the data to be coded without forcing it into existing frameworks or preconceptions. Furthermore, using the inductive method allowed the significant findings to emerge from the participant data enabling the participant voice to be heard.

In addition to the analysis process being inductive, it was important that it fitted with the associated philosophical framework that aligned this study. It has been highlighted in the literature (Clark, 2008, Maxwell, 2012), that in order to apply critical realism in practice the researcher must have an extensive understanding of the phenomena under review. Furthermore, Clark (2008) indicated that the analysis process should also provide rich and detailed explanations of patterns in data. An example of the use of thematic analysis within realist research is the study conducted by Rycroft-Malone et al. (2012). In this study, theming was the first stage of data analysis undertaken before the more detailed explanatory realist analysis was conducted. In this part of the analysis the themes were viewed through a realist lens allowing contexts, mechanisms and outcomes to be identified. Therefore, the inductive use of thematic analysis supported the detailed understanding of the phenomena and identified patterns that affected the use and impact of interventions to reduce interruptions to the medication process. The use of an inductive analysis method, enables the researcher to actively identify meaningful themes and concepts that have not been identified before (Chell, 2004, Braun and Clarke, 2006). Although it should be acknowledged that it is impossible for the researcher not to be uninformed by prior knowledge (Bryman, 2016) and in this case personal experience. Consequently, some themes will reflect the literature whilst others have not been identified before.

The thematic analysis process followed within this study was the six phased approach suggested by (Braun and Clarke, 2012). The information in Table 13 describes the thematic analysis process followed within the study step by step. The process began with immersion with the data, initially through the transcribing process (see Appendix 3), followed by the reading and coding of each transcript (see Appendix 4). The coding process enabled the researcher to collate the codes and their data into themes, these were discussed with and verified by the supervisory team. Finally, the themes were explained and supported by evidence from the data using direct quotes.

Table 13 - Thematic analysis process

Braun and Clarke	Data analysis process
Familiarising Yourself with the Data	The surveys were audio recorded and transcribed verbatim by the researcher which contributed to their immersion into the data (Braun and Clarke, 2012). Familiarity with the transcripts was gained by repeatedly reading them and notes

	being made on initial thoughts in margins (Bailey, 2008). This allowed the researcher to understand the scripts as a whole (Graneheim and Lundman, 2004).
Generating Initial Codes	The data was manually coded using Microsoft Word© tables document the coding process. Sections of the data were initially summarised and then a name was applied. A coding index was maintained which allowed the researcher to define and redefine the code as the analysis progressed. The data from the survey and healthcare professional interviews was coded individually.
Searching for Themes	The survey and healthcare professional data were initially searched separately for themes. Each coding set was searched for actions, behaviours, decisions and reactions that were affected by medication practice, interruptions or interventions that aimed to reduce interruptions. Any similarity or overlap was grouped together to suggest an developing theme (Braun and Clarke, 2012)
Reviewing Potential Themes	The themes from each individual dataset were reviewed (both transcripts and coding) for a quality check (Braun and Clarke, 2012) The themes from both datasets were reviewed together to search for similarities and overarching themes. Sub themes were grouped together to create and evidence an overarching theme.
Defining and Naming Themes	These identified themes and sub themes were critically discussed with and verified by the supervisory team. They were then allocated names.
Producing the Report	The survey and MDT analysis were presented as one findings chapter and parent/carers separately. CMO's were identified and described at the end of each findings chapter

Throughout the process the supervision team reviewed transcripts (n=2), coding tables (n=10) and the themes. This ensured that each step of the process was verified, and the researcher was challenged to ensure the evidence to support the process was robust and quality standards were maintained.

3.5.9 Summary

This section has outlined the rationale for undertaking a survey of practice in England. Following on from the rational the method of data collection a using a telephone survey was explored and critiqued. Finally, the process of thematic analysis method was clearly presented to ensure quality and rigour could be evidenced.

3.6 Stage 2 (Part b) – semi-structured interviews with health professionals

3.6.1 Introduction

Part two of the second stage included a cross-sectional exploratory study that included semi-structured interviews with the wider multidisciplinary team in PICU (see Table 5). The published literature included within the narrative review (Chapter 2) indicated that the wider team involved in delivering healthcare was rarely included within the study. Yet they are expected to understand and adhere to the intervention in use, but the impact on their role has not been comprehended. The dominant focus and voice within the literature has been nursing. Nevertheless, PICU nurses were included as no other study had sought to understand the impact of interventions to reduce interruptions to medication administration within this environment.

3.6.2 Aim

To explore the perceptions and experiences of the multidisciplinary team in the medication process and interventions to reduce interruptions in PICU.

3.6.3 Multi-disciplinary Team (MDT) Interviews

Semi-structured interviews are a common tool used for data collection in qualitative research. McIntosh and Morse (2015) and Jenner et al. (2004) highlight that this type of interview allows for the exploration of subjective viewpoints and experiences. Furthermore, McIntosh and Morse (2015) acknowledge that semi-structured interviews are used when the researcher is aware of objective knowledge about the phenomena but require further subjective knowledge. Furthermore, Newcomer et al. (2015:464) suggest that semi-structured interviews are ideal when probing questions

are required to explore individual thoughts. As the subjective knowledge and experience of the wider team in PICU had not been explored within the literature, semi-structured interviews were identified as an appropriate method to collect data. This interview method allowed the interviewer to explore and probe the individuals' thoughts and experiences of interventions to reduce interruptions to the medication process in PICU. Within realism (Manzano, 2016) notes that interviews should allow the researcher opportunity to discuss possible theories and explanations, the use of the semi-structured interview with an open ended interview schedule would allow this to occur.

3.6.4 Sample

A purposive method of sampling was used, described by (Palys, 2008:697) as stakeholder sampling. This method is particularly relevant within evaluation research where the researcher wants to recruit participants who are involved with the delivery of a service (Palys, 2008). This is related to realist methods as studies within this paradigm are often guided by stakeholder views and opinions (Pawson, 2006).

The sample size was selected using Morse (2000) list of influential factors (see Table 14). The guidance outlined and justified in table below indicated that there were several influencing factors that could guide the sample size. Firstly, it was important to acknowledge that the study was focused on a process that occurs every day in the intensive care environment. Secondly, the potential participants were frequently present in the environment where medications were prepared administered. Thirdly, it was anticipated that they would have been involved in the process or observed it. The interviews were arranged at a convenient time for the participant, and they could choose whether to complete the interview over the phone or in person, allowing them to select the type most comfortable to them. Finally, the study was informed by prior empirical studies and prolonged engagement with the literature.

Table 14 - Factors affecting sample size

Factor	Definition	Study factors
Scope	The broader the scope of the study the more participants will be required.	The scope of this study was focused on interventions to reduce interruptions to

		medication administration. The interviews also focused on experience, barriers and enablers to use and perceptions of effectivness.
Nature	If the topic is obvious and clear it is easily attainable and fewer participants are required.	Medication administration is an activity which occurs frequently daily so participants should have increased ability to recall their experiences. Although, it may raise potentially distressing issues or pressure from the work environment which may negatively impact on recall.
Quality	This relates to the ability of the participant to talk about the topic.	The choice of method of interview ensured that the participant was interviewed within a comfortable environment which may have increased their willingness to share. However, sharing difficult experiences may have negatively impacted on this.
Design	Understanding how the design of the study influences the collection of data	This study was informed by the findings from a previous study (Bower et al., 2017) and information gained from the realist review.
Use of shadow data	The concept of shadow data relates to participants talking about the experience of others.	The interviews captured data from participants about their perceptions of the

		experiences and behaviours of other professionals.

These guiding principles from Morse (2000) do not provide a definitive sample size, but after discussion of these factors with the supervision team a maximum sample size (n=15) and framework was agreed. The sample framework is presented in Table 15 and outlines the anticipated representation. The maximum sample of 15 professionals concluded with the inclusion of 14 healthcare professionals (Registered Nurses, Medical Consultants, AHP's and Support Staff). These professionals were involved in the delivery of intensive care to critically ill children, as it was important that their differing perspectives on the phenomena were recorded. However, the sample aimed to have greater representation from professional groups (Medical Professionals, AHP's and Support Staff) because their views and experiences had been largely missed within the literature, but they were expected to engage with interventions within the clinical area. However, the study recruited seven members of the wider MDT which equated to half of the final sample.

Table 15 - Sampling framework

Sampling Framework	**Study sample**
Healthcare professionals were invited to be considered for participation in the study and they were informed within one month of volunteering whether they had been included or not.	All participants who completed the recruitment process were interviewed. One nurse and one physio did not complete the process as when the researcher responded to their initial email, they did not respond with a convenient interview date.
Representation from each healthcare professional groups Nursing Medical team	The final sample included 7 Registered Nurses, 3 Medical Consultants, 2 Pharmacists, 1 Physiotherapist and 1 Receptionist

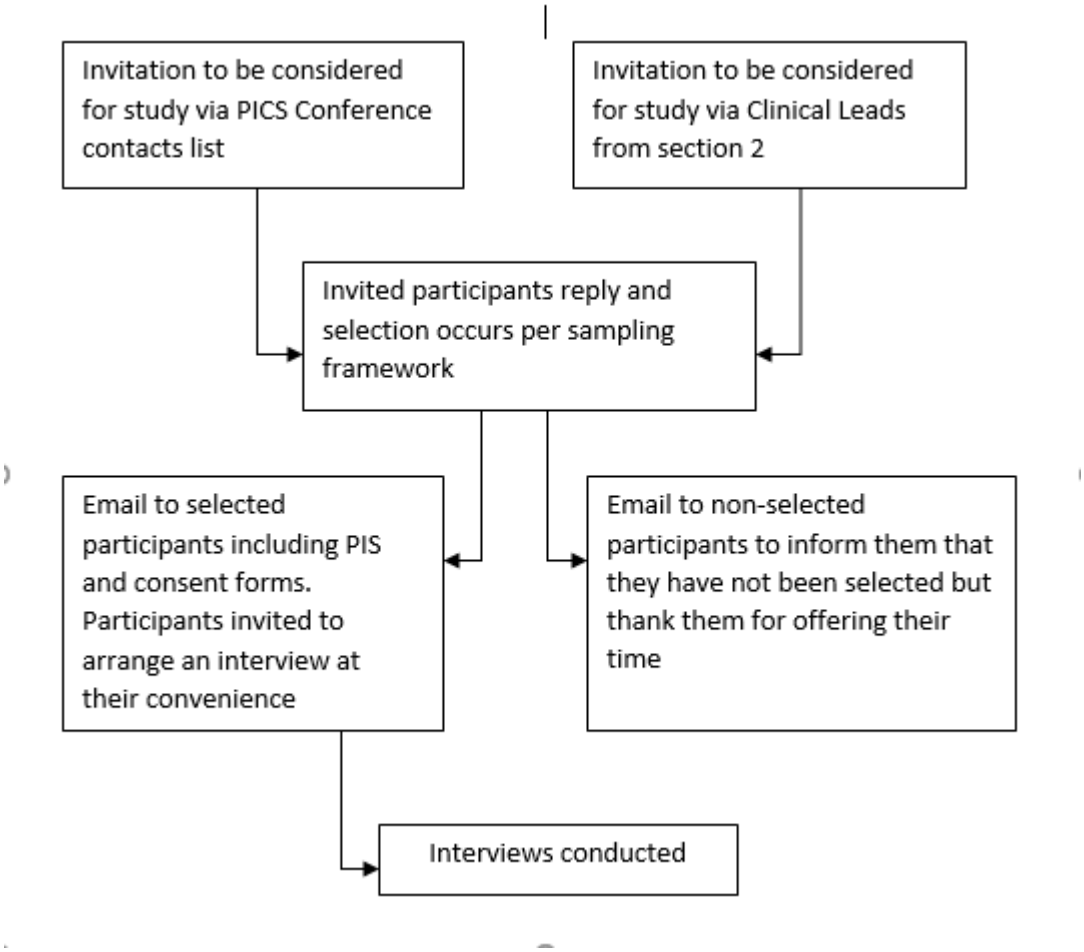
AHP's Support team (receptionists, housekeepers, health care assistants)	
A maximum of 4 Registered Nurses would be interviewed. The other 11 professionals (at least two of each professional group) would be recruited from the other groups named above. Recruitment of healthcare professionals would be from as many different PICU's as possible.	The sample included more than 4 Registered Nurses due to the slow response rate after being discussed and agreed with the supervisory team. Representation of each profession was achieved. Interviews were conducted with professionals from 9 different PICU's. Two units included more than one participant but each of them was from a different healthcare profession.

3.6.5 Recruitment

The timing of the study allowed two concurrent approaches to be used to contact potential participants (see Figure 10). The study received University ethical review and HRA approval in time to allow participants to be recruited at a national PICU conference organised by the PIC Society. Unfortunately, the programme for the conference was busy, so a second recruitment process was formulated through the PIC Society via their email list. It has been highlighted by (Newington and Metcalfe, 2014) that research participants often consent to participate in research for altruistic reasons, however, they also acknowledged influence that clinicians (medical and nursing) can have on recruitment. Therefore, it was anticipated that if the study was promoted by the national PIC Society and endorsed by their chair, recruitment strategies would be more successful.

In addition to the recruitment processes via PICS an additional snowball sampling method allowed access to a wider population (Bryman, 2012:424). If the primary recruitment strategies through PICS did not recruit a large enough sample a backup strategy was available. Snowball sampling relates to the participants already involved in the study identifying other potential participants (Jenner et al., 2004)

Figure 10 - Recruitment flow chart



The recruitment process followed the diagram in Figure 10 and an email invitation to be considered for selection for the study (see Appendix 2) was circulated. An invitation was sent to the multidisciplinary members of the Paediatric Intensive Care Society registered for the 2017 national conference via the administration team associated with the conference. In addition, an invitation was circulated via the clinical leads from stage two who agreed to circulate the email. This second method of invitation allowed the request to reach a wider AHP and support team. The request informed the participant of the rationale for the study and details of the interview such as estimated length of time. In addition, each volunteer participant was asked if they could recommend any professionals who may wish to take part. The volunteer participant was asked to pass on a business card with the researchers contact details, to allow the recommended professional to choose whether to participate or not. The sample of participants was selected as per the framework identified in the sampling section.

An email was sent to all volunteers, within one month to inform them whether they had been selected and to thank those who had not for offering their time. The email to the participants included the PIS and consent form (see Appendix 2). The participant had the choice of a telephone interview or face to face (at PICS conference), and this was arranged at a convenient time for them

3.6.6 Informed consent

The email contained details concerning the rationale of the study and estimated length of interview. A PIS and consent form was attached. Contact details were included so the participant could contact the researcher to arrange an interview (via telephone or face to face) at a convenient time. Participants were offered the opportunity to ask questions before consent forms were signed and before the interview began. Consent was verbally re-confirmed at the beginning of each interview.

3.6.7 Data collection

The use of a semi-structured interview enables the researcher to use an interview schedule but also allows flexibility in its use (Bryman, 2012:471). In addition, the interviewer can follow up and explore interesting points within the answers provided by the participant. This combination ensures the interview remains focused on the topic being researched but allows participants to express their views and experiences (Bryman, 2012, Adams, 2015). Although, semi-structured interviews may be limited by interviewer experience (Jenner et al., 2004), cost and time (Adams, 2015, McIntosh and Morse, 2015). Furthermore, McIntosh and Morse (2015) acknowledge that face to face interviews may be compromised by the presence of the interviewer, particularly if sensitive questions are being asked.

Within this study the participants were only given the option for the interviews to be conducted face to face at the conference, all other interviews were conducted via the telephone. All interviews were audio recorded to allow transcription and face to face interviews were conducted in a quiet space to enable a clear recording to occur. Twelve of the interviews were conducted by phone therefore, potentially increasing participant comfort to share feelings, perceptions and experiences. All interviews were organised at a time suggested by the participant and phone calls were paid for by the researcher. This allowed the participant to have some autonomy and choice over the

modality of interview. This choice contributed towards ensuring they were comfortable with the method will help to build rapport and produce richer data (Novick, 2008).

There are four different types of semi-structured interviews identified by McIntosh and Morse (2015);

I. Descriptive/confirmative (testing hypothetical assumptions)

II. Descriptive/corrective (evaluate what is written in the literature with what is actually experienced by the participant)

III. Descriptive/interpretive (aim to discover the experiential world of the participant)

IV. Descriptive/divergent (to contrast different perspectives of different groups)

A descriptive/confirmative type of semi-structured interview was designed as this linked to the iterative theory driven realist approach. The interview schedules (see Appendix 2) were informed by the findings from a previous study (Bower et al., 2017) as well as the theory and studies included within the contextual chapter. This enabled the schedule to be informed by the contemporary practice from one study but ensured it was not restricted to observations from a single unit. Furthermore, a separate schedule was developed for AHP's and support staff who may not be involved in the delivery aspect of the medication process. Using the findings to support the development of the interview questions aligns with the critical realist theory driven interview technique(Pawson, 1996). The type of interviewing then allows theories to be tested and refined (Manzano, 2016).

Furthermore, Manzano (2016) highlights interviews are often the only way to collect data about programme effectiveness and that semi-structured interviews are commonly used within realist research. Furthermore, it was noted by Manzano (2016) that it is acceptable for realist interviews to begin with structured questions, but these should develop into more explanatory questioning about the programme under evaluation. In this study the initial structured questions focused on the medication process as experienced by that participant before the interviewer moved into questions that asked why actions, behaviours and reactions occurred. Within these explanatory questions, the interviewee may clarify the important mechanisms of which the

interviewer was less familiar with. On this occasion the researcher is an insider so was able to apply the theory to the context of medication administration in PICU, nevertheless, she needed be extremely careful within her reflexivity to ensure she did not enforce her perceptions with regards to the influential mechanisms. This was completed by documenting questions and thoughts after each interview in a diary. This contributed to the recognition of possible themes that may contribute to the identification of CMO's within the data. Manzano (2016) and Pawson (1996) identify this process as searching for 'nuggets of evidence' which then contributes to the development of the programme theory.

3.6.8 Data analysis

The interviews were audio recorded and transcribed verbatim and familiarity with the data was gained through transcribing and reading of transcriptions (Bailey, 2008). As with the National Survey of Practice a Thematic Analysis process was used (see section 3.7.9). The purpose of these interviews was to understand the experiences and perceptions of the wider PICU team, therefore professional role needed to be recognised within this analysis. Within this analysis process it was important to allow the different professional voice to be heard, Mazzei and Jackson (2012), Mazzei and Jackson (2008) acknowledged that qualitative researchers often privilege the participant voice as it is associated with the telling of truth. Furthermore, they note that is easy to oversimplify the participant voice, especially if their views conflict. Therefore, the analysis was guided by the following questions:

i. Were there any situations or reasons identified by the professionals within the MDT that influenced their decisions to interrupt medication administration?

ii. Were there any situations or reasons identified by professionals within the MDT that influenced their experiences of interventions to reduce interruptions to medication administration?

iii. Were there any behaviours, actions, feelings and reactions stimulated by interruptions and interventions to reduce them? Did these impact on or influence other members of the team and how? How did they affect the outcome of the intervention?

These questions were developed from the overall aim of the study, to help to understand how and when interventions are effective. This analysis combined with

that of Survey of Practice were combined to highlight the differences between unit, team and individual behaviours within the medication process. The analysis then examined how these elements interacted with each other and influenced outcome.

3.6.9 Stage 2 Summary

This section of the chapter has outlined and critiqued the semi-structured interview method used to collect data from the PICU MDT within this study. This was followed by a comprehensive review of the purposive sampling methods used. Finally, the process used for the thematic analysis was discussed and was supported with theoretical evidence to contribute towards a robust study design.

3.7 Stage 3 – Parent/Carer Interviews

3.7.1 Introduction

The findings from a previous study (Bower et al., 2017) demonstrated the importance of parents/carers when nurses were deciding how to manage interruptions to the medication process. These findings suggested that nurses were unlikely to behave in a way that would appear to be seen as rude or leave parents/carers unsupported. Moreover, studies included in the contextual chapter (Chapter 2) indicated that some interventions could be perceived to be rude and restrict the availability of the nursing team. From these studies, only two were conducted within paediatric settings and neither had included parents/carers in their design. Therefore, it was important to understand parent/carer views and experiences of the medication process, interruptions and interventions to reduce them. In order to achieve this a study was designed to include semi-structured interviews with parents/carers of critically ill infants and children (see Table 5).

3.7.2 Aim

Explore the perceptions and experiences of parents/carers in the medication process and interventions to reduce interruptions in PICU.

3.7.3 Patient and public involvement and engagement (PPIE)

Patient and Public Involvement and Engagement (PPIE) is an increasing requirement in the research process, supported by the National Institute for Health Research (2017) defining this as research being conducted ‘by’ or ‘with’ patients and their families. Investigations into the impact of PPIE in healthcare research (Brett et al.,

2014, Mitchell et al., 2019b) acknowledge that patients or service users can impact on the design resulting in both benefits and challenges for the researcher. Although a recent systematic review (van Schelven et al., 2020) has identified that there are varying definitions and operationalisation of PPI. In addition, Mitchell et al. (2019b) indicate that it is important that PPI is embedded within a study and not a tokenistic gesture. Benefits were found to be the offer of pragmatic advice, criticism about protocols and instruments, improved recruitment, increased data collection particularly in interviews, interpretation of data from lay point of view and better dissemination. This was also evidenced by Snodin et al. (2017) who found that engaging with PPI shaped the focus, influenced the design and ethical basis of their study. In contrast Brett et al. (2014) found that the main challenge in PPI was the clash of views between science and service user knowledge which was demonstrated when scientific methods had to be compromised, for example the removal of a placebo arm of a trial. Although it could be argued that this change may have improved the ethical design of the study or aided recruitment. Although ethical approval is not required for PPI, (Mitchell et al., 2019b) note that similar principles such as informed consent and minimising harm should be applied to this process.

Exploring the use of PPI in PICU is less common within the literature, although (Menzies et al., 2016) highlights that in this environment it is critical that research studies are well designed due to the sensitivity of working with parents/carers of critically ill children. They illuminated within their systematic review that PPI was viewed positively within PICU studies but that there was no assessment of the impact of this role. Within this study, the design was formulated with the input of parents/carers who had experience of their child being admitted to PICU. Informal discussion with parents/carers within PICU highlighted that they were happy with a study, which was designed to use either questionnaire or semi-structured interview. However, one parent/carer noted that an interview would be better as there may be medical terminology used within the questions that would be more understandable if explained.

In addition, a parent/carer of a patient who was an inpatient on a PICU in the past shared her experience of being involved in research. When questioned about the best way to approach parents/carers to participate she advocated the use of different methods due to there being significant differences between families. There are many

different pathways into a PICU and significant differences in experiences, all of which can affect their ability to retain information. Therefore, staff, posters and leaflets were used to promote the study and engage parent/carer involvement. All leaflets, posters, participant information sheets (PIS) and consent forms were reviewed by a mixed group of parents/carers, both with and without PICU or hospital experience.

The timing of the interview was also discussed as the researcher was unsure whether to offer interviews post-discharge from hospital. The parent/carer felt recall about medication administration would be affected and that for some family's discharge home signifies a time to move on. When asked about the risk of parents/carers becoming upset during the interview, she felt that this may be a possibility and that the researcher would require a plan to address this.

3.7.4 Sampling

Robinson (2014) described a four-point plan, which was useful in the planning of a sample,

i. defining the sample universe,
ii. deciding on the sample size,
iii. selecting the sample strategy
iv. sourcing the sample. Using this plan contributed to the transparency, impact and trustworthiness of the study (Robinson, 2014).
v. Sample universe

The parameter used within this study to identify the population was life history homogeneity (Robinson, 2014) as the sample aimed to recruit parents/carers whose child has been an inpatient on PICU and received medications. Additionally the population of the sample was also defined by the inclusion and exclusion criteria (Robinson, 2014), which can improve the homogeneity of the sample. The information contained in Table 16 clearly defines the inclusion and exclusion criteria for the study. The researcher was unable to fund an interpreter within the study so there was a requirement to understand and speak English. There was also a requirement that parents/carers had observed the medication process and that they were the legal guardian for the child. Families who were proceeding through an active end of life

pathway were excluded to reduce the emotional burden on these families (Latour et al., 2011).

Table 16 - Inclusion/exclusion criteria (parent/carer)

Inclusion Criteria	**Rationale**
Parents/carers who understand and speak English	The researcher is unable to gain access to an interpreter
Parents/carers who are admitted to PICU for at least 24 hours	To enable parents/carers to have significant exposure to the medication process
Parents/carers who have legal responsibility of the critically ill child	To ensure parent/carer views, experiences and perceptions are collected
Exclusion Criteria	
Parents/carers whose children are receiving end of life care	To reduce the emotional burden on parents/carers (Latour et al, 2011)

i. Sample size

Within qualitative research large generalisable samples are generally not achievable (Silverman, 2013). Table 17 demonstrates the factors that have been taken into consideration when determining the sample size for this study (n15). A sample of this size allowed for rich data analysis and enabled individual participant views to be located within the data (Robinson, 2014)

Table 17 - Factors affecting sample size (parent/carer)

Factor	**Definition**	**Study factors**
Scope	The broader the scope of the study the more participants will be required.	The scope of this study was focused on parent/carer experiences, perceptions and views of medication administration and interventions to reduce interruptions.
Nature	If the topic is obvious and clear it is easily attainable and fewer participants are required.	Medication administration is an activity which occurs frequently over the day so parents/carers should be able

		to recall their experiences. Although, it may be difficult for them to isolate the medication administration process from other care delivered to their child. Therefore, the interviews were conducted whilst the child was an inpatient on PICU. Information shared before the interview indicated the topic under discussion allowing parents/carers to think about the topic beforehand if they wished. The interview could raise distressing topics which may affect the parent/carer's ability to talk about the subject or may influence the parent /carer to stop the interview early. The parents/carers were offered the opportunity to operate the recording of the interview so that they could feel more in control.
Quality	This relates to the ability of the participant to talk about the topic.	The choice of method of interview helped to ensure that the participant was interviewed within a comfortable environment which may increase the willingness to share. Sharing difficult experiences may have negatively impacted on this.
Design	Understanding how the design of the study influences the collection of data	The design of this study was informed from the findings of a previous one (Bower et al., 2017) that indicated the importance of parent/carer actions and behaviour.
Use of shadow data	The concept of shadow data relates to participants talking about the experience of others.	Parents/carers were only asked about their own experiences, not their observation of other parents. Although they were asked to comment on their observations of the care delivered to their child.

ii. Sample strategy

The previous study completed by Bower et al. (2017) highlighted that parents/carers have a significant influence on PICU nurse-decision making when interrupted during medication administration. This prior theoretical knowledge determined that a purposive method of sampling will be used as these participants had a unique understanding of the phenomena under examination (Robinson, 2014).

Quota sampling was a purposive method which allowed the researcher to have a flexible but multi-case approach to obtaining a sample (Robinson, 2014). This was employed within this study to ensure multiple specialties from different types of units were included as interruptions to medication administration is a phenomenon that is experienced across a range of patients and units. It has been noted that medication regimes and workload can vary, dependent on diagnosis. In addition, the input from the wider multidisciplinary team is specialty dependent, the presence of these teams was associated with increased rates of interruptions (Hall et al., 2010). Therefore, the sample aimed to include at least one participant from each specialty to a maximum of four (see Table 18) The specialties were those that PICANET (2015) identified as the most common diagnostic reason for admission to PICU.

Table 18 - Sampling framework (parent/carer)

Diagnosis
Cardiovascular
Neurological
Respiratory
Gastro-Intestinal
Infection
Musculoskeletal

iii. Sample source

The participants were recruited from three different NHS Trusts, but one Trust included two separate units with different nursing teams, so four sites were used in total. Table 19 indicated the distinct differences between the four PICU environments. Accessing the four different units helped to achieve the sampling strategy identified in the previous section.

Table 19 - Sample source framework (parent/carer)

Site	Rationale for inclusion
Hospital B	Standalone children's hospital Cares for children of all specialities Supra-regional PICU (31 beds)
Hospital A	Part of a large teaching trust Does not admit children with cardiac conditions (8 beds) Specialities include neuro, major trauma, renal, oncology, spinal, general surgery
Hospital F (site 1)	Part of a large teaching trust Specialist cardiac centre Not attached to an Emergency Department (9 beds)
Hospital (site 2)	Part of a large teaching trust Specialities include general surgery and respiratory medicine (6 beds)

3.7.5 Recruitment

Due to the differences within the four PICU environments, each unit had a bespoke recruitment process, these were summarised within the Figure 11 and Figure 12. These were negotiated individually with the clinical teams to ensure that the process complimented existing workflows and maximised recruitment opportunities.

Figure 11 - Hospital A recruitment process

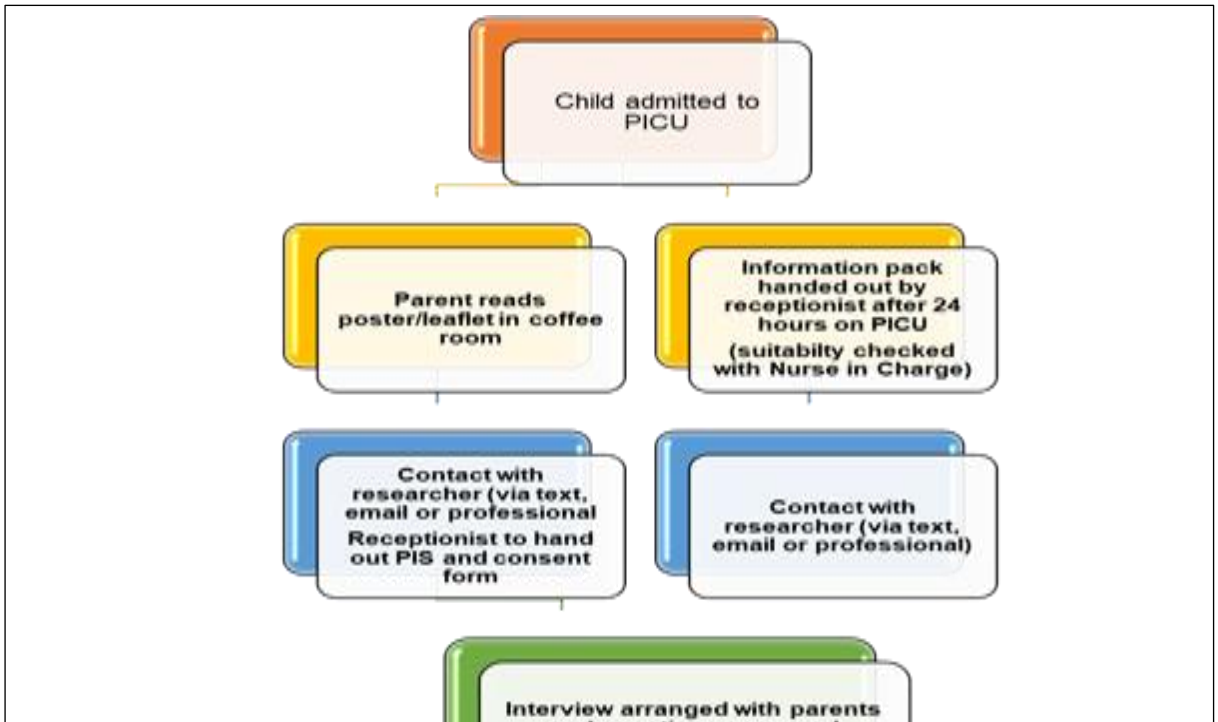
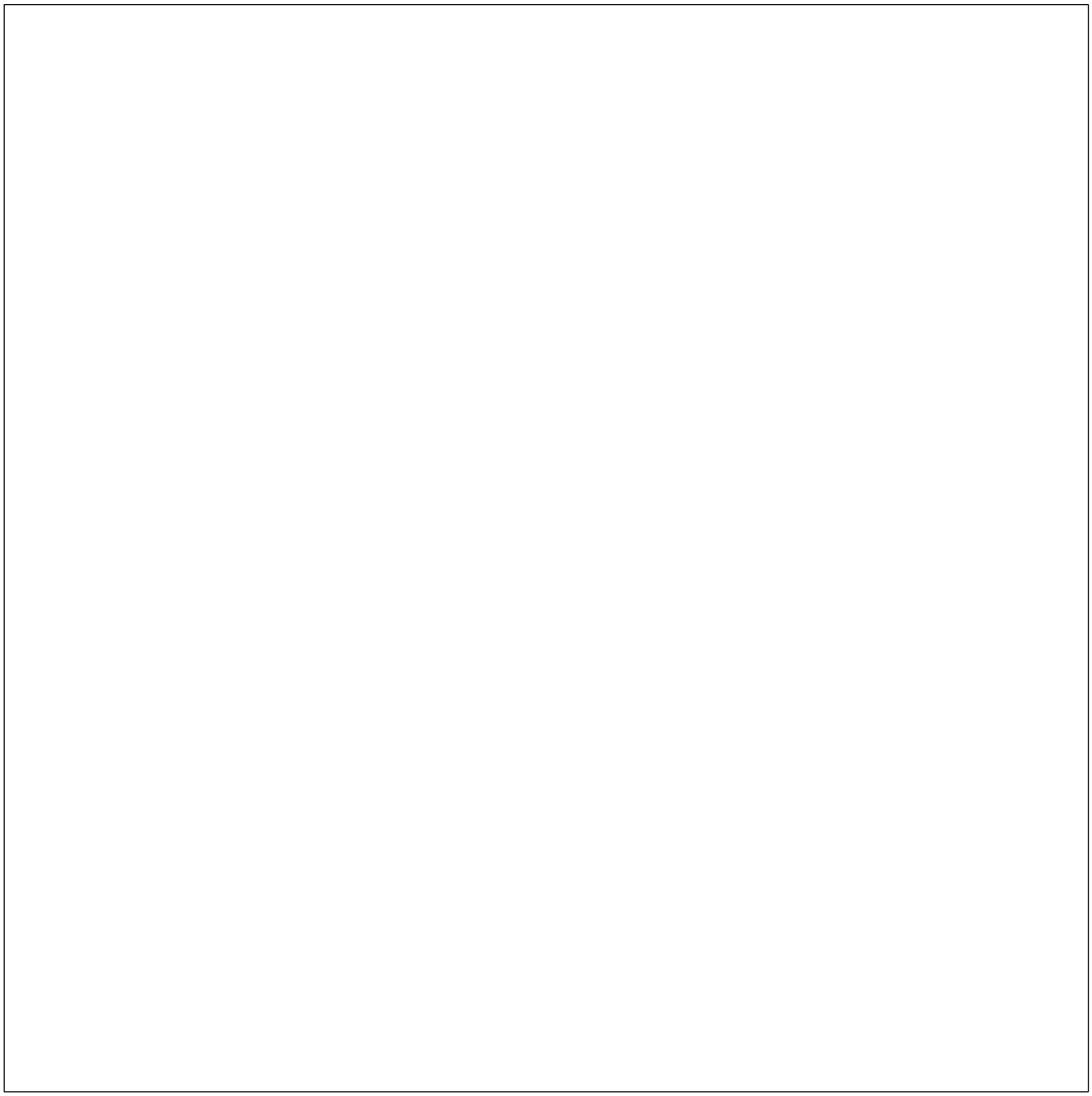
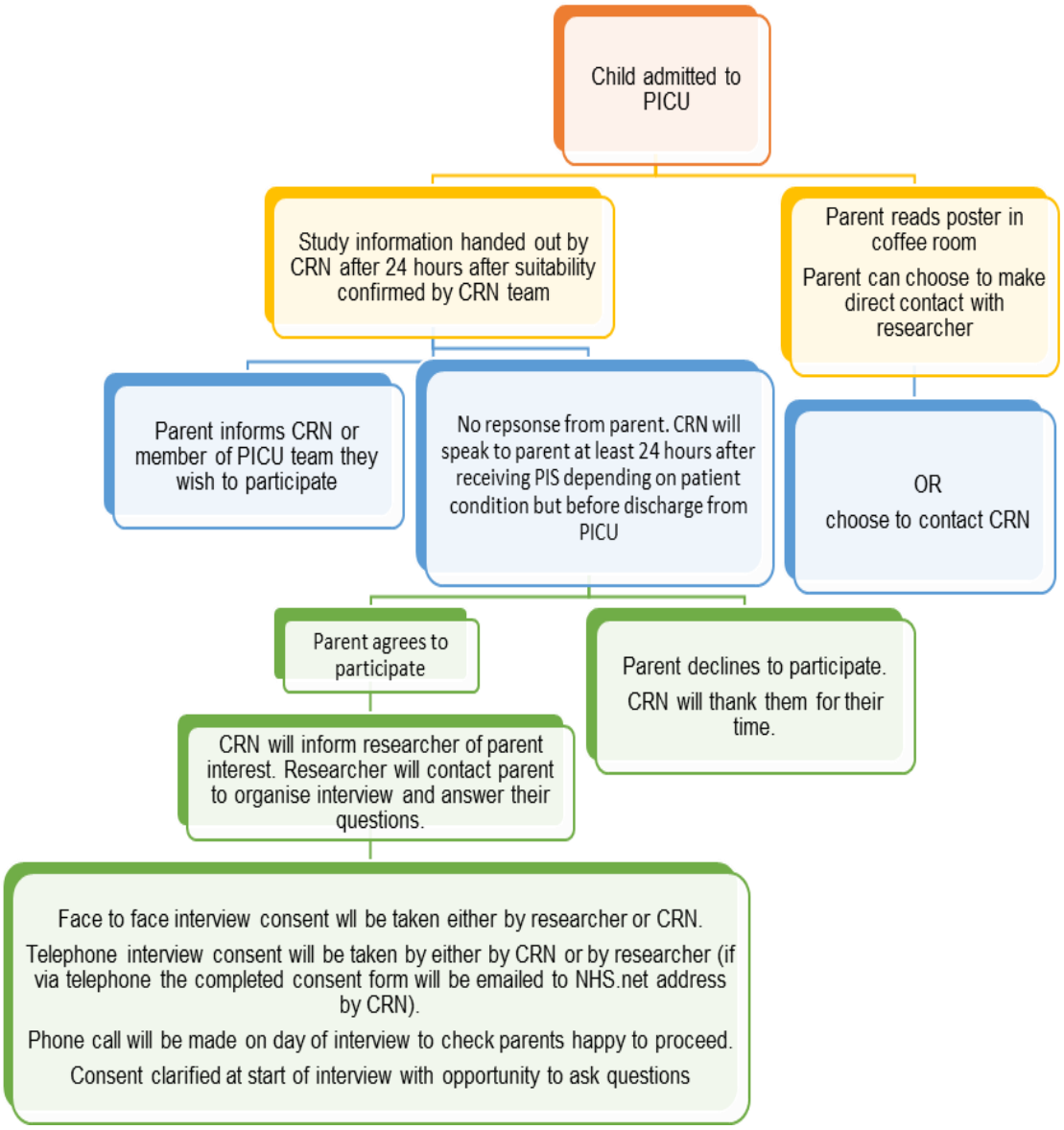


Figure 12 - Hospital B, C and D recruitment process





Parents/carers were recruited via posters, leaflets and information sharing from the clinical team. Investigations into the barriers and facilitators of recruitment in paediatric studies highlight that parent/carer engagement is reduced if too much information is given out (Keightley et al., 2014). It was therefore decided that the poster/invitation leaflet (see Appendix 5) would use graphics with a small amount of text to invite parents/carers to participate.

Other studies have highlighted the importance of information in ensuring informed consent is gained (Burgess et al., 2003). Therefore, it was important that study information was reviewed by parents/carers during the design phase and that the

clinical team or the researcher was available to answer questions and support parents/carers in their decision whether to participate or not (Keightley et al., 2014). To achieve this within the study design a more detailed Participant Information Sheet (see Appendix 5) offered more detail about the study and during the consent process parents/carers were encouraged to ask questions.

Feedback from a parent/carer who was an advisor to several research projects and whose child had been an inpatient in PICU, also indicated that it would be beneficial to conduct the interviews whilst the child is an inpatient. She noted that once parents/carers are discharged, they feel that it is time to move on. Therefore, parents/carers were approached whilst their child was in PICU, this also allowed them to think about the process and their real-life experiences.

3.7.6 Informed consent

Informed consent is essential criteria within the Good Clinical Practice Guide for Research (National Institute of Health Research, 2013) and is an important ethical principle within research (Miller and Bell, 2002, Alahmad, 2018).To ensure that consent was informed a clear process of was followed. When the parent/carers were recruited a PIS, and consent form was given to them. The parent/carer was given time to read the information before being asked if they would take part in the study. Following this a telephone consent interview occurred before the interview was arranged to ensure the parent/carer understood the information contained within the PIS and any questions were answered. If they had access to the facilities, the parent/carer was asked to sign the consent form and send a photo of it to the researcher. Consent was reconfirmed at the beginning of the interview verbally and the form signed if not done so already. Re-visiting the issue of consent allowed it to be part of the whole research process, rather than a check at the beginning, (Miller and Bell, 2002) indicate that consent should be considered throughout the study not only at the start.

3.7.7 Data collection

Semi-structured interviews were designed to collect data within this part of the study. As with Stage Two, Part Two, and highlighted by McIntosh and Morse (2015) a descriptive/confirmative style of semi-structured interview was designed that aligned with realist methods (Manzano, 2016, Pawson, 1996). Interviewing parents/carers of

critically ill children has been completed in previous studies, Dampier et al. (2002) and Gaudreault and Carnevale (2012) both reported this method of data collection as successful resulting in new insights into the parent/carer's experience. More recently, Menzies (2018) highlighted that approaching families on PICU to take part in research was seen as appropriate by both children, young people and parents/carers. Nevertheless, she also notes that the design of the study is important, and the researcher tried the ensure the study process was as convenient and comfortable for parents/carers as possible.

Semi-structured Interviews were conducted as requested by the participant via two different methods (face to face or telephone) at a time convenient to them. This allowed the participant to have some autonomy and choice over the modality of interview. These interviews were in depth as they aimed to explore participant's experiences and perceptions, therefore it was important that they were comfortable with the method used to conduct the interview (Carr and Worth, 2001). Therefore, allowing participants to choose from range of methods allowed them to select a structure that they were comfortable with. Ensuring they were comfortable with the method helped to build rapport and produce richer data (Novick, 2008). All interviews were audio recorded with permission, to allow transcription. Face to face interviews occurred in a quiet space to enable a clear recording to be taken.

The interviews were conducted at the parents/carer's convenience in a location of their choice. A telephone call was made on the day of the interview to ensure the child was well enough for the parents/carers to feel comfortable with the interview taking place. The interview occurred while the child was still an inpatient on PICU, and a quiet room within the locked doors of PIC was used. The nurse looking after the child was informed of the location or a phone number agreed so that if the parent/carers was required at the bedside they could be easily located. The PIS and consent interview emphasised that any data collected before an interruption would be included in the study and plans to resume or reorganise the interview will be made. An interruption plan was outlined within the research protocol to ensure parents/carers were aware of their options should the interview need to be suspended for any reason. This was also refreshed at the commencement of the interview.

The interview schedule was informed by the findings of an exploratory study which explored clinical decision-making when interrupted during medication administration (Bower et al., 2017) as well as the theory and studies included in the contextual chapter (Chapter 2).

3.7.8 Data analysis

The aim of qualitative inquiry is to engage with the participants in a natural setting to gain an overview of the phenomenon as a whole and from the participant point of view (Miles et al., 2018). Following on from data collection, the selection of a qualitative analysis method is often influenced by the research question. The reasoning for allowing the research question to direct the choice of method is discussed by Miles et al. (2018:21) who indicate, that if the best answers are to be obtained, then the best research genre and its associated methods should be selected. The overarching research question in this thesis is to understand how interventions to reduce interruptions to medication administration work, for whom and under which circumstances in PICU? Consequently, qualitative methods were chosen to understand the experiences of professional and parent/carer experiences in PICU. Moreover, this stage of the study aimed to explore the parent/carer experiences and experiences. To critically explore this parent/carer data, the method of inductive thematic analysis was used. The same process that was used within previous two stages was followed (see section 3.6.9 for a comprehensive review of the thematic analysis process used within each stage).

The use of thematic analysis in research studies with parents/carers is not uncommon (Tambling et al., 2021, Weis et al., 2015, Roulstone et al., 2012) as it aims to explore the data for both explicit and implicit ideas (Guest et al., 2011). Moreover, it has a primary aim of presenting experiences and perceptions in the participant's voice. It was important within this study to ensure the parent/carer voice was heard as clearly as the professional one. Conducting a thematic analysis of parent/carer data contributed to them having a strong voice as their perceptions and experiences could be comprehensively presented and evidenced within that process.

The same process of Thematic Analysis began with an emersion within the data from reading and transcribing each interview by RB. She then re-read the interviews and marked them with notes of salient or emerging points, before manually coding each

transcript. To ensure quality, the coding was reviewed and discussed with the supervisory team to check for consistency and identify any overlap. The initial coding was presented to the supervisory team and collective decisions were taken to identify the overarching themes with their linked sub-categories (see Appendix 6 for pictures of thematic discussion). Prior to completing the discussion with the supervisory team, the researcher (RB) had attempted to theme the data into CMO categories, but this method appeared for force the findings and not enable a clear participant voice to be heard.

In summary, this section has provided a clear rationale for the choice of data analysis method used. Whilst the process had been previously presented in detail (Section 3.6.9) this section has applied the method of Thematic Analysis to parent/carer data and its important contribution to allowing a distinct participant voice.

3.7.9 Stage 3 Summary

This section explored and critiqued the rationale for the study design for stage 3. This included the critical discussion about decisions made regarding sample size and population as well as collecting and analysing data. The section also highlighted that research with parents/carers needs to be flexible and sensitive to the needs of their children. In addition, these parents/carers may be perceived as a vulnerable participant group, a robust management plan was in place to help support parents/carers if they required it.

3.8 Ethical Considerations for Stage 2 and Stage 3

Following the realist review, the study design (see Table 5) indicates that three empirical sets of data were collected. The rest of this chapter will present a discussion about the ethical issues that were considered during the design and conduction of each stage.

Consideration of ethical issues within research is essential to ensure that studies not only choose the appropriate methodology, but one which is responsible and morally defensible (Gray, 2013). A deontological (the adherence to rules) perspective will be applied to this study to ensure that the rights of the research participant are protected, such as the right to privacy and the right to choose (Gray, 2013). There is an ethical viewpoint which believes that these issues may vary across different participant

groups (Gray, 2013). Nevertheless, within this study the ethical issues which are discussed in the following section are relevant to each individual participant regardless of their role.

3.8.1 Ethical review

All stages of the study were reviewed by Coventry University's (CU) ethical review process. Stage 2 (Part a and Part b) required and received Health Research Authority (HRA) approval in addition to CU ethical review. Stage 3 required and received approval from CU ethics, HRA and local Research Ethics Committee (REC). Documentation associated with these approvals is evidenced at the beginning of this thesis.

3.8.2 Informed consent

The process of obtaining informed consent for each stage of the empirical study was discussed in sections 3.6.6, 3.7.6 and 3.8.6. It was essential that the participants received sufficient information which they are able to understand, as this enabled them to provide informed consent (Gray, 2013). For parents/carers it was important that the information did not use medical terminology as (Alahmad, 2018) found that its use could impact on their ability to provide informed consent.

Ensuring participants did not feel pressured to consent was another important factor. It was anticipated that allowing participants time to read the PIS, opportunity to ask questions and control over when and how the interview was conducted would help to prevent them feeling pressured. (Alahmad, 2018) found in their systematic review of the consent process in oncology trials that consent could be influenced by professionals. In this study a third party who was not involved in the research was used to approach participants either the PICS society or a snowball referral in stage 2 or clinical teams in stage 3, to try to prevent any undue influence.

Participants were also made aware they could withdraw at any point and there was no consequence to this decision (Robson, 2011). This was important in all stages of the study but ensuring this was written in plain English in Stage 3 was important so that they were aware it would have no detrimental effect on their child's care. Involving parents/carers in the review of the parent/carer PIS ensured that it contained information which clearly stated that their child's treatment would not be affected by

their decision to participate or not. All consent forms were returned to the researcher either via email or as a hard copy. They were stored securely in the site file.

The participants involved in the interview stage of the study were given a £10 Amazon voucher as a 'thank you' for their time. The invitation email highlighted the award of a voucher, but it was not named, and no value mentioned. This reduced the likelihood that participants are induced to take part in the study.

3.8.3 Participant harm

One of the central principles of any research study is non-maleficence; to do no harm (Gray, 2013). There was a potential risk that participants may become upset during the interview if issues of previous or current medication errors were raised. If this occurred, the participant was given the choice of the following actions:

i. To continue
ii. To have time out
iii. To stop the interview
iv. To rearrange for another day
v. Referral to an NHS counselling helpline

If the participant decided to stop the interview, they were reminded that data collected up until that point will be used as indicated in the PIS.

3.8.4 Disclosure

If the researcher were to hear of an actual event with associated evidence of patient harm she would comply with the following process.

i. Determine if this event had been recorded as per hospital trust incident reporting guidelines
ii. If the event had been documented no further action would be taken
iii. If the event did not involve the participant and it was an error they had observed, the nursing manager of the unit would be informed of the details of the incident

iv. If the event involved the participant and had not been reported, then the nursing manager of that unit would be informed of the details with the participants' name

This process was documented within the PIS. In addition, the researcher was required to act within the Nursing Code of Conduct both within practice and as a researcher within the clinical field (Nursing and Midwifery Council, 2015a).

3.8.6 Confidentiality

Ensuring that a participants' identity is protected throughout the study is an essential ethical requirement linked to the principle of beneficence (Kaiser, 2012). The principle of beneficence seeks to ensure that the research participant is not exposed to any harm. On this occasion the researcher was required to ensure that the participant was not harmed by their interview data being identifiable and linked to them. This is an essential requirement as there are potential negative risks associated with confidentiality breaches such as harm to relationships or the sharing of personal information.

This study used a dominant approach to confidentiality, data was collected, analysed and disseminated without compromising the participants' identity (Kaiser, 2009). This approach ensured confidentiality was protected throughout the processes of data collection, transcription, analysis and reporting. The PIS describes how the participant's identity was protected and an NHS.net account was used for the secure transfer of information. During transcription, all identifiable information (names, roles, geographical locations, unit descriptions) was removed. This created a clean data set; but contextual data remained. The number of PICU's in England is small and some have unique patient cohorts that could help to identify them. Therefore, the researcher discussed these issues with her supervisory team to help ensure that confidentiality was maintained in the reporting of the study's findings.

3.9 Stage 4 - Synthesis of Stage 1, 2 and 3 findings

The findings from all stages of this study were collectively synthesised using a retroductive strategy which is linked with critical realism (Blaikie, 2000a:112). Retroductive strategies involve a technique where the researcher identifies the circumstances which need to be present for the concept or mechanism needs to exist

(Meyer and Lunnay, 2013). A realist synthesis is noted by (Pawson, 2006) to provide an explanation of how an intervention may work, thus using a retroductive strategy to help understand the circumstances that are needed for a mechanism to work helps with this explanatory discussion. The aim of this synthesis was to synthesise the multiple perspectives from stages 1, 2 and 3 to develop understanding of the context, mechanisms and outcomes in relation to interventions to reduce interruptions for medication administration within the PICU setting.

The first stage of the synthesis process was to review of the CMO sections from the finding's chapters with a group of colleagues. These colleagues were either experts in patient safety or parent/carer decision-making literature. This review contributed towards the verification of the initial CMO's identified. Realist synthesis can be guided by the following questions suggested by Pawson (2020):

i. What works for whom, in what circumstances and why?
ii. Speculate about what does not work and why?

For the purpose of this synthesis additional questions (see Table 20) were developed to help explore and examine the hidden mechanisms within the findings:

Table 20 - Questions to guide synthesis analysis

What situations, environments or circumstances (contexts) influenced behaviour, actions or decisions? • When being interrupted • When using interventions to reduce interruptions to medication administration • When responding to interventions to reduce interruptions to medication administration

What feelings, behaviours or actions (mechanisms) were triggered • When interrupted • When using interventions to reduce interruptions to medication administration • When not using interventions to reduce interruptions to medication administration • When choosing whether to use an intervention to reduce interruptions to medication administration
What were the outcomes associated with the circumstances and feelings?

These questions were applied to each of the three individual sets of findings. Due to the fact that an overall synthesis was required, there was an exploration of how each of the CMO's from each set of findings interacted and influenced the other. These were then summarised into CMO configurations (CMOCs) to demonstrate the interactions. This overall synthesis was discussed with the supervision team for verification. This synthesis followed a similar process to the one used by Rycroft-Malone et al. (2012), where their data was themed and discussed with additional stakeholders before the synthesis was completed.

In summary, this section has provided a rationale for the method used within this synthesis; the application of a retroductive lens to each set of findings. This was then developed into an overall synthesis with the production of CMOC's to present a diagrammatic representation of how the CMO's interact with each other. This synthesis offers an explanation of what circumstances influence the effectiveness of interventions to reduce interruptions to medication administration in PICU.

3.10 Quality and rigour

There is a necessity in all research to assess quality and rigour. Assessing quality and rigour within qualitative work is suggested to be not as clearly defined as it is in quantitative studies where validity (internal and external), reliability and objectivity are routinely described (Baillie, 2015). However, researchers (Lincoln and Guba, 1985, Denzin and Lincoln, 2005, Bryman, 2016, Miles et al., 1994) all suggest clear and transparent quality criteria for qualitative studies. There is a debate within the literature concerning the use of terms such as rigour within qualitative work it may reduce the creativity required to explain the phenomena under investigation (Baillie, 2015). Ultimately, it is essential that qualitative studies are conducted to a high quality maintaining rigorous standards to ensure ethical work is completed that colleagues in

practice can have confidence in. Within this study the criteria provided by (Lincoln and Guba, 1985) was used to demonstrate the concept of trustworthiness. This quality assessment is presented in Table 21 where it outlines how credibility, dependability, transferability/confirmability and reflexivity are defined and evidenced. Added to the end of the table are the realist elements of plausibility and coherence.

Table 21 - Quality assessment

Criteria	Explanation	Techniques used
Credibility	The degree to which the study offers a plausible explanation of the phenomenon under investigation and acknowledges possible alternate explanations.	Use of an aligned, appropriate methodology. Use of realist methods which searches for explanations. Synthesis chapter where findings from each stage of study are compared and alternate explanations explored. Verification of coding processes.
Dependability	Study has been completed with a clear process which can be audited.	Verification of coding process. Documented process of question development for interviews. Documented decision-making during coding process
Transferability/ Confirmability	Potential for findings to be transferred to other areas Confirmation of researchers position and influence	By seeking to understand the complexities of interruptions to medication administration in PICU the findings will be relevant to other intensive care areas such as Adult Intensive Care and Neonatal Units. Providing rich descriptions will allow practitioners to see if the findings are transferrable. Maintenance of reflexive diary. Use of critical realism throughout the whole study.

		Documented awareness of being an insider researcher.
Reflexivity	Examination of researchers own assumptions, pre-conceptions and values	Detailed reflexive diary. Challenge during supervision Discussion of insider-researcher issues
Trustworthiness (in realist studies)	Having an awareness of underlying data and searching for multiple sources of evidence	Clear evidence of data sources and data analysis processes
Plausibility	Contributing plausible evidence to the theory	Detailed audit trail of decision-making when developing CMO's
Coherence	Offering a good explanation	Robust supporting evidence from literature and empirical data

In addition to the framework provided by Lincoln and Guba (1985) described in Table 21, Wong (2018) notes that within realist research plausibility and coherence should be assessed. It is necessary to examine trustworthiness, plausibility and coherence due to the explanatory nature of the methods used to generate a programme theory (Wong, 2018:140) Haig and Evers, 2016). To produce this explanatory theory the researcher is required to look at a mixture of data which may not be from an empirical study, such as opinion pieces or editorials. Therefore, additional methods are required to assess the quality of methods used to support the development of a theory (Wong, 2018:140). The highest quality theory is only plausible because it is coherent and is supported by trustworthy data. Coherence relates to how logical and consistent an argument is. Haig and Evers (2016) note that the end theory is more likely to be coherent if it offers a good explanation. To achieve coherence the theory must explain as much as possible about the phenomena. It should be simple and not have ad hoc assumptions within it. Finally, the theory should fit with current knowledge.

3.11 Insider researcher

At the beginning of the study, I was a PICU nurse with 20 years of experience of providing care to critically ill children and implementing changes to clinical practice. This knowledge and experience could be viewed beneficial in that I understood the detailed descriptions of practice that used medical and nursing terminology. However, there was a risk that I could use this knowledge to place my views and experiences in the analysis of data from other healthcare professionals. To try to stop me enforcing

my views on to the data I used strategies do develop awareness of my own perceptions and beliefs during the study. I maintained reflective diary throughout to enable me to examine my own perceptions and to have an awareness of their impact on the research (Ortlipp, 2008). The reflexive diary was anonymised to ensure participant identity is protected. Furthermore, I routinely discussed the data and my views in twice monthly supervision sessions and was regularly challenged to ensure I was presenting the participant voice and not my own. Finally, I asked three colleagues to review my interpretation of a selection of data to ensure I was truthfully reflecting the data provided by participants.

3.12 Reflexivity

Within qualitative studies the researcher is the data collection tool and is therefore subject to influences from their own experiences and perceptions (Baillie, 2015). Furthermore, the participant may also be influenced by the researchers verbal and non-verbal communication (Baillie, 2015). To address these issues a reflexive diary was maintained, which allowed for the critical evaluation of oneself as a researcher (Denzin and Lincoln, 2005). The diary focused on the researchers' assumptions, expectations, emotional responses and unconscious responses (Finlay, 1998). Excerpts from this diary have been added into the thesis to demonstrate the reflexivity process that occurred throughout the study.

3.13 Conclusion

This chapter has provided a critical overview of the four stages included in the study as set out in Table 5. Further, there has been a detailed, critical exploration of:

- Research paradigm of Critical Realism
- Methodology and a rationale for choice
- Methods
- Ethical issues
- An assessment of quality and rigour

In addition to these elements the challenges of conducting research in PICU were identified and with a discussion of the actions taken to ensure a robust and ethical study was delivered and that it met the aim and objectives as set out. The use of critical realist philosophy throughout each stage of the study provides has provided a

comprehensive lens for the researcher to use to seek to explain the context and mechanisms that influence the outcomes of interventions to reduce interruptions to medication administration within PICU. This chapter has set a detailed and transparent scene to enable the reader to comprehend how the data was collected that informs the findings and synthesis presented in the next four chapters.

Chapter 4 – Findings 1: Realist Review of the literature

4.1 - Introduction

This chapter will present the findings from a Realist Review of literature of interventions aimed at reducing interruptions to medication administration. Search results, data extraction and analysis in relation to the contexts, mechanisms and outcomes will be presented

4.2 Programme theory

The initial programme theory explains how the intervention should work in practice or real life. The theory for this review was (see Table 22) developed by the researcher through insights gained from clinical practice, existing literature, and undertaking previous empirical research in this field (Bower et al., 2015) (Bower et al., 2017). Conclusions drawn indicated that interruptions to medication administration were complex, reactions to interventions were varied, and their impact at times limited. This knowledge about complexity was developed further during the writing of chapter two where the development of the interventions and their theoretical frameworks, used to reduce interruptions were explored.

Table 22 - Initial programme theory

Initial Programme Theory
'Within an inpatient health healthcare setting, the interventions such as vests/tabards/aprons, signs, NIZ's, protocols within the medication process aims to eradicate interruptions. The reduction of interruptions will improve efficiency, by reducing the length of medication administration time, and patient safety, by the reduction of medication errors.'

Within realist literature it is highlighted by Pawson and Tilley (1997) that it is not the intervention itself that is evaluated, but the programme theory that underpins it. Therefore, the Realist Review should seek to explain how the intervention brought about the changes in practice (Shearn et al., 2017). To identify the initial programme theory, the interventional studies included within the narrative literature review and empirical study were explored for nuggets of data that explained how researchers perceived the intervention to work (see Table 23).

Table 23 - Evidence to support initial theory

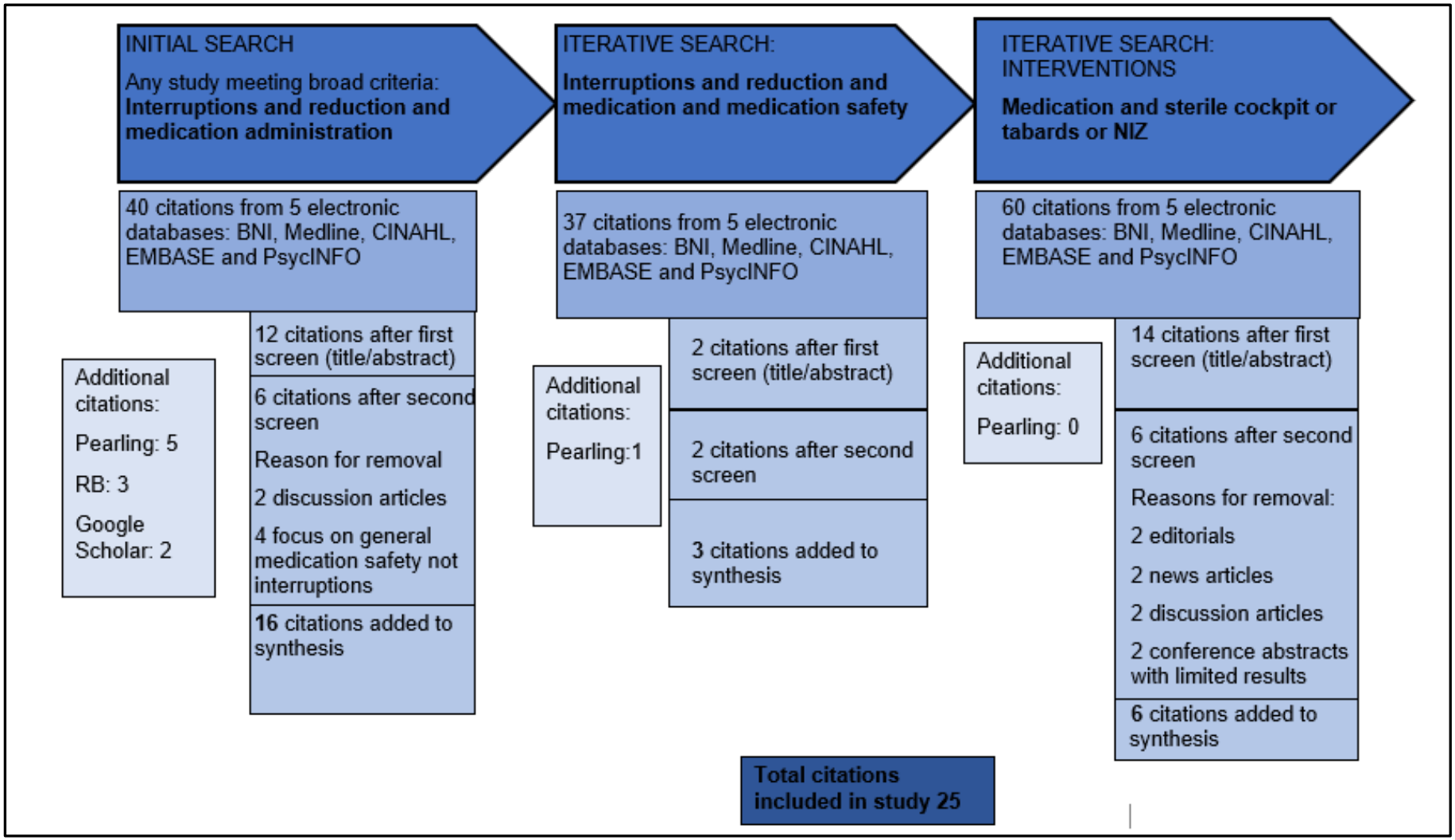
Supporting evidence
‘the purpose of the NIZ is to eliminate conversation and activities unrelated to medications’ (Anthony et al., 2010) page?
‘the aim is to improve efficiency, reduce distractions and improve safety’ (Conrad et al., 2010)
‘to implement a sterile cockpit principle to decrease interruptions and distractions during high-volume medication administration times (09.00 and 11.00 hours). The goal was to reduce the number of medication errors and ultimately improve patient safety.’ (Fore et al., 2013:108)

The initial programme theory presented in Table 22 states how interventions to reduce interruptions to medication should work. The examples identified within Table 23 identifies the evidence to support the researcher’s perceived theory.

4.3 Search Results

The initial literature search was conducted in spring 2017 and updated in September 2019 which is summarised in Figure 13. The preliminary search yielded 25 studies that were deemed suitable following full text review and were included in the synthesis

Figure 13 - Search results



A secondary search in 2019 identified an additional three relevant papers that were included resulting in a total of 28 papers being included in the review and synthesis.

Twenty-six were original research papers and two were literature reviews creating a sample of twenty-eight studies. One of the literature reviews (Raban and Westbrook, 2014) reviewed 11 studies, eight of which are included within this study. In contrast, Hayes et al. (2015a) focused their review on undergraduate education so only four studies were reported within this review. The information included in Table 24 presents the salient information from this literature. The location of the studies demonstrates an international interest in the phenomenon, with studies from North America (n=17), Australia (n=3) UK (n=1), Canada (n=1), Netherlands (n=1), Ireland (n=1), Italy (n=2), New Zealand (n=1) and Singapore (n=1). It is important to acknowledge that 17 studies were completed within the North American healthcare system. This is important to acknowledge as it is significantly different to the UK system as it receives funding from private sources, and this has resulted increased funding for technology. This is particularly prevalent in medication administration where prescribing, preparation and access to medicines is controlled by electronic systems (Truitt et al., 2016). Furthermore, a significant number of studies were conducted in acute adult settings (n=24), with two completed within acute paediatric units.

Table 24 - Studies included in review

Name and date	Intervention	Design and Method	Analysis	Outcome measured	Findings	Limitations
Anthony et al (2010)	No interruption zone	• Pilot study • Quasi-experiment • 2 ICU's on a single site. • Observation data collected pre and post implementation. Staff informed of patient safety initiative. • Baseline data collected during peak medication times for a total of 8 hours. • Tape placed around medication areas and nurses trained how to use the zone. Intervention used for 3 weeks before post data collected (using same protocol as baseline)	Descriptive statistics and 2-tailed independent t test	Rates of interruption	Pre-intervention interruptions occurred in 31.8% of episodes Post intervention 18.8%. statistically significant p=0.03 with an effect size of 1.3	• Single site reduces generalisability • Potential for Hawthorne effect. • Use of staff nurse as observer may introduce bias however, they were trained by researcher, but no interrater reliability assessed.

Name and date	Intervention	Design and Method	Analysis	Outcome measured	Findings	Limitations
Capasso and Johnson (2012)	Visible signs for medication cart Education	• Quality improvement study using DMAIC method • Baseline data collected during mapping exercise • Intervention was implemented and post intervention data was collected 30 days after implementation.	Descriptive frequencies	Interruption rates and duration	Number of interruptions per medication episode reduced from 4 to 1. Percentage of episodes interrupted reduced from 93%-50%. Time per interruption dropped from 6 minutes to 0.3 minutes.	• Single site reduces generalisability • Limited statistical analysis
Choo et al (2013)	A vest with 'do not disturb written on it'	• Descriptive, prospective observational study • Observational data collected over 12 weeks (during peak medication times 07-09 and 19-21) using MADOS. • Compliance with protocol and distractions were recorded. • Short interview occurred at end of observation period	Descriptive statistics, frequencies and percentages	Compliance rates	45.4% of medication administration episodes included errors. 90% of nurses were distracted during medication administration on average 1.8 interruptions/participant (n140). 45% of nurses felt that environment was conducive to medication administration.	• Experience of research assistant unclear. • Potential Hawthorne effect • Lack of generalisability (based in Singapore)

Name and date	Intervention	Design and Method	Analysis	Outcome measured	Findings	Limitations
Colligan et al (2012)	Targeted areas of central medication station had frosted glass screens applied	• Evaluation using human factors theory • Evaluation of current practice through simulation, interviews and observation. • Intervention designed and efficacy assessed by a pre/post observational study (assessing perceptions, frequency and interruption type	Hierarchical task analysis Descriptive statistics Mann Whitney U test	Interruption rates and nursing perceptions	Favourable nursing perceptions of medication area with significant P values (p=0.01). Except for efficiency and making medication administration safer. Mean interruption rate/minute reduced from 1.4-0.27 (p<0.01)	• Single unit reduces generalisability • Potential for Hawthorne effect. • Observers not blinded to intervention.
Connor et al (2016)	Ambassador Red zone badges Visible signs Scripted responses Interdisciplinary education Patient information	• Quality improvement study using Six Sigma process • Pre/post medication events recorded and compared within two areas	Descriptive statistics	Reduction in medication events	CICU – events reduced from 0.97/1000 doses to 0.20/1000 doses (p 0.00184) Acute cardiac care unit – events reduced from 1.04/1000 to 0.36/1000 (p 0.035).	Dependent on retrospective reporting which can be unreliable

Name and date	Intervention	Design and Method	Analysis	Outcome measured	Findings	Limitations
Conrad et al (2010)	Education Protocol Environment	• Quality improvement study using DMAIC process • Pre and post intervention survey • Pre intervention observation	Descriptive frequencies	Interruption rates Duration of medication administration Medication errors	Interruptions reduced from a mean of 4/episode Duration of medication time decreased from 15 minutes to 10 minutes Medication errors reduced by 53% after 3 years	• Single unit on single site reduces. generalisability • Potential for Hawthorne effect.
Craig et al (2014)	White vest with red lettering 'Please do not interrupt while passing medications' written on the back. Education to unit secretaries Planning for method of transport for patients	• Quasi-experimental design. • Pre and post-test observational study. • Completed in 4 units (wards) • Baseline data (type and frequency of interruptions) collected before implementation for two weeks. • Intervention implemented during week three. • Follow up two-week data collection period	Independent two-sided t-tests to compare duration and frequency pre and post intervention. Homogeneity of variance assessed. Statistics for unequal variance if assumptions violated. Bonferroni correction applied to reduce risk of type 1 error.	Interruption type and frequency	Interrater reliability 0.781 ($p<0.01$). most frequent interruptions (pre and post) (n3714): staff 32.7%, phone calls 13%, missing equipment 8.2%. Over all units there was statistically significant reduction in interruption rates ($p=0.004$) mean rate decreased from 58.85-34 with 95% confidence intervals. However, there was no statistically significant reduction in duration of interruptions, and this could not be explained.	• Single hospital reduces generalisability • Observers were volunteers from nursing team and were not blinded. • Concerns raised about accuracy of duration of interruptions.

Name and date	Intervention	Design and Method	Analysis	Outcome measured	Findings	Limitations
Dall'Olgio et al (2017)	Yellow sashes NIZ Checklist Education sessions Patient and family information	• Quasi-experimental design using Pre/post observational study (within a quality improvement programme) • Baseline data collected during a 2-month period before implementation of interventions. • Interventions were then implemented (in all wards) over a two-month period before post data was collected over a two-month period	Descriptive statistics and due to non-normal distribution non-parametric tests used for inferences and proportions (Mann-Whitney, Fishers exact and Chi-squared)	Interruption type and frequency	Total number of interruptions decreased from 2303 to 797. Statistically significant with p <0.001 (despite different numbers of cycles observed) Decrease seen in all types of interruptions except emergency.	• Possible seasonal bias due to baseline data being collected in winter and post in summer.
Federwisch et al (2014)	Medication quiet time Bedside rounding Visible signs Support staff education Patient/family information	• Quality improvement study • Post implementation of intervention medication error rates were monitored, and a survey captured	Descriptive statistics	Medication error rates Nurses' perceptions	Medication errors reduced from 42 (0.03% of medications administered involved an error) to 23 (0.01% of medications administered). Two months after implementation 66% of	• Single unit at single site reduces generalisability • Small rates of medication error mean that it is difficult to statistically

		nurses' experiences and assessment of efficacy			nurses reported no reduction in interruptions. After six months 58% reported no change in interruption rates.	analyse the data.
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**
Flynn et al (2016)	Visible clothing Hourly patient rounds Triage of phone calls and scripts Signs Protected time No interruption zone Patient/family leaflets	• Pilot/ quality improvement project • Pre/post observational study. Performed on 3 (2 study units and 1 control) units within 1 hospital.	Percentages	Interruption rates and medication errors	Interrater reliability 96%. Interruption rates decreased on unit 1 (23%-4%) p=<0.001. No change on unit 2 and increased in the control unit. Largest decrease was in phone calls (48%). Avoidable interruptions decreased in unit 1 by 83%, unit 2 53% and increased in unit three by 71%. Medication errors decreased in all 3 units.	• Single site restrict generalisability • Convenience sample is not representative. • Potential Hawthorne effect • Lack of statistical analysis
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Fore et al (2013)	Orange vests Do not disturb signs on medicine carts. Staff and patients informed and asked to reduce interruptions Information sheets given to patients on admission	• Audit/ quality improvement • Self-report questionnaire completed at the end of medication round by medication nurse. • Completed Mon-Fri for 11 weeks	Frequency data captured mean number and type of distraction. Z scores to determine differences each week with week 11. Linear regression was used to calculate association between time and mean number of distractions (95% confidence intervals). Pre and post implementation data analysed by fisher exact and chi squared tests	Mean number of interruptions. Medication error rates per bed days from hospital adverse event reporting tool.	Mean number of distractions reduced from 4.1-1.5 over 11 weeks. Hospital staff contributed to 44% of interruptions, patients 25%, nurses 15% and visitors 15%. Regression analysis demonstrated decrease in mean number of distractions (p=0.02). Medication error rate decreased from 3.95/1000 bed days to 2.26 (p=0.04)	• Single unit design limits generalisability • Self-reporting may not capture all data. • No baseline data concerning rates of interruptions
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Freeman et al (2012)	No interruption zone in medication room identified by signs on door Lighted lanyard Triage of phone calls Patient and family education Medication chart review at handover Scripting cards Multidisciplinary education Support staff available during medication process	• Quality improvement project • Modified MADOS used to collect data pre and post intervention. • Observations recorded both day and night.	Descriptive frequencies	Interruption rates Error rates	Pre-intervention average of 3.29 interruptions/episode. Post intervention average 1.18 interruptions/episode. Medication errors decreased from 41-13 when compared to same period year before.	• Multiple interventions assessed at once. • Single site, single unit reduces generalisability • Interrater reliability not assessed statistically. • Sample size not large enough to distinguish statistical significance.
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Hayes, Jackson, Davidson and Power (2015)		Systematic, critical literature review	Thematic		Existing interventions seek to eliminate interruptions. Little is known about nurses manage them and learn those skills. Sustainable interventions are required.	Limited to literature relating to undergraduate studies
Johnson et al (2019)	E-learning programme	• Cluster randomised feasibility study • Four intervention and four control wards across four hospitals – e-learning programme how to manage interruptions implemented	Linear mixed-effects modelling	Interruption rates Medication errors Procedural errors	Number of interruptions did not occur but there were small changes in management strategies used	• Moderate Kappa scores reported in the inter-rater reliability testing • No record of whether all nurses completed whole of module
Johnson et al (2018)	E-learning programme	• Qualitative study • Focus groups post implementation of an e-learning programme	Thematic	Nurses' perceptions	Identification of barriers and facilitators to the use of the programme	• Small sample (N=9) • Focus groups completed 3-6 months post-trial
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Nelms and Treiber (2011)	Yellow sash Educational prompt Buddy system Personal phones answered by unit secretary Caritas process - centre self	• Nursing intervention research • Intervention implemented for 7 weeks. Medication error rates compared 1 year before intervention, 4 weeks before implementation of intervention and 4 weeks after intervention. • 3 focus groups held after implementation with nurses and wider MDT.	Rates and types of medication error. Thematic analysis by 2 independent researchers of qualitative data from focus groups	Medication error rates. Perceptions regarding intervention.	No reduction in error rates. Nurses perceived that interruption rates decreased. Nurses found it nice not to be interrupted. Nurses had a fear of missing information particularly from their phones. Nurses appreciated the notion of focus and concentration. Unwillingness to support and care for other nurses. Nurses felt guilty about delaying other medical personnel. The method reduced nurse's ability to provide total patient care.	• Short period of implementation of 7 weeks. • Medication error rates low before implementation so seeing differences may be difficult.
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Palaese et al (2015)	Red tabards	• Interviews • 12 closed questions and 3 open questions • 104 patient interviews – asked to look at 3 different tabards with different wording over 3 consecutive days	Descriptive statistics Chi square	Attitudes towards tabards	58% thought red colour appropriate Negative reasons for tabards – incongruent with nurse/patient relationship, aggressive, useless	• Limited analysis of qualitative data • Pictures of tabards used rather than being experienced in practice • First interview conducted prior to surgery, two interviews post-surgery. This may have influenced their response
Pape (2003)	Red vest with white lettering 'Medsafe nurse, do not disturb' on front and back. Focused protocol	• Quasi-experiment three group design • Interruptions were recorder using a validated tool (MADOS) which had interrater reliability of 0.9. • Interruptions experienced by control group were compared to two interventional groups.	One-way ANOVA Multiple bivariate regression	Interruption rates	Control group = 484 distractions Focused protocol 180 distractions Medsafe protocol 64 distractions One-way ANOVA: F (2,23) = 68.229 p=0.00. Post hoc tests showed statistically significant difference in distraction rates between Control group focused protocol (p=0.00), focused protocol and medsafe group	• Potential for Hawthorne effect • Lack of generalisability

		• One that used the focused protocol and one that used the protocol and a red vest.			(p=0.14) and between control group and medsafe protocol (p=0.00). Bivariate regression analysis all 10 distraction predictors significantly related to total number of distractions nurses experienced (p=0.00)	
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**
Pape et al (2005)	7 step protocol Visible signs Education	• Process improvement study using rapid cycle testing • Protocol and education implemented and nurse educators randomly selected staff to observe compliance. • Distractions were measured using a modified MADOS.	Descriptive analysis	Self - reported distractions. Observed compliance with protocol.	Statistically significant reduction in perceived distractions (p=0.000). particularly from other nurses.	• Lack of generalisability • Use of self-report is dependent on good memory recall.
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Pape (2013)	Visible signs Area marked by yellow tape as a no interruption zone Checklist Teamwork to field calls Fluorescent sash	• Pre/post quality improvement study • Conducted in a single medical unit using a convenience sample (n=8). Sample size calculated from a previous observational study (Pape, 2003) • Pre and post intervention data (interruption and distraction rates) was collected during 4 medication cycles (using MADOS). • After each observation period nurses completed the distraction perception survey.	Data was analysed using means, standard deviations and frequencies.	Frequency and type of interruption. Length of medication times.	Length of time to administer medication 5.03min (control/pre) and 3.47min (intervention/post). Interruptions reduced from 142 to 23 (84%) post intervention. Highest number of interruptions counted were for conversations. These reduced from a mean of 10 to a mean of 2.5 post intervention. Nurses' perceptions were not compared pre and post intervention.	• Single site limits generalisability • Potential Hawthorne effect • Small numbers of observation (63 medication episodes pre and 57 episodes' post) • Nurses involved in teaching students were not included that may have affected rates of interruptions seen
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Raban and Westbrook (2014)		• Systematic review • Database search of empirical studies assessing impact of interventions to reduce interruptions to medication administration		Interruption rates or medication errors	10 studies included. Weak evidence for significant reduction in interruption rates and limited evidence of impact on errors	Limited to quantitative studies
Relihan (2010)	Red plastic aprons Behaviour modification, Staff education, Checklists Visible signs	• Pre and post observational study • Single observer shadowed 16 medication rounds. • Interruptions recorded using MADOS.	Descriptive statistics Poisson regression analysis	Interruption rates/hour pre and post intervention (95% confidence interval)	Statistically significant reduction on drug rounds at 06 and 12 (p= 0.024 and 0.028 respectively). Not significant at 18 and 22 (p= 0.082 and 0.079 respectively) Poisson regression rate ration 0.432 (p= <0.0001)	• New medication policy launched at same time. • Potential for Hawthorne effect • No control group
Scott et al (2010)	Red tabard & 'Drug round in progress. Please do not disturb' on front and back Education	• Audit • Pre and post intervention data collected by self-reported questionnaire	Descriptive statistics	Rates of interruption per drug administration episode	Interruption rates decreased from 6 per episode to 5	• Self-report data • Limited analysis of data
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**

Tomietto et al (2012)	Medication room Red tabard 'Please do not interrupt me, I am managing medications' Educational strategies	• Pre and post observational study • 56 randomised medication rounds observed across 7 units. • 4 observers collected data (Cohens Kappa, was >0.90)	Descriptive statistics T-test Chi- Square comparison	Interruption rates per round Causes of interruption Management of interruption	Interruptions reduced from 1 every 3.2 medications to 1every 2.3.	• Potential for Hawthorne effect • Long data collection period (4 years) but only 2 timepoints of measurement
Westbrook et al (2017)	Do not disturb vest Workshops Education Reminders Patient information	• Cluster controlled randomised feasibility study • Parallel 8 cluster; 4 wards randomised to the intervention and 4 wards blinded	Descriptive statistics	Non-medication related interruptions Secondary outcomes-total interruption rates and multitasking rates	Non-medication interruptions reduced from 50/100 doses to 34/100 doses on intervention wards. Non-medication related interruptions stayed at similar rates on control wards (51/100 doses)	• Control group did not remain blinded
Verweij et al (2014)	Florescent yellow tabards with printed text 'Do not disturb, medication round in progress' on front and back	• Mixed methods • Pre/post observational study • Three observational period (pre, 2- and 4-weeks post intervention) on 3 wards. • Personal inquiry and focus groups.	Descriptive statistics and univariable linear regression (Kruskal-Wallis) Thematic analysis of qualitative data.	Interruption rates and error rates. Relationship between interruptions and errors. Nurses experience of wearing tabards.	Interrater reliability >.80. 75% reduction in interruptions (p=<0.05). 66% reduction in errors. Linear regression demonstrated that interruptions were a significant predictor for errors (p<0.05) – 10.4% of errors can be explained by interruptions.	• Single hospital reduces generalisability • Observers were student nurses not blinded to intervention.

					Qualitative data demonstrated that nurses perceived that they were unapproachable. But it was seen as effective if supported by whole team.	
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**
Williams et al (2014)	White vest with red sign 'medication round in progress please do not disturb ' Education No Interruption Zone Responses to interruptions Visible signs	• Pilot/quality improvement study • Pre/post observational study. • Baseline data was recorded before implementation of intervention. • Two months' worth of error data from hospital system used as baseline for error rates. • Nurse perceptions about interruptions collected using modified distraction perception survey before implementation. • Data collection was then	Descriptive statistics and Mann-Whitney U tests.	Interruption rates and error rates	100% compliance with all interventions except vests and use of response cards where it was 0. Statistically significant decrease in interruptions (reduction in mean from 7.94/round to 2.13) $p<0.001$. Greatest reduction in staff interruptions, phone calls and non-medication conversation. Nurses perceived that hospital staff frequently interrupted. Perceived the use of red tape around trolley to be most effective intervention. Medication error rates reduced by 60%.	• Single unit, on single site. • Hawthorne effect. • Testing of multiple factors

		repeater post implementation.				
Name and date	**Intervention**	**Design and Method**	**Analysis**	**Outcome measured**	**Findings**	**Limitations**
Yoder et al (2012) and (2015)	Vests Visible signs Checklist Education	• Pilot study using a one-group pre-test/post-test • Data collected pre and post intervention using MADOS (self-reporting). • Medication error rates were measured over 3 months pre and post intervention. • Patient satisfaction was co-incidentally measured over this time.	2 tailed t-test	Hospital data concerning adverse events	Statistically significant increase in interruptions by nursing and medical staff (p=.003), noise (p=.018) and families (p=0.025) Reported medication errors increase from 1.74 to 2.88/1000 bed days. 40% increase in patient satisfaction scores.	• Limited description of method and analysis • Self-report bias. • Single site single unit.

There were 26 primary research studies included within this review which included 1313 participants. Within this sample 23 studies included RN's, with the addition of student nurses in two and patients in one. Occasionally feedback was obtained within the implementation phase from the wider multi-disciplinary team and patients (Federwisch et al., 2014). Most of the studies used direct observation as their method of choice (n=20). Although, a significant number (n=13) gained feedback from users using surveys, focus groups or interviews. The commonest tool (n=9) used for collecting data was the Medication Administration Distraction Observation Sheet (MADOS) which was a validated tool designed by Pape (2003). In addition, two studies used unvalidated self-perception surveys to collect data about perceived impact of interruptions.

Twelve studies were conducted as part of a quality improvement programme. The DMAIC process (n=4) was the most frequently used quality improvement methodology, which is a more statistically robust method (Sokovic et al., 2010). The data collection methods used within this sample of quality improvement studies were observational (n=13) and eight of the studies used quasi-experimental methods. Surveys (n=4), audit (n=1), self-reporting incident forms (n=3), interviews (n=1) and focus groups (n=3) were other methods used to evaluate interventions. There were multiple interventions tested within the literature base.

The components included within interventions varied significantly between studies. Only six studies (Anthony et al., 2010, Colligan et al., 2012, Verweij et al., 2014, Choo et al., 2013, Campbell, 2013, Prakash et al., 2014) implemented single component interventions (for example a tabard/vest). The other studies included a bundled approach that mixed components such as tabards with a protocol (Pape, 2003), although each study selected different combinations within the bundle (see Table 25). The information contained within Table 25 identifies that the commonly tested interventions were NIZ, tabards and signs. The NIZ and tabard were occasionally test on their own, but signs were always accompanied by another intervention.

Table 25 - Interventions implemented in the literature

Study	Interventions									
	NIZ	Apron/ sash/ tabard	Signs	Education /Training	Badge /Lanyard	Protocol/checklist	Patient info	Protected time	Phone Triage	Behaviour change
Anthony (2010)	☑									
Capasso and Johnson (2012)			☑	☑						
Choo et al (2013)	☑									
Colligan et al (2012)	☑									
Connor et al (2016)			☑		☑					
Conrad et al (2010)			☑	☑		☑				
Craig et al (2014)		☑		☑						
Dall'Olgio (2017)	☑		☑	☑	☑		☑			
Federwisch et al (2014)			☑	☑				☑		
Flynn et al (2016)	☑	☑	☑			☑	☑			
Fore et al (2013)		☑	☑				☑			
Freeman et al (2013)	☑		☑	☑	☑	☑	☑		☑	

Study	

	NIZ	Apron/ Sash/ Tabard	Signs	Education/ training	Badge /Lanyard	Protocol/ checklist	Patient info	Protected time	Phone triage	Behaviour change
Johnson et al (2018)				☑						
Johnson et al (2019)				☑						
Nelms et al (2011)		☑		☑					☑	☑
Nguyen et al (2010)	☑			☑						
Pape (2003)		☑				☑				
Pape et al (2013)	☑	☑				☑			☑	
Palaese et al (2015)		☑					☑			
Relihan et al (2010)		☑	☑	☑		☑				☑
Scott et al (2010)		☑		☑						
Tomietto et al (2012)	☑	☑		☑						
Verweij et al (201										
Westbrook et al (2017)		☑	☑	☑			☑			
Williams et al (2014)	☑	☑	☑	☑		☑				

Yoder et al (2015)		☑	☑	☑		☑				

The outcome measures reported by researchers were not consistent, as demonstrated by Table 26. The most frequently used measure of effectiveness was interruption rates (n=17) with studies also reporting interruption type (n=5); rates of error (n=10); length of medication time (n=3); nurse perceptions (n=3); compliance rates (n=2); length of interruption time (n=1); and multitasking (n=1). Whereas such direct comparison between studies is difficult and conclusions indicate that further research is required with standardised outcome measures (Raban and Westbrook, 2014).

Table 26 - Primary outcomes and associated data collection methods

Primary outcome measured	Data Collection Method
Interruption rates	Pre/post observation (Anthony et al., 2010) Survey and observation (QI) (Capasso and Johnson, 2012) Observation and interviews (Choo et al., 2013) Observation, interviews and survey (Colligan et al., 2012) Pre/post observation (Craig et al., 2014) Pre/post observation (Dall'Oglio et al., 2017) Self-reporting (QI) (Fore et al., 2013) Pre/post intervention (QI) (Freeman et al., 2013) Quasi-experimental (3 group) pre/post observation (Pape, 2003) Pre/post observation (Pape et al., 2005) Pre/post observations and Survey of perceptions (QI) (Pape, 2013) Pre/post observation, personal enquiry and focus groups (Verweij et al., 2014) Parallel 8 cluster RCT with pre/post observation (Survey) (Westbrook et al., 2017) Pre/post observation and error data (Williams et al., 2014)
Rates of error	QI (method) (Connor et al., 2016) Pre/post survey (QI) (Conrad et al., 2010) Pre/post observation (Federwisch et al., 2014) Pre/post observation (QI) (Flynn, 2016)

	Pre/post error rates and focus groups (Nelms et al., 2011) Pre/post observations (Relihan et al., 2010) Questionnaire post error (audit) (Scott et al., 2010) Pre/post observation and error data (Williams et al., 2014)
Length of medication time	Survey and observation (QI) (Capasso and Johnson, 2012) Pre/post survey (QI) (Conrad et al., 2010)
Nurse perceptions	Quasi-experimental (Campbell, 2013) Observation, interviews and survey (Colligan et al., 2012) Pre/post observation and survey (Federwisch et al., 2014) Pre/post observations and Survey of perceptions (QI) (Pape, 2013) Pre/post error rates and focus groups (Nelms et al., 2011) Parallel 8 cluster RCT with pre/post observation (Survey) (Westbrook et al., 2017) Pre/post observation, personal enquiry and focus groups (Verweij et al., 2014) Pre/post observation of e-learning and focus groups (Johnson et al., 2019, Johnson et al., 2018)
Compliance	Observation and interviews (Choo et al., 2013) Pre/post observations and patient satisfaction scores (Yoder et al., 2015)
Patient satisfaction	Patient satisfaction scores (Yoder et al., 2015) Patient interviews (Palese et al., 2019)

Frequently more than one outcome was measured within the study such as Conrad et al. (2010) who measured interruption rates, length of medication time and error rates. In addition to inconsistent outcome measures, the unit of measurement also varied from total interruption rates, interruptions per episode, interruptions per hour and non-essential interruption rates. This inconsistency results a challenging comparison of effectiveness of interventions and prevents the completion of a meta-analysis, that was highlighted in the rationale for a realist review.

4.4 Contexts, Mechanisms and Outcomes

Line by line coding of the results/findings and discussion sections focused on the identification of these contexts, mechanisms and outcomes. This was achieved by asking the following questions when analysing the data:

- Is this a situation that triggers feelings, behaviours or reactions in the participant?
- What are the feelings or reactions that are triggered?
- Why are those feelings or reactions triggered?
- What was the outcome of the situation?
- Was this outcome expected or unexpected?

The contexts, mechanisms and outcomes generated by this analysis are presented in Table 27.

Table 27 - Contexts, mechanisms and outcomes

Context	Mechanism	Outcome
• Leadership and culture • Patient and family centred care • Education and engagement • Environment • Understanding interruptions	• Isolation of task • Empowerment • Trust in the team	• Interruption rates • Medication errors • Time and money • Satisfaction • Adherence to policy

The line-by-line coding generated 32 different codes, that were then defined and identified as either a context, mechanism or outcome. Within each group the themes were then identified and are outlined in Table 27. Understanding the factors that influence each of these was important knowledge as it may contribute to the future development of interventions to reduce interruptions to medication administration.

4.4.1 Contexts

The data analysis process has identified five influencing contexts (see Table 27). The review has identified that clinical areas where the complexity and differences in interruptions have been examined and analysed, experience different reactions to those where interventions have been implemented without this exploration. Furthermore, studies also highlighted the impact of the environment and the need to consider this within the design and implementation of interventions. It is evident from the research that there is a need for interventions to comprehend the delivery of patient and family centred care. The different methods of engaging staff within interventions also highlighted as a contextual factor that triggered different behaviours and reactions. The final influencing context identified was leadership within the clinical area and their participation within the intervention.

Within the literature analysed, it was identified within six studies that the impact of any intervention was influenced by what/who causes the interruption (Anthony et al., 2010, Freeman et al., 2013, Raban and Westbrook, 2014, Tomietto et al., 2012, Verweij et al., 2014, Westbrook et al., 2017). Most studies (n=21) collected data about the number of interruptions pre and post implementation although only six studies analysed the type of interruptions observed. Only one study (Colligan et al., 2012) used the data concerning the type of interruptions seen to inform the design of their intervention.

Many of the studies reviewed did not tailor the intervention to the most frequent type of interruptions experienced (Anthony et al., 2010, Freeman et al., 2013, Tomietto et al., 2012). An example of this was evident in the work of Tomietto et al. (2012). One of the most common interruptions pre-intervention was a lack of available equipment. This remained the second highest post-implementation as there was no strategy within the intervention to ensure the medication trolley was appropriately stocked. In contrast, Colligan et al. (2012) extensively studied the whole medication process, noting the

type of interruptions to medication administration and tailored their intervention to match. The result of this study was increased staff satisfaction with the intervention and a significant reduction in interruption rates. The exploration of this context suggests that the analysis of types of interruptions and the tailoring of interventions to address this may result in a more useful design that comprehends the complexities of the clinical environment.

Identifying and understanding the type of interruptions experienced within the clinical area helped to influence the effectiveness of interventions. Eight studies (Raban and Westbrook, 2014, Relihan et al., 2010, Tomietto et al., 2012, Freeman et al., 2013, Anthony et al., 2010, Pape, 2003, Verweij et al., 2014, Westbrook et al., 2017) demonstrated that no intervention could reduce all interruptions. Anthony et al. (2010) decreased interruptions from personnel outside of the NIZ but was less effective at reducing those from staff inside the zone, due to conversations regarding medication administration. In their study, Verweij et al. (2014) used a single component of a tabard and found that it did not reduce interruptions from patients. This was also replicated by (Westbrook et al., 2017) whose intervention (vest, education, patient information and signs) had no impact on patient interruptions. In contrast, Freeman et al. (2013) used a multi-component intervention (which included patient and family information) did reduce patient interruptions. Conversely, Relihan et al. (2010) did individualise their intervention based on commonly seen interruptions in their unit, but it was less effective at reducing interruptions from doctors, other patients and the telephone.

Furthermore, the literature illuminated that the design of the interventions is focused primarily on staff rather than patients. Studies frequently reported that interventions reduced interruptions from nurses and their conversations (Freeman et al., 2013, Relihan et al., 2010, Westbrook et al., 2017, Williams et al., 2014) but had less impact on patient interruptions (Relihan et al., 2010, Tomietto et al., 2012, Verweij et al., 2014). A possible explanation for this outcome was the paucity of literature that collected data from patients and families. Six studies included patients and or family information within the design of the intervention and stated that it was an important element within the intervention (Capasso and Johnson, 2012, Federwisch et al., 2014, Freeman et al., 2013, Nelms et al., 2011, Relihan et al., 2010). Although, only two studies (Palese et al., 2019, Nelms et al., 2011) included the collection of data from patients or families. This lack of patient and family inclusion suggests that frequently

the information included within the intervention is not informed and may not comprehend the needs of patients and families.

The context of family and patient centred care was important as nurses frequently stated that they should always be available to patients (Colligan et al., 2012). The studies suggested that interventions were unlikely to succeed if nurses felt that they were expected to ignore patient, family or visitor requests (Capasso and Johnson, 2012, Federwisch et al., 2014, Freeman et al., 2013, Flynn, 2016, Nelms et al., 2011, Relihan et al., 2010). Within the study conducted by Nelms et al. (2011) the findings highlighted that nurses felt they should be available to doctors, patients, families and other departments. Furthermore, it was important to them that they were at the heart of the co-ordination of patient care. The use of interventions such as tabards or NIZ's was sometimes perceived by nurses to make them feel unapproachable (Verweij et al., 2014, Federwisch et al., 2014, Nelms et al., 2011). This was also echoed by patient data, Palese et al. (2019:33) reported that 43% of patients interviewed felt that the use of a red tabard was incongruent with the nurse/patient relationship.

The literature suggested that there was a requirement for additional patient family information. This information was required to reduce the patient and family need to ask what is happening and why (Nelms et al., 2011). This information was able to inform patients and families about the role of the intervention so that less verbal explanation was required. Studies indicated that interventions were more successful if patient and family information focused on how the intervention promoted patient safety. Furthermore, there were occasions were this encouraged patients or families to protect the integrity of the intervention (Freeman et al., 2013). This increased engagement from patients and families which allowed nurses to see that it did not have a negative impact on nurse/patient relationships.

An important element of keeping patients and families informed was the admission rates of the clinical area. It was noted by Relihan et al. (2010) and Federwisch et al. (2014) that keeping patients and their families informed was difficult when there was a rapid turnover of patients. In their studies they provided written information on admission but felt that this was impractical for frequent short-term admissions and more useful in long stay environments.

Environmental considerations were important in the design of interventions that involved infrastructure such as zones or medication rooms. If a zone or medication room was included within the intervention it needed to be clearly identified with attention grabbing signs or tape. The physical act of isolating the medication process is associated with the context of creating a visual barrier. Commonly this is generated using zones, signs or visual clothing (Anthony et al., 2010, Colligan et al., 2012, Yoder et al., 2015, Tomietto et al., 2012, Federwisch et al., 2014). Zones were created by placing signs on the door of a medication room (Tomietto et al., 2012) or placing brightly coloured tape on the floor around a stationary trolley (Anthony et al., 2010). If a mobile medication cupboard was in use, researchers created their zone by placing signs on to the trolley itself (Federwisch et al., 2014). In some studies signs were also used in patient rooms or at the entry point to the clinical ward to inform staff and patients of the intervention (Federwisch et al., 2014, Flynn, 2016).

No interruption zones were more successful if no other nurses were present within it, as their presence and conversations could serve as an interruption to others (Anthony et al., 2010). In addition, the zone should not be an area where nurses congregate (Colligan et al., 2012). As highlighted previously, nurses feel that they need to be always available to patients, and Colligan et al. (2012) found that this applied to the use of medication zones as well. Their human factors analysis concluded that nurses being able to see patients and parents/carers being able to see nurses was an important factor in the design and use of the zone.

The context of creating a physical barrier also generated reactions in those outside of the medication administration process, as it stimulated a decision-making process. This was seen with healthcare professionals, visitors and patients. The presence of the visual intervention encourages active thinking rather than automated actions. This can improve the impact of the intervention as it decreases unnecessary interruptions. This in turn can demonstrate benefits to the professionals involved with the process.

An important influential context identified within this analysis was staff engagement with the intervention (Conrad et al., 2010, Connor et al., 2016, Federwisch et al., 2014, Yoder et al., 2015). Engagement with the intervention was more successful if staff were included in the design of the intervention (Colligan et al., 2012, Freeman et al., 2013). The benefit of including staff in the design of the intervention is their

understanding of how it would fit with the workflow of the area (Colligan et al., 2012, Federwisch et al., 2014, Nelms et al., 2011, Pape, 2003, Westbrook et al., 2017, Yoder et al., 2015). The learning from these studies have identified that issues such as appearing unfriendly, increasing another person's workload, anxiety when separated from phones and prolonging the time of a process can all have negative impact on the engagement and success of the intervention.

Furthermore, the impact of an intervention was increased if the programme was accompanied by staff who were passionate about the change in practice (Conrad et al., 2010, Connor et al., 2016, Federwisch et al., 2014, Yoder et al., 2015). These roles had different names such as ambassadors, champions or respected nurses. These roles were always allocated to nurses and did not include the wider MDT. Nevertheless, their remit was similar; to promote and role model the use of the intervention in clinical practice. Therefore, it was important that these nurses were clinically based and believed in the intervention. One study (Yoder et al., 2015) demonstrated that engagement was seen to increase with rewards. They generated monthly contests within the intervention and rewarded positive results with sweets. The use of competition and reward has not been widely reported within the literature, this may be reflective of healthy eating strategies or an expectation that staff would perceive the intervention to be beneficial without requiring rewards.

Education about the intervention was frequently described as an important element within the implementation process and help to engage staff (Anthony et al., 2010, Connor et al., 2016, Conrad et al., 2010, Federwisch et al., 2014, Flynn, 2016, Fore et al., 2013, Colligan et al., 2012, Dall'Oglio et al., 2017, Pape, 2003, Verweij et al., 2014, Williams et al., 2014, Yoder et al., 2015). Furthermore, it was seen in many studies as a key factor to its success. The impact of interventions was increased if the education programmes within it included the wider MDT (Anthony et al., 2010, Flynn, 2016, Freeman et al., 2013, Dall'Oglio et al., 2017). The provision of MDT education was noted to be important as it was likely to increase engagement from the surrounding team who have an important decision to make, whether to interrupt or not. In addition, multidisciplinary education was viewed as vital in both cementing changes to practice and increasing adherence (Anthony et al., 2010, Flynn, 2016, Fore et al., 2013, Dall'Oglio et al., 2017).

There were multiple methods of education included in the implementation of interventions such as face to face sessions, online resources and noticeboards (Conrad et al., 2010, Federwisch et al., 2014, Williams et al., 2014). Interestingly, if an intervention was implemented without educating staff it was likely to increase interruptions as it raised more questions about its use (Pape, 2013). In contrast, environmental changes, such as placing a screen around a medication area, were noted not require additional costly educational programmes (Colligan et al., 2012). This was attributed to the human factors' analysis understanding how the intervention was required to work.

The research studies analysed within this review identified that leadership was an influential context and an important factor in their success (Capasso and Johnson, 2012, Connor et al., 2016, Conrad et al., 2010, Federwisch et al., 2014, Flynn, 2016, Verweij et al., 2014). These studies suggested that the presence of credible, strong, and visible leadership was able influence the intervention in multiple different ways. Leadership was used enforce adherence to the intervention, as well as motivating staff to use it (Flynn, 2016, Federwisch et al., 2014, Verweij et al., 2014). One study identified that leaders were able to set challenging goals and expectations from their teams (Verweij et al., 2014). The staff involved in the focus group within this study noted the importance of being a role model and motivating others. They were able to empower staff who promoted the use of the intervention (Capasso and Johnson, 2012, Freeman et al., 2013, Federwisch et al., 2014, Verweij et al., 2014). It is important to note that these leaders needed to be in a position where they could influence other professions or departments to follow the intervention and have access to financial resources (Capasso and Johnson, 2012, Freeman et al., 2013).

Furthermore, Flynn (2016) and Verweij et al. (2014) identified that the context of leadership had more influence if it was visible in the clinical area. Conversely, in their study Federwisch et al. (2014) identified that in addition to being visible, leadership was important within the implementation phase of the intervention; coaching, monitoring, responding to concerns and facilitating the process. On this occasion the outcome was poor with the intervention and study being abandoned. On this occasion the context of leadership did not overcome the greater influence of the increased workload for support staff generated by the implementation of the intervention.

The impact of leadership could be influenced by the culture of the unit. Anthony et al. (2010) and Federwisch et al. (2014) noted that it was important to understand the culture of a unit before implementing an intervention as this could influence its success. Some clinical areas were described as having an ingrained acceptance of interruptions that made changing practice more difficult. Furthermore, areas where values such as flexibility and availability to meet patient need were important the implementation of an intervention without addressing this culture was difficult.

In summary, this review has highlighted five contextual factors that can influence interventions to reduce interruptions to the medication administration process. Awareness of these contextual factors is important as they can trigger hidden mechanisms within individuals that impact on the success or failure of the intervention.

4.4.2 Mechanisms

The analysis process within this review has highlighted three mechanisms that can be triggered (see Table 27 in section 4.4). These mechanisms include isolation of task, empowerment and trust in the team.

Isolating medication administration is a fundamental principle within two of the associated theories that underpin the design of interventions to reduce interruptions, Crew resource management and Watson's Theory of Caring. By isolating the task, the process is prioritised, and the resource of time is allocated. Five studies (Dall'Oglio et al., 2017, Nelms et al., 2011, Pape, 2013, Relihan et al., 2010, Yoder et al., 2015) identified that outcomes improved if this resource created relief amongst nurses, as they were allowed and expected to only focus on a single activity. Nelms et al. (2011) described nurses as appreciating some 'me time'. This was linked with Watsons theory of caring's principle of being authentically present (Nelms et al., 2011). The provision of allocated time also created a feeling of being protected from interruptions. When nurses experienced this protection, it allowed them to complete a task with no interruptions. This was perceived to be beneficial due to increased efficiency but there were occasions when nurses used the intervention inappropriately to complete other tasks with no interruptions, such as documentation (Yoder et al., 2015, Nelms et al., 2011). This decreased the effectiveness of the intervention as the MDT failed to respond appropriately due to the prolonged timeframe.

In contrast to feelings of luxury and relief (Nelms et al., 2011, Dall'Oglio et al., 2017, Yoder et al., 2015), other studies noted that the context of isolation created feelings of unavailability (Federwisch et al., 2014, Verweij et al., 2014, Yoder et al., 2015), both to other members of the MDT and patients/families. Isolating the process was also viewed negatively because on occasions it prioritised medication administration at times when it was not the priority (Yoder et al., 2015, Nelms et al., 2011). This was especially noted when medications were administered outside traditional medication times such as 08.00, when medicine rounds are likely to occur. If single medications were being administered outside of these times, Nelms et al. (2011) recognised that the to deliver timely nursing care, tasks may be combined. This method is particularly associated with productive working, which encourages the grouping of tasks within the planning of care. This resulted in perceptions of inefficiency in the delivery of care.

The physical act of isolating the medication process is associated with the context of creating a visual barrier. Commonly this is generated using zones, signs or visual clothing (Anthony et al., 2010, Colligan et al., 2012, Yoder et al., 2015, Tomietto et al., 2012, Federwisch et al., 2014). Zones were created by placing signs on the door of a medication room (Tomietto et al., 2012) or placing brightly coloured tape on the floor around a stationary trolley (Anthony et al., 2010). If a mobile medication cupboard was in use, researchers created their zone by placing signs on to the trolley itself (Federwisch et al., 2014). In some studies signs were also used in patient rooms or at the entry point to the clinical ward to inform staff and patients of the intervention (Federwisch et al., 2014, Flynn, 2016). The tabards/vests were commonly bright in colour (red or yellow) some had ‘do not disturb’ writing on whilst others were plain (Verweij et al., 2014, Fore et al., 2013, Freeman et al., 2013, Westbrook et al., 2017, Relihan et al., 2010). In one study the vest/tabard was replaced by a lighted lanyard (Freeman et al., 2013).

The reactions generated by this mechanism were dependent on the individual role within the process. Nurses administering medications reported reactions of increased focus and engagement with the task at hand. Conversely, Nelms et al. (2011) identified that eventually habituation decreased the impact of focus and engagement. The context of creating a physical barrier also generated reactions in those outside of the medication administration process, as it stimulated a decision-making process. This was seen with healthcare professionals, visitors and patients. The presence of the

visual intervention encourages active thinking rather than automated actions. This can improve the impact of the intervention as it decreases unnecessary interruptions that in turn can demonstrate benefits to the professionals involved with the process.

Some studies (Federwisch et al., 2014, Capasso and Johnson, 2012, Verweij et al., 2014) described an environment where interruptions were ingrained and accepted as normal. When interventions to reduce interruptions were introduced into these cultures, nurses felt that they could challenge others who interrupted the process (Connor et al., 2016). This generated an ownership of the process that was associated with increased confidence levels. Nurses were equipped with the 'guilt free' freedom to delay non-urgent activities or delegate them to others (Dall'Oglio et al., 2017). In addition, in generating an ownership of the process a responsibility was stimulated within nurses, to manage and challenge interruptions. There were reports of increased accountability levels relating to nurses as they felt responsible for their own interruptions and feeling empowered to challenge others. There was no evidence to indicate whether these feelings of empowerment were transferred to other members of the team. Interventions include education programmes that promotes the practice of challenging interruptions. This empowers nurses to challenge individuals who interrupt (Connor et al., 2016, Dall'Oglio et al., 2017, Nelms et al., 2011).

Teamwork within the MDT is an important factor that can ensure effective delivery of an intervention to reduce interruptions to medication administration (Flynn, 2016, Federwisch et al., 2014, Nelms et al., 2011). Effective teamwork is essential in two areas; helping to manage interruptions external to the process for example, screening telephone calls and ensuring continuity of care whilst the nurses' focus is on medication administration. Furthermore, the mechanism of trust must also be present as nurses need to feel confident that care and communication will be delivered for their patients whilst they are isolated within medication administration. When effective teamwork is present staff satisfaction improves and the intervention is more likely to be effective. although, this deteriorates if there is reduced support staff available outside of business hours to manage interruptions. Furthermore, effectiveness is reduced if the management of interruptions impacts on the workload within other roles. If this is perceived to increase the intervention is less likely to succeed (Federwisch et al., 2014). In addition, Nelms et al. (2011) found an associated increase in stress levels

if the team support and trust were not present to support the implementation of the intervention.

The role of the MDT team was an important factor in the success and failure of these interventions. Success was more common if the whole MDT team adhered to and respected the intervention. However, success was inhibited if an increase in another professional's workload was seen; the intervention then became a burden (Federwisch et al., 2014). Furthermore, reliable systems need to be in place to ensure care and communication continues whilst medication is administered. Furthermore, the timing of medications needed to ensure not all nurses were involved in medication administration at the same time. Nurses were less likely to use an intervention if their workload had resulted in them rushing the delivery of care (Capasso and Johnson, 2012, Nelms et al., 2011, Pape, 2003, Verweij et al., 2014, Yoder et al., 2015).

In conclusion, this review has identified three mechanisms that were triggered by the implementation of interventions to reduce interruptions to medication administration. The future design of interventions to reduce interruptions need to comprehend these mechanisms if they are to be successful within the clinical setting.

4.4.3 Outcomes

The predominant expected primary outcome associated with the introduction of these interventions is a reduction in interruption rates (Anthony et al., 2010, Capasso and Johnson, 2012, Colligan et al., 2012, Flynn, 2016, Conrad et al., 2010, Pape, 2003, Pape, 2013, Relihan et al., 2010, Dall'Oglio et al., 2017, Verweij et al., 2014, Tomietto et al., 2012, Westbrook et al., 2017, Williams et al., 2014). The perception within this literature base is that a reduction in interruptions rates would lead to a decrease in medication errors. Therefore, a reduction in medication errors is a frequently measured outcome (Connor et al., 2016, Westbrook et al., 2017, Conrad et al., 2010, Verweij et al., 2014). Although, there were limited studies that could demonstrate a significant reduction in medication errors. Three studies did not measure a reduction in medication errors (Colligan et al., 2012, Nelms et al., 2011, Westbrook et al., 2017). Furthermore, researchers anticipated a reduction in medication administration time. Within the research that measured administration time, three studies (Capasso and Johnson, 2012, Nelms et al., 2011, Pape, 2013) concluded that there was a reduction. In contrast, five studies (Colligan et al., 2012, Conrad et al., 2010, Dall'Oglio et al.,

2017, Flynn, 2016, Westbrook et al., 2017) found that there was no impact on administration time. However, medication administration was not defined by any study. This may have resulted in different processes being measured. The demonstration of a reduction in administration time may be perceived to be beneficial as there may a cost saving or an increase in time available for other aspects of nursing care.

Staff satisfaction was mixed in most studies, as they cited benefits such as being protected from interruptions, but highlighted that negative issues such as image, hygiene, being too hot and appearing to be unavailable to patients (Nelms et al., 2011, Verweij et al., 2014, Westbrook et al., 2017, Williams et al., 2014). Furthermore, Nelms et al. (2011) found an increase in complaints from other professionals if medication was prioritised rather than the interruption. In addition, undergraduate student nurses perceived that the use of interventions increased their confidence in their own medication skill (Yoder et al., 2015)

The inclusion of patients and families has been discussed in section 4.5.1 and the lack of engagement noted. Only one study measured patient/family satisfaction, this demonstrated a 40% increase whilst the intervention was implemented (Yoder et al., 2015). Three studies (Capasso and Johnson, 2012, Flynn, 2016, Dall'Oglio et al., 2017) reported support from patients and families in the implementation of the intervention. Especially if the key message in verbal and written communication was that they were not being ignored but were being protected from harm.

Consistent practice as an outcome was identified in five studies (Anthony et al., 2010, Capasso and Johnson, 2012, Pape, 2013, Pape, 2003, Yoder et al., 2015, Pape et al., 2005) and linked interventions to reduce interruptions to medication administration and the delivery of standardised care, primarily by using protocols or checklists. The use of protocols/checklists promotes the delivery of a timely, safe and focused process that incorporates the standard practice commonly known as the ‘five rights’, that form the basis of safe medication practices across the world (Elliott and Liu, 2010, Jones and Treiber, 2010). The use of a protocol/checklist creates a mechanism that promotes a responsibility within nurses to adhere to it (Pape et al., 2005). Although, it can also create delays in care as the protocolised approach can reduce flexibility in the delivery of care (Nelms et al., 2011). There were two contexts that influenced the consistent practice; an ongoing, multidisciplinary programme of education (Anthony et

al., 2010, Conrad et al., 2010) and clear presence of leadership (Capasso and Johnson, 2012, Verweij et al., 2014, Connor et al., 2016, Federwisch et al., 2014, Flynn, 2016).

The review illuminated five outcomes that were reported when interventions to reduce interruptions to the medication process were implemented. The outcomes identified were influenced by both context and mechanism and this needs to be factored into future interventions.

4.5 Conclusion

In conclusion, from predominantly adult literature, this review critically analysed the evidence and has identified how interventions to reduce interruptions to medication administration are influenced. Contexts such as cause of interruption, leadership, patient and family involvement and the environment were illuminated within the review. In turn, these contexts can generate hidden mechanisms, such as guilt free delegation of tasks. Furthermore, the review has explored and discussed how these mechanisms can influence individual reactions and behaviour when the interventions are implemented. Finally, the outcomes associated with the interventions were identified illuminating inconsistencies in measurement. However, the review has not explored the medication process and interruptions within PICU. Additionally, this review has suggested that it is important to explore the impact of interventions to reduce interruptions to medication administration on the wider MDT. Therefore, the following Chapter (5) will critically analyse the data from the MDT within PICU to understand the mechanisms that are pertinent to these interventions within this clinical setting. Furthermore, when this study was conducted parents/carers had unlimited access to PICU so could influence the effectiveness of interventions to reduce interruptions so Chapter 6 will present the critical analysis of their findings.

Chapter 5 – Findings 2 - Healthcare professionals

5.1 Introduction

The aim of this chapter is to present the findings Stage 2, Parts a and b, the thematic and realist analysis of the healthcare professional data in terms of interruptions to the

medication administration process. As outlined in Chapter 3 (section 3.8), this data set was collected in two stages:

a) a survey of PICU's in England (n=11) to explore the types of interventions used to reduce interruptions to the medication administration process and understand their effectiveness; and
b) 14 interviews conducted with members of the multidisciplinary team from nine PICU's in England.

This chapter begins with a demographic summary of the participants who participated in the study, followed by a detailed presentation of the thematic analysis of the empirical data. Three themes were identified within the data:

i. 'Standardised Care?',
ii. 'Trying Harder?'
iii. 'A patient led service?'.

To conclude the chapter the realist analysis will illuminate any contexts or situations that trigger hidden reactions or behaviours, that may influence any outcomes associated with the interventions.

5.1.1 Survey Data

Eleven PICU's (n=23) responded to the invitation circulated via the Paediatric Intensive Care Society in the six-month data collection period, from October 2017 to March 2018. There is a wide geographical spread of PICU's within England, as shown in and the units that participated within the study were also widespread with one from the north, five from the midland's region and five from the southern part of England. Seven of the units were based within acute NHS Trusts and four units were located within stand-alone Children's Hospitals. Data were collected through a telephone survey with 10 healthcare professionals from the 11 PICU's, as participant 2 worked in two different PICU's. Demographic information about the participants is outlined in Table 28 – Survey participant demographics(below).

Table 28 – Survey participant demographics

Survey Number	Role	Hospital	Gender	Experience	Clinical time

1	Junior Sister (band 6)	K (20 beds)	F	20 years	Non-clinical
2	Medical Consultant	F (20 beds)	M	5 years (as Medical Consultant)	80%
3	Staff Nurse (band 5)	A (14 beds)	F	18 months	100%
4	Matron (band 8)	H (15 beds)	M	10 years (4 months in matron role)	20%
5	Medical Consultant	B (31 beds)	M	8 years (as Medical Consultant)	65%
6	Matron (band 8)	L (17 beds)	F	20 years (6 months as job share matron)	50%
7	Medical Consultant	D (6 beds)	F	10 years' experience (as Medical Consultant)	70%
8	Medical Consultant	E (8 beds)	M	20 years (as Medical Consultant)	75%
9	Sister (band 7)	J (20 beds)	F	20 years	50%
10	Medical Consultant	C (17 beds)	M	16 years	80%

Respondents from the units were from both medical (n=6, 55%) and nursing (n=5, 45%) roles. In addition to the roles held within the participant group, experience and specialist knowledge was varied. Eight of the participants had between 50 and 100% time within their role delivering clinical care. It was anticipated that the clinical component would contribute towards participant knowledge of local current policies and working practice.

The telephone survey was conducted at the participants' convenience, with interviews ranging between seven minutes and 26 minutes (mean time = 15 minutes). The survey was conducted over the winter period which impacted on the time and availability of staff. Three surveys (numbers 1, 3 and 6) were interrupted by the clinical needs of the unit, but all participants were happy to continue the interview once the issues were resolved.

5.1.2 Interview Data

In the second phase of data collection 14 semi-structured interviews were completed with members of the wider MDT. The length of the interviews varied from 12 minutes to 57 minutes with a mean of 27 minutes. Within this sample, nine different PICU's from across England were represented, four were standalone children's hospitals, the others worked in a PICU within a large trust that treated adults and children. Of the nine PICU's included, seven were represented in the survey and two were not.

The study sample was recruited from the MDT involved in the delivery of patient care within PICU (see Table 29). The aim was to have two participants from each of the dominant professions within PICU: Medical Professionals, Registered Nurses, AHP's) and relevant Support Staff (PICU Receptionist). This was achieved in each profession except support staff. The sampling strategy of using the Paediatric Intensive Care Society limited the connection with support teams as they did not have membership. It was anticipated that the addition of snowball sampling would allow support staff to be recruited by healthcare contacts within PICU, but the minimum was not achieved. This may have been influenced by a perception that they do not play a role in medication administration.

Table 29 - MDT interview participant demographics

Participant Number	Profession	Hospital	Length of interview	Mode of interview
1	Registered Nurse	I (18 beds)	35 minutes 30 seconds	Face to face

	(Junior Sister)			
2	Medical Consultant	F (20 beds)	34 minutes	Telephone
3	Registered Nurse (Staff Nurse)	B (31 beds)	16 minutes	Telephone
4	Registered Nurse (Sister)	E (7 beds)	22 minutes	Telephone
5	Medical Consultant	A (14 beds)	26 minutes	Telephone
6	Medical Consultant	D (6 beds)	12 minutes	Telephone
7	Registered Nurse (Sister)	H (15 beds)	33 minutes	Telephone
8	Pharmacist	C (17 beds)	49 minutes	Telephone
9	Physiotherapist	A (14 beds)	19 minutes	Face to face
10	Pharmacist	A (14 beds)	57 minutes	Telephone
11	Registered Nurse (Sister)	D (6 beds)	18 minutes	Telephone
12	Nurse (Junior Charge Nurse)	G (48 beds)	19 minutes	Telephone
13	Receptionist	A (14 beds)	40 minutes	Telephone
14	Nurse (Junior Sister)	C (17 beds)	37 minutes	Telephone

The sample included seven Registered Nurses and had a large representation from those in senior roles. Six of the Registered Nurses within the sample were in roles that involved leading a team (Junior Sister/Charge Nurse, Sister and Matron). This was also reflected within the sample of medical professionals who were all Medical Consultants. The sample may have been affected by the sampling strategy as it may be reflective of the membership of the PIC Society.

5.1.3 Combined Data Sets

Initially the surveys and interviews were viewed individually, the transcribing and line by line coding ensured that the researcher was equally immersed in each data set (Braun and Clarke, 2012). At first the codes were themed by context, mechanism and outcome, but both the researcher and supervision team felt that this approach did not allow an inductive approach to analysis, the findings were being forced into realist categories. After a period of reflection, it was decided that an inductive process of thematic analysis would be used. The researcher met with the supervisory team to discuss and debate the themes present within the data see Appendix 7 for photos of the brainstorming session. In this session, the themes were initially identified for the individual data sets. These were then combined as Terry et al. (2017) note that thematic analysis can be used appropriately with both interview and qualitative survey data. Therefore, three overarching themes were identified that that could be evidenced from both datasets

The datasets were then combined, and the coded transcripts were collated per NHS Trust (see Chapter 3, section 3.7.8 for discussion of analysis process). The thematic analysis process was guided by the following questions:

- Are there any similarities or differences between the survey and interview data within the theme?
- Are there any similarities or differences between professional groups and how they behave?
- Are there any other factors which influence the data such as type of Trust or size of PICU?

Realist analysis (Maxwell, 2012) suggests that the researcher should search the data for similarity and active relationships, therefore the questions listed above were developed to guide the analysis. The outcome of this analysis was the identification of three themes identified in the introduction of this chapter.

5.2 Theme 1 ‘Standardised Approach’

As part of medication administration, 16 participants described multiple different interventions and safety practices within the different units. The information shared by these participants demonstrated that multiple similar interventions had been tried in

their PICU's with differing levels of success. This data suggested that there was no national standardised implementation strategy and that individual PICU's were working in isolation. The theme identifies the multiple different interventions used and explores the rationale for implementation. Furthermore, this theme examines the barriers and facilitators associated with the interventions described by the participants who had used them. In the final section the risks and rituals associated with the different interventions were also explored.

5.2.1 Types of Interruptions

Overall, participants within the combined sets of data identified multiple different types of interruptions in medication administration within the PICU setting. Registered Nurses and Medical Consultants described interruptions that were *'urgent*' (Survey (Junior Sister) 1, line 22), a *'very serious matter'* (Staff Nurse (Interview 3), line 82) and *'life threatening'* (Survey (Medical Consultant) 10, line 131). Registered Nurses predominately listed interruptions that were related to the patient *'alarms, patient turning over or going bradycardic and ward round'* (Survey 9 (Sister) lines 59-60). Alternatively, a minority (n=2 Registered Nurses) identified parents/carers as the cause of the interruption when they asked questions. In contrast Pharmacists reported their observations of the medication administration process where chatting and non-medication interruptions by healthcare professionals occurred; *'did you watch the football?'* (Pharmacist 1, line 193). This may suggest that some healthcare professionals have a lack of awareness of non-medication conversations as an interruption.

Arguably, as a result of the multiple different types of interruptions, a multitude of interventions were identified that had attempted to reduce interruptions to medication administration. A summary of this data is presented in Table 30 and highlights a plethora of interventions with 13 different ones used within PICUs within England. Predominantly the interventions included a visible sign that aimed to identify the medication administration process as different to other elements of patient care. The dominant intervention in medication administration was the wearing of red aprons or tabards and prescribing zones. Only four units had not implemented red aprons or tabards and two of those had not tried prescribing areas either. These PICUs were based within acute trusts and participants did not report active unit-based, safety or

governance teams. This suggests that the presence of unit-based safety or governance teams influences the use of interventions within the clinical area.

Table 30 - Interventions identified

Name of intervention	Description	Participants
Aprons or tabards	Disposable plastic apron (placed over the head and tied at the back) or tabard (placed over the head and has a full red front and back) Colour – red Can be plain or have 'do not interrupt' messages written on them Other colours (yellow/white) associated with infection control or general nursing care	Survey 2,4,5,8,9,10 Interviews 2,3,5,7,8.10,12,14
Gloves	Black gloves identified as those to be used for medication administration	Survey 9
Prescribing zone	Designated physical area for prescribing Includes resources such as computers, calculators and medication information: British National Formulary for Children (BNFC), Drug monographs – locally prepared instructions for medication preparation Compatibility charts – locally prepared instructions indicating compatibility between medicines	Survey 2,5,6,7,8,10 Interviews 2,5,6,8,10,11,14
Signs	'Do not interrupt' signs placed in medication prescribing/preparation/bed space areas	Survey 2 Interviews 2,7
Headphones	Allocated headphones to be worn the during the prescribing of medication	Survey 2,10 Interviews 2,8
Clothes pegs	Red peg scheme – nurses preparing medications wore a red clothes peg attached to their uniform	Survey 1
Alterations to checking process	Silent checking (checking without comment)	Survey 1,6
	Independent second check (both nurses check the medication at the same time but ensure calculations and interpretation of the prescription are completed independently of each other)	Survey 4 Interview 7

	Restricted prescribing times (defined times often around handover of care where medications should not be prescribed)	Interview 4
Tape on floor	Red plastic electrical tape applied on floor around prescribing zone	Survey 2 Interviews 2,5
Changing culture	Creating a psychologically safe culture (an environment where staff feel safe to report errors and are not fearful of recriminations) Say ‘no to interruptions’ culture	Survey 2 Interviews 2,8
Language	Language strategies to respond to interruptions For example, ‘Stop – Drugs’ or ‘is it an emergency or can it wait?’	Survey 2 Interview 1,4
	‘Do not disturb policy’	Survey 4 Interviews
Communication	Use of posters, emails, discussion groups	Survey 2
Education	Re-enforcement of policies eg Controlled Drug policy Responsibilities within accountability Role of second checker	Survey 4 Interview 7
Position of IV trolley	Medication trolley is moved away from immediate bed side and positioned at an angle so that only one nurse is facing the patient	Survey 9
	Medication station in centre of unit	Survey 2 Interview 2

Nine participants (six Registered Nurses, two Medical Consultants and a Pharmacist) from both the survey and interviews highlighted similar rationales for the implementation of interventions to reduce interruptions to medication administration. They described an increased risk of medication error due to increased rates of interruptions. They noted that an environment which increased focus and concentration may help this. This was demonstrated by this description of the rationale for the use of red aprons:

> *'Red is a signal to say do not disturb so the nurse is doing checks, medications usually at the bedside erm will put on the red aprons and the objective of that is to reduce interruptions, so they don't make, are less prone to drug errors* (Survey (Matron) 4, lines 21-23).

Similarly, prescribing zones were also noted to incorporate a similar ethos to the one underpinning the use of aprons. The rationale referred to a visual prompt to reduce interruptions:

> *'We had like a big desk at the end of the bed space and they had like a red flap that came over so that a doctor would then lean on that and would prescribe the drugs and wouldn't be interrupted cause it was seen as a visual prompt not to distract them during that process'* (Junior Sister (interview 14), lines 50-54).

Although, two Medical Consultants highlighted those prescribing zones were only used when complex prescriptions were being written rather than for small numbers of commonly prescribed medicines. The relationship between the prescribing zone and the complexity of prescription was highlighted:

> *'If it's you know a patient's being admitted and they need inotropes and sedation and steroids and all sorts of complicated things writing up then yeah that would have been done in the prescribing area'* (Medical Consultant (Interview 2), lines 173-175)

The units where these two Medical Consultants worked were very different as one was large (31 beds) whilst the other had seven beds. The larger unit was in a Children's Hospital, whilst the smaller was in an acute trust. This may suggest that the lack of use of the prescribing zone was a reaction to the intervention itself rather than the environment.

Although the rationale for the interventions were similar, the design of them focused on different types of interruptions. Interventions such as red aprons or prescribing zones attempted to reduce interruptions from all personnel external to the medication administration process. In contrast, four Registered Nurses described interventions

such as silent or independent checking which focused on the interruptions between the nurses involved in the process:

> *'They have brought in what they call silent checking. Cause we double check most of our drugs. They are trying that at the moment actually. Where the person comes to check basically checks without comment so that then it's actually in silence so they can actually concentrate on what they are thinking.'* (Survey (Junior Sister) 1, Lines 62-65)

The participants that described the introduction of silent or independent checking were all in nursing leadership positions (Junior Sister, Sister or Matron). Although, it was important to note that one Medical Consultant, both Pharmacists and a Junior Sister highlighted that checking procedures in their PICU did not follow the policy used within the Trust:

> *'I don't know if people feel it's wrong that they're doing that you know that it's a wrong thing. I think sometimes they think that's ok no to independent check, I mean I don't know the research and whether that makes a difference on errors but that's our policy'* (Interview (Sister) 7, Lines 45-48)

These participants worked in different units to the ones that had implemented enhanced checking procedures. The participants who highlighted problems with the checking procedures worked in four different units, suggesting that this is a common problem within intensive care units.

During the checking intervention there was a focus on one type of interruption, namely nursing interaction during the checking process within medication administration:

> *'They would work undisturbed, they would do the independent, the second independent checker'* (Survey (Matron) 4, lines 35-36).

In contrast, the interventions that attempted to reduce interruptions from professionals or parents/carers not involved in the medication administration process, all included a visible element within their design. A visible cue was described by 23 participants, these included red aprons, black gloves, red tape or do not disturb signs. This group of participants included RNs, Medical Consultants and Pharmacists from acute trusts and standalone children's hospitals. These visible elements all had the key objective

of informing the interrupter that the nurse is not to be disturbed during medication administration. This was highlighted by one participant:

> *'Like making you realise that someone is doing something I think it's a sign of importance red so you kind of stop.'* (Survey (Staff Nurse) 3, lines 75-76).

It was recognised by participants that these items of clothing were used as a visual cue to alert others to the process of medication administration:

> *'I've seen visual cues in other, in some places, I've seen like a fabric bib being worn by a member of staff who's drawing up drugs. In another place that I've worked they've used red coloured plastic aprons rather than the usual white ones at the bedside to kind of indicate that visually that they're doing something different',* (Medical Consultant (Interview 2), lines 106-112).

In one unit where the practice of wearing red aprons had been embedded over a four-year period, this message was summarised succinctly; *'so if it's red at the bed don't come and talk to me,'* (Pharmacist 1, lines 198-199).

Nevertheless, multidisciplinary involvement and belief in the design of the intervention was not described by all participants. The following participant suggested that the wider team may not be as involved as much as they wished to be:

> *'I've been seeing these little tabards emerge bit by bit over the last 10 years I want to say there was a single study published somewhere like one of the nursing journals about how it reduced medication administration errors in one ward in one hospital for a week and then suddenly everybody started doing it. I've never been that convinced about the evidence to do that but it's something that nurses have taken up and taken on.'* (Pharmacist 1, lines 225-230).

Engagement with the interventions to the medication administration process was reported to be variable with participants able to identify both barriers and facilitators that could assist or prevent their success. A common barrier that was highlighted within the data related to the use of red aprons and the procurement of them. Issues with the supply of coloured aprons were acknowledged by nineteen participants, as described in the following survey:

> *'It was just, just a few days so that it happened er we came up with the issues and problems. Partly the supply issue, …. and partly the fact they were getting interrupted anyway'* (Survey (Medical Consultant) 8, lines 53-56).

It was interesting to note that members of the MDT noticed the supply issue as it suggested that they were recognising and responding to the intervention. The lack of

supplies of coloured aprons led to participants noting increased levels of confusion and decreased effectiveness:

> *'One of the other problems is that if the erm if the white aprons run out then people are forced to wear red aprons when they should really be wearing a white apron (laughs). Which happens not infrequently when we're, when we're busy erm so that also causes a bit of a problem and er tends to impact on the effectiveness generally during those times.'* (Survey (Medical Consultant) 10, lines 50-54).

Ensuring healthcare professionals had easy access to the equipment was also described by six participants as an important part of the planning process. These participants included three Medical Consultants, two RN's and one Pharmacist, indicating the impact of the issue on the whole team. The participants worked within four different units indicating that the NHS supply chain has an important role within the implementation interventions. The following highlighted how increased effort to locate the apron could easily result in it not being used:

> *'I think erm first of all there's the time erm it's time to find the apron erm it's time to er locate it be able to put it on and I know it's very it only takes a second to put it on but it's if you're having to move around taking more than 4 or 5 steps away from your own bed space in a different direction to go and put on a red apron'* (Junior Sister (interview 14), lines 103-106)

Furthermore, a key element in the use of no interruption or prescribing zones was their location. Six participants explained that they needed to feel close to the clinical area to ensure they were aware of the condition of their patient. This highlights the continual awareness that staff have even when trying to maintain focus on an individual task:

> *'Somewhere that is I guess for me from a prescribing point of view it needs to be close by so that actually the person is you know able to be called in an emergency* (Pharmacist 2, lines 446-448)

Indeed, the location also had to comprehend the activity within the unit and careful planning was required. This was identified by the following Medical Consultant:

> *'But unfortunately, one of the prescribing areas happened to be near the erm door to the ladies so there was quite a thoroughfare past there (L179-181) and often there would be a bit of erm interruptions with chit chat (laughs) erm yes'* (Medical Consultant (Interview 5), lines 179-182)

In summary, there were multiple interventions described by 20 participants in efforts to reduce interruptions to medication administration. Despite there being a common rationale for their use, there was no standardisation in their focus. It was noted within

the data, that despite well intentioned plans, interventions were easily disrupted by issues such as supplies and location.

5.2.2 Risky business

One Medical Consultant within the survey noted that the implementation of interventions to reduce interruptions to medication administration created different risks to the one they were attempting to remove. The use of zones away from the bedside was questioned due to it reducing numbers of staff within the clinical area for prolonged periods of time. It was described as a balancing act between a quiet area for concentration and reduced numbers of staff to deliver care:

> *'The fact that people have an opportunity to go off and concentrate and do what they need erm is good er but there's the fact that they are then not available if somebody needs them is less good'* (Survey 8 (Medical Consultant), lines 156-158).

This was further developed by five participants (two Registered Nurses, two Medical Consultants and a Pharmacist) within the interviews, essentially it was described as creating a patient safety conflict for the team involved. Two of the Registered Nurses identified a balancing act between the maintenance of overall patient safety versus prioritising a focus on medication safety; *'it's either you do your drugs straight away or you go and do your bed space checks'* (PICU Sister (Interview 4), lines 149-150). In contrast the Pharmacists and Medical Consultants were more aware of an impact on the whole unit, as indicated in the following:

> *'so you've an argument that actually when a patient safety point of view it's better not to take them away from the you know the bedside in order to make the, to prepare the medicines although they obviously by being out there then, although they are in one sense it makes patient safety better because they're not you know removed from the area you've still got if you like a greater number of nurses around what that means is they, you possibly affect patient safety in another way by making them more erm prone to interruptions'* (Pharmacist 2, lines 47-52).

Furthermore, the incorrect use of an intervention was noted by participants to create additional risks, especially with the use of aprons as interruptions were likely to increase. Within the interviews and surveys, three Registered Nurses described problems with the use of coloured aprons, particularly if there was a supply shortage:

> *'if I can't see a red apron and I need to put an apron on, I'll put a white apron on, erm but I'm very aware that if people are coming up trying to talk to me during I will say hold on I'm just doing a few drugs here and highlight to the*

> *nurse cause they can't officially see from a distance cause I'm not wearing a red apron that they don't know I'm doing drugs when they come to me'* (Junior Sister (Interview 14), lines 124-129).

Additionally, in her interview, one Registered Nurse highlighted an overwhelming use of different coloured aprons within her unit. This had led her to question the impact of the colour:

> *'Because we wear a multitude of different coloured aprons now, it seems to be whatever is available, we've got red out there now it doesn't mean that you're doing drugs, we've got white, we've got all different colours, we've got yellow. It wouldn't be seen having the red plastic apron as 'oh I'm doing drugs'.* (Staff Nurse (Interview 3), lines 214-217).

Nevertheless, the use of aprons was associated with a positive change in mental attitude. The survey data suggested that interventions encouraged silence and privacy to focus. However, the interview data developed this further as participants described the impact. It was acknowledged by two Registered Nurses who noted a change in mental focus:

> *'I think the people that do put the aprons on I think they do it as like a more of a change in mental attitude'* (Junior Sister (Interview 14), lines 109-111).

Furthermore, the implication of this change in mental attitude was described by Registered Nurses, Medical Consultants and Pharmacists. It was noted to create time for an isolated task, this concept linked back to the rationale given for implementing the intervention:

> *'So, I think when you've got the red apron on you're prepared that you're going to be doing something, a task that you are going to start and complete and you shouldn't be interrupted during that'* (Junior Sister (Interview 14) lines 145-147).

An additional positive factor highlighted by two other Registered Nurses was, that wearing the apron created a feeling of protection. They suggested that the apron facilitated a protected, interruption free period:

> *'I hope it has been positive in that people feel that they've got that protection of time and less interruption.'* (Sister (Interview 7), lines 174-175).

In turn, this helped to empower nurses to actively manage the process. Six participants (three Registered Nurses, two Medical Consultants and a Pharmacist) acknowledged that wearing a red apron empowered the nurse to challenge interruptions:

> *'I mean I know that when that came in they may be felt more empowered to challenge interruptions (L134-136)because they'd already, they'd taken an obvious step to say do not disturb me by wearing the apron, so I suppose it's a little bit more challenging if actually I'm drawing up these drugs, can you speak to me in five minutes, or can you leave me a note or that sort of thing.'* (Medical Consultant (Interview 5), lines 134-139).

In summary, this section highlighted that the interventions could be associated with positive feelings of protection and empowerment in terms of the process of medication administration. Although, conversely there were also risks in using interventions which resulted in conflicting issues such as patient safety and interference with communication.

5.2.3 Rituals or routines?

All the participants interviewed noted that routines were important in the medication administration process. Each of the participants, regardless of their professional background, were able to describe the process in detail. This was also important when interventions were introduced; *'if it's not something that's routine, it's not something that's very strictly adhered to.'* (Junior Sister (interview 14), lines 133-134). If the intervention was not able to be built into the medication administration process routine, it did not become a rule that had to be adhered to; *'but erm in an ideal world if there was a red apron at my bedside, I would put it on'* (Junior Sister (Interview 14), lines 128-129). This quote also highlighted factors such as location, accessibility, communication and prioritisation within the normal routine as having an influence on the effectiveness of interventions. This was discussed by participants in relation to an 'ideal world', other embedded routines and their ability to engage with the interventions.

Interestingly, five participants (three Medical Consultants, one Registered Nurse and a Pharmacist) referred to an 'ideal world'. In this perfect environment there would be no interruptions, increased staffing to allow for extra nurses to help check and professionals would not take short cuts. The description of the 'ideal world' concept indicates the difficulties experienced by professionals in enforcing an accessible process that humans can follow within a complex environment.

Furthermore, routines that were previously embedded in practice such as Aseptic Non-Touch Technique (ANTT) were described as more of a priority. It was described how

the aprons needed to be easily accessible to ensure use, as their use was not the top priority within the process:

> *'But if it's not there then I probably won't go searching for it, because it's, it's probably isn't one of my priorities, my priority is to ANTT. And ensuring I've got some kind of personal protective equipment on is the goal'* (Junior Sister (Interview 14), lines 129-132)

Another issue highlighted frequently by all members of the MDT was that critical care nurses could spend a large amount of their time preparing and administering medications to the child. This was identified within the survey and interview data as an important factor that had a negative impact on the effectiveness of the red apron intervention, due to it reducing routine communication between professionals:

> *'We tried to introduce it as a pilot but erm it, it in the end it didn't work cause they were putting the red on for so long. So, you know it looked like they were going to use the red tabard so often that nobody would be able to speak to them at all'* (Survey 8 (Medical Consultant), lines 47-50).

A factor that was described by both medical and pharmacy professionals as being important within prescribing zones was the need for it to be resource rich. These resources were noted to facilitate the prescribing routine:

> *'That they had a dedicated prescribing area, with all the resources a calculator, a BNFC, and there were compatibility charts on the wall, there was drug monographs, err you name it anything you could think of that might be useful'* (Survey 2 (Medical Consultant), lines 140-143).

This planning was important as it ensured all information resources and equipment were available and accessible to deliver medication safely. If the professionals remained in that area for the medication routine, the associated culture of not interrupting during that time could be promoted:

> *'so yeah again the resources er are available to the nurses em er so drug monographs, the em er there is em an encouraged culture of saying no to interruptions in a similar way and there is, there is a particular area where all drugs are drawn up so that whilst its mobile it's em it is, it's encouraged to have that they are left alone to do do that work'* (Survey 2 (Medical Consultant), line 184-187).

Furthermore, three participants described an addition to the routine within the prescribing zone, the use of ear defenders:

> *'We invested in some noise cancelling headphones, almost some cans people should have worn while they were prescribing'* (Pharmacist 1, lines 163-166).

This initiative was linked to two units and was described within both the survey and interviews. One unit was located within a stand-alone Children's Hospital and the other, an NHS Trust that treated adults and children. Within the interviews, where participants highlighted the use of this equipment, it was acknowledged that they both had active patient safety teams who frequently implemented quality improvement programmes. However, their impact was minimised because they generated feelings of discomfort and being cut off from the environment:

> *'Also felt a bit silly sitting there with ear defenders on so they sort of dropped out and now they've gone and that's something which yeah, died a death.'* (Survey 10 (Medical Consultant), lines 76-78).

In summary, this section has identified the impact of routine within the medication administration process and the implementation of new interventions. Overall, this theme has identified 13 different interventions that have been implemented within PICU's in England to try to reduce interruptions to the medication administration process. There also appears to be a lack of standardised practice between units, as well as repeated use of interventions that do not always work. Participants described a fundamental patient safety conflict between observing the child and complete focus on the medication process. Finally, it was acknowledged that even when interventions were designed with the medication routine at its forefront, adherence was easily abandoned.

5.3 Theme 2 - Trying harder?

The data presented within this theme identified the factors that participants highlighted as impacting on the effectiveness of interventions to reduce interruptions to medication administration. Within this theme the following sub-themes were identified that related to quantity and quality of the evaluation of these interventions; the rules of medication administration in PICU; and the behaviours and actions of professionals which will be explored in this section.

5.3.1 Measurement and monitoring?

Survey and interview data revealed there was often an inconsistent level of monitoring when an intervention was introduced. This resulted in participants being unable to provide information that demonstrated the impact of any intervention implemented. The data displayed in Table 31identifies the limited evaluation or monitoring of implemented interventions and a lack of consistency in measurements. This was also

reflected in the wider literature included within the Realist Review (see Chapter 4). Out of the 11 PICUs included within the study, only four were able to describe any form of monitoring of the impact of interventions.

Table 31 - Monitoring the impact of interventions

Monitoring	Unit
Reduction in interruptions (Audit)	Survey 1 Interview 6
Proposed observational audit of adherence to silent checking policy	Surveys 1,4,7 Interview 6
Measuring length of interruptions	Survey 5
Medication errors	Survey 2 Interview 6, 8

One unit was able to provide the data that demonstrated a reduction in interruptions within the interview, despite nine units stating that they had implemented interventions. This unit was a PICU within an NHS Trust and the participant described the intervention being implemented by the clinical team within PICU. Furthermore, the intervention (red clothes peg) used in the unit represented by participant one demonstrated a 50% reduction in interruptions in a pre and post observational audit. Despite this successful reduction in interruptions the intervention failed to embed in practice. The Medical Consultant who provided the information in Survey Five was aware that a study had been conducted to measure the length of time interruptions took but unfortunately, he was unable to recall the results of the study. Another participant in survey two stated that their unit had measured multiple elements of medication error reporting. However, this unit had implemented red aprons, prescribing zones with headphones and no interruption zones but had not measured their impact. This absence of measurement was repeated in the other six units where interventions had been implemented.

Within the sample there were three units where participants acknowledged that there were experts in quality improvement methods or patient safety. This data was collected from one survey and three interviews. The units were based in two Children's Hospitals and one NHS Trust. The participants acknowledged that these units

promoted the use of quality improvement and research methodology to evaluate the use of interventions to improve the medication administration process and the management of interruptions:

> *'They did a deeper dive as well so one of the nurses who led the initiative has done a time and motion study measuring interruptions'* (Survey 5 (Medical Consultant), lines 51-52).

The participants from three surveys and two interviews described the intervention being implemented by professionals, usually senior members of the nursing or medical team, who had an interest in patient safety. These professionals were described as Medical Consultants with special interests or Quality Nurse/Matron:

> *'I'm also a since **** an ICU quality and safety lead, since **** the children's hospital quality and safety lead,'* (Survey 2 (Medical Consultant), lines 8-9).

The use of this expertise was associated with a perception that the intervention was informed by robust knowledge and data. The following outlines the process within one unit:

> *'we've got quite well at embedding into the practice that we know when we're doing like a service improvement on critical care that we follow IQP (Improving Quality Programme) methodology so you look at, what, you have a sense of what the problem is and then you try to understand why that's happened and then you have an issue and the you set yourself an action of what you're going to do.'* (Junior Sister (Interview 14), lines 165-170).

Within this PICU the use of the prescribing zone had been evaluated by a Pharmacist who monitored errors before and after its implementation. It was found to be ineffective at reducing medication errors, primarily because it was not used. In contrast, despite prolonged use of red aprons, no data had been collected to assess their impact on interruptions.

The team structure within PICU was also described within the data as an influencing factor in the implementation of the interventions. Four participants (Registered Nurses and Medical Consultants) described the use of different teams in the implementation process. The teams included education, safety and clinical governance:

> *'so, when we decide that we are going to introduce something different like wearing different gloves then erm the either the education team or the clinical governance team depending on who's affected erm you know will bring out 4*

> *things so it will be you know that make sure you know that your patient's stable and safe before you check drugs,'* (Survey 9 (Sister), 101-104).

The eight participants (Registered Nurses and Medical Consultants) who worked in units with safety or clinical governance teams embedded within the area, described a very structured approach to the implementation and monitoring of interventions:

> '*I think because the clinical governance team are on it quite an awful lot so I think you know because everybody's aware of all the incidences that happen and you know then there's erm if it's fed everything's fed back erm and I do think that you know if there suddenly becomes a flurry of them it's really pulled in very quickly and everybody's made aware and it's pointed out and we have newsletters from the clinical governance team and it highlights all the different problems you know relating to drug administration'* (Survey 9 (Sister), lines 305-310).

Alternatively, three participants (RN's) identified that their unit searched for ideas to improve practice by asking for suggestions from the wider clinical team; *'now we have a suggestion box of what did people think we could do and how we could do it'* (Survey 9 (Sister), lines 65-66). In addition to this wider engagement, leadership was also identified by participants as an important element of the implementation process. The professional in survey five highlighted that interventions were led by a member of the safety team:

> *'so, for the interruptions I'd say ********** is our main erm lead for that she's the safety she's on the safety team, she's got a number of roles that take, but erm medication interruption has become quite a big part of her er role in the safety team'* (Survey 5 (Medical Consultant), lines 119-121*).*

When asked why these interventions had been implemented there were three rationales described; responding to increases in reported incidents, experience from elsewhere or application of patient safety theory:

> *'the idea with Safety Two* [see glossary for definition] *is that it's a new concept of safety that erm a safe environment or a safe unit has a condition whereas many things as possible go right'* (Survey 5 (Medical Consultant), lines 189-191).

There were also units in both children's hospitals and acute trusts, where interventions were implemented by safety or governance teams that were stimulated by responding to incident rates:

> *'when there's been a flurry of, of erm incidences then erm they tend to be ok what can we do about it. How are we going to address this so it's usually erm I'd say initiated maybe by the clinical governance team?'* (Survey 9 (Sister), lines 78-80).

In contrast, the unit with a formal leadership post in patient safety, the implementation process was underpinned by relevant theory:

> *'so em so we know from high reliability organisations that having em sort of a psychologically safe culture where people feel safe, able to report openly aren't fearful of recriminations, moving away from a blame culture, towards sort of proactive mitigation of risks is a, is a healthy culture,'* (Survey 2 (Medical Consultant), lines 33-36).

Alongside the implementation strategy, three participants identified that additional enforcement and review of incident numbers were required to promote sustainability. Seven survey participants and seven interviewees noted that incident rates, themes and trends were analysed within their unit. Interestingly, in units where safety and governance teams or a senior leader with a strong patient safety focus were present this was performed on a weekly basis.

> *'I know that the safety team erm keep a pretty close eye on reported medication errors and obviously that's erm reviewed pretty er regularly so weekly meetings to look at reported stuff'* (Survey 5 (Medical Consultant), lines 46-50).

In the remaining units, participants noted that medication errors were reported but the analysis and learning from these reports was limited. Although, the impact of this continual review was not fool proof, survey nine noted that in their response to reported incidents, the focus of the governance team could be distracted, and practice did not embed:

> *'so, you tend to do something for 3 or 4 months or maybe longer than that and then you're not able to get it or something changes and then people get back into the habit of just not using it, so there's always, it's always due to some incident that it's all erm you know scaled up again erm* (Survey (Sister) 9, lines 348-349).

Most participants (five surveys and seven interviewees) included in this study identified the influence that implementation had on the success of the intervention. A common theme was the distinction between an intervention being implemented officially compared to one that had a more informal implementation process; *'But that's the only official one I know of'* (Survey 1 (Junior Sister), line 23). In contrast, other participants described a more informal process of encouragement:

> *'I don't know of anything formal er but people are reminded not to interrupt nurses while they're drawing up drugs'* (Survey 7 (Medical Consultant), lines 29-31).

This informal encouragement was commonly described as an important resource in units that had a less formal safety strategy. Informal encouragement was also used to improve impact when interventions were described as not working:

> *'periodically there seems to the approach to just re-inform, re-educate and re-emphasise the fact that red aprons signal do not disturb so erm which is you know I suppose a fairly typical approach to quality improvement, the first step is just to try harder isn't it?'* (Survey 6 (Matron), lines 59-62).

Thirteen participants (seven surveys and six interviewees) noted that the process of implementation was important in maximising engagement. Eight participants acknowledged that intervention needed to be enforced by informing, re-iterating and role emphasising its importance. Alternatively, the other participants discussed the importance of understanding the issues and encouraging individuals to choose to use it.

The need for continual review, feedback and monitoring was frequently highlighted as thirteen participants (six surveys and seven interviewees) recognised the difficulties they experienced in achieving sustainability. One Pharmacist described how the impact of interventions were diminished over time:

> *'you know we've got like the flashing ear sensors on the unit at the minute that kind of you know, sort of say how noisy people are in background noises and that sort of thing erm when they first arrived then you know actually people are probably very aware of it em but as with any intervention they kind of, they become, they lose their impact slightly over time'* (Pharmacist 2, lines 385-389).

In summary, this section has identified that there has been limited measurement and monitoring of any intervention to reduce interruptions to medication administration, even when quality improvement expertise was available. Although there was limited measurement of interruption interventions, the presence of patient safety teams in both children's hospitals and acute trusts, did improve the monitoring and measurement of medication error reporting.

5.3.2 Rules of the game

As identified in section 5.2.3, elements of the medication administration process included rituals. In addition to these rituals, data showed that participants identified

rules that team members were expected to follow within the process. Furthermore, it was also acknowledged that these rules should sometimes just be known:

> *'I know people should just look at the tray and look at you doing medicines and just stop but it's just habit I think.'* (Survey 3 (Staff Nurse), lines 78-80).

Adherence to the medication policy was highlighted within the interviews as being important. Interestingly, six out of the eight Registered Nurses interviewed described the impact of policy on the medication administration process demonstrating the influence it had. In contrast, only two Registered Nurses had invested a significant amount of time enforcing adherence to medication policy:

> *'I found when I first started here, I found that the medication administration wasn't to policy, so we needed to definitely deal with that'* (Sister (Interview 7), lines L307-309).

One Junior Sister perceived that the policy was well known but staff chose not to or were unable to follow it:

> *'But everyone is aware of what the process is when you're checking it, it's just that in practice it doesn't really happen very often.*' (Junior Sister (Interview 14), lines 31-32).

To address this lack of adherence to policy, training programmes were implemented that aimed to improve the standards of medication administration; *'we communicated the golden standards, the handy hints of documentation'* (Survey 4 (Matron) line 117). Often the content of the training programme included multiple elements, to address the issues required:

> '*I think it's an overall combination, we have tried to address the drug administration errors from the 3 aspects, from the individual by wearing the drug apron, erm from the team by introducing the independent second checker and then we did the overall documentation and how people handle CD drugs, what they document, you know, all we've focusing more on the erm documentation of the medications and you know safe prescriptions and erm safe error entries and all, just trying to bring it all together really*.' (Survey 4 (Matron), lines 128-133)

Participants identified that the introduction of interventions often increased awareness of medication errors as attention was focused on the activity:

> *'but I think that was down to the fact that we erm pushed the medication policy erm and there were different types of errors reported so I think it looked at peoples' awareness of what was an error and what wasn't an error before and*

> *after. So, it's raised peoples' awareness about medication administration and errors if nothing else'.* (Sister (Interview 7), lines 137-141).

It was also acknowledged that an increased focus on medication safety was noted to contribute to the engagement of professionals with interventions:

> *'So, I suppose there's a greater prioritisation of medication safety-based discussions and greater em awareness which probably does feed into the prioritisation which may well the em er say no to interruptions.'* (Medical Consultant (Interview 2), 259-261).

Four Registered Nurses identified that adherence to the medication administration policy was often addressed at the same time as implementing an intervention to reduce interruptions. An example was described by the following Registered Nurse, who implemented a combined package that addressed policy adherence and wearing red aprons:

> *'I found when I first started here, I found that the medication administration wasn't to policy, so we needed to definitely deal with that but then I thought well let's roll something else at the same time to see if we can try and combat interruptions'* (Sister (Interview 7), lines 307-310).

Although the medication administration policy was noted to influence practice, another rule that was frequently described was that the process needed to be completed at the bedside. Four participants within the survey and 13 interviewees acknowledged that the medication administration process had to be completed at the bedside:

> *'we can't take medication away from the bed space, that can't happen, that's not a possibility so it's identifying when we're doing those tasks,'* (Sister (interview 7), line 86).

Furthermore, it was identified predominantly within the interviews that the continual presence of the nurse at the bedside was the driver for medications to be prepared and administered close to the patient:

> *'emm, I think because you have to do medications by the, you tend to do medications by the bedside in PICU and understandably so, it's an emergency situation, you don't want to be in a drug room doing them you want to be by the bedside'* (Survey 3 (Staff Nurse), lines 56-62).

Conversely, in two units the medication administration process had moved slightly away from the bed into the center of the unit. Despite this move, these two participants (one Registered Nurse and one Medical Consultant) recognised that the nurses needed to be close enough to the patient to be aware and to respond to an emergency.

In contrast to all other units, one Registered Nurse described the use of a medication round where all medicine infusions had to be prepared during a fixed time with an allocated nurse. This process fixed the time of administration but did not remove it from the bedside:

> *'so, we tried to have one dedicated person to do like a drug round and like an infusion round in the morning erm and then they'd check with the bedside nurse'* (Junior Charge Nurse (Interview 12), lines 167-169).

Despite isolating a specific timeframe for the medication round, the Registered Nurse identified that interruptions still occurred although not as frequently:

> *'I'd say that tends to go uninterrupted but it's still, you'd probably find in a round of eight patients you will get an interruption every fourth place.'* (Junior Charge Nurse (Interview 12), lines 170-171).

The third rule within the process that nurses were expected to follow, was the use of a second person to check the medication:

> *'we would have the two people there together I would draw up the medication and the other person would independently check the vial and the dose or the volume of drug'* (Sister (Interview 7), lines 17-19)

This description of second checking was supported by 21 of the other participants. The use of the second check was recognised as important by Registered Nurses, Medical Consultants, Pharmacists, the Physiotherapist and the Receptionist:

> '*erm and you'll often find that you know that they are both there, but one person will make it up then the other person checks it and then they you know erm put it together so that and write the label erm and everybody does double checks'* (Survey 9 (Sister), lines 258-262).

Nine participants (Registered Nurses, Medical Consultants and Pharmacists) highlighted that adherence to a robust second checking process was inconsistent. The Registered Nurses and Pharmacists described episodes of administration where the process of independently checking (see glossary for definition) the medication was not followed:

> *'we should be independently checking but that doesn't always happen erm so erm I would check the dose and time etcetera, etcetera erm and then the other person would independently check that. Erm so for example if we were to draw up some IV medication that I would draw up the, we would have the two people there together I would draw up the medication and the other person would independently check the vial and the dose, or the volume of drug'* (Sister (Interview 7), lines 13-19).

The independent checking strategy was identified as important because of the influence that can be exerted by another nurse if they talk through it:

> *'we mean by that that it's not a leading question, so I wouldn't lead a question to say this is .6mls of frusemide for example I would expect them to work that out because sometimes that can be quite leading,'* (Sister (Interview 7), lines 30-34).

Furthermore, the involvement of two nurses within the process was highlighted as having a potential to increase interruptions. This potential increase was explained by the following participant:

> *'And then if we see someone making up drugs unless there's suddenly something urgent with your patient then people are just not supposed to start just talking in the middle of it'* (Survey 1 (Junior Sister), lines 36-37).

Within the medication administration process, primarily at the beginning, nurses described a need for organisation and planning. There was a drive to fit the volume of medication into the delivery of other elements of nursing care:

> *'you tend to cluster them together so that you can be not interrupted during that time, so you know that between 12 and 1 I've got 3 infusions to do erm because I don't want to be doing cares during that time'* (Junior Sister (Interview 14), lines 330-332).

The strategy of clustering was perceived by one Registered Nurse, to create a protected time and reduce interruptions. She suggested that personal ownership of organisation of medications leads to the creation of protected time:

> *'I find it easier to make sure I've got a time set aside to do them rather than when you've got 48 drugs to do if you were doing them constantly taking and doing one at a time you would never have time for anything else to do. So, you need to make sure the time you do is protected.'* (Junior Sister (Interview 14), lines 339-341).

In summary, this sub-theme highlighted that the medication administration process is routine, and that all staff should be aware of it. However, the findings from this study suggest that whilst the routine can be described by all healthcare professionals the volume and frequency can lead to it becoming normalised and interrupted. There are general agreements about the process that appear to be followed in all clinical areas in this study such as the second checking process. However, there were also guidelines that are specific to each PICU, such as the use of independent checking. Interventions that have attempted to move the process away from the bedside were

noted to have limited impact as staff were expected to maintain an awareness of the patient's condition.

5.3.3 Safety 'mavericks'

All participants within the survey and interviews were able to describe being or observing others being interrupted during medication administration; *'but there's constant interruptions'* (Junior Sister (Interview 1), line 205). Furthermore, they were able to describe reasons, rationales and barriers as to why interventions to reduce interruptions to medication administration did not always work. Some of these were associated with individuals who would not adhere to the rules of an intervention leading to a unit culture where non-engagement had become the norm. This suggested that individuals were sometimes able to influence practice significantly, both positively and negatively. A possible identity for these individuals was that they may be viewed as a lone dissenter or as a person pursing rebellious or disruptive policies or ideas (Soanes and Hawker, 2005). The data also identified that the medication process and engagement with interventions to reduce interruptions could be influenced by actions, that when scrutinised raise questions about safety.

Six participants (Registered Nurses, Medical Consultants and Pharmacists) acknowledged that engagement with interventions to reduce interruptions in medication administration was influenced by individual dissent and disruption. Survey Two acknowledged the importance of the individual in engaging with the process:

> *'I think as an intervention on itself I'd see it like a guideline that a guideline is only as good as somebody, as it being integral into practice.'* (Survey 2 (Medical Consultant), lines 177-179)

Engagement with interventions was frequently affected by individual feelings, these were acknowledged within the surveys and described in more detail in the interviews. Thirteen participants (five surveys and eight interviews) described the reactions health care professionals experienced when using interventions to reduce interruptions. Within this sample, six participants noted that the feelings identified were often negative, such as, discomfort, embarrassment, and frustration. This was noted by a Pharmacist:

> *'when we qualitatively spoke to the prescribers about why uptake was poor, they basically said you're sat in the middle of the depart, you're sat in the middle*

of the unit with these enormous pink headphones on you look like a dickhead' (Pharmacist 1, lines 170-173).

Although, some actions were perceived to impact negatively on working relationships within the team. Engagement was poor if the professional felt the proposed action could be perceived as being rude:

> *'to put your hand up at them, that it was never going to work and because we all felt quite, that it was quite a rude thing to do and that we all felt really uncomfortable doing it'* (Junior Sister (Interview 1), lines 250-252).

The impact of interventions on communication has been previously mentioned in section 5.2.2. This was described by four participants as a reason for individuals or teams not to engage with an intervention:

> *'in the end it didn't work cause they were putting the red on for so long. So, you know it looked like they were going to use the red tabard so often that nobody would be able to speak to them at all.'* (Survey 8 (Medical Consultant), lines 47-50).

There were three units where it was described that red aprons/tabards had been embedded into nursing practice; *'red tabards is a sustained practice'* (Survey 2 (Medical Consultant), line 198). However, the wearing of the tabard was only one half of the process, preventing interruptions occurring was dependent on the behaviour and actions of those outside the intervention; *'so there are people who will interrupt people wearing red* aprons' (Survey 10 (Medical Consultant), lines 43-44). Therefore, it was important that professionals both within and outside of the process engaged with it.

An important factor identified by five participants, was a culture where interruptions were not accepted. This was reported by both Medical Consultants and Registered Nurses, and did not always require an intervention to support it:

> *'but we do have quite a few very vocal staff members you know (laughs) .. it's good, that's what we want them to be',* (Survey 9 (Sister), lines 352-356).

In contrast, the Physiotherapist reported that nurses needed to be more confident to challenge other professionals when they interrupt. This was in a unit where no interventions were in place, suggesting that nurses may benefit from an intervention that encouraged them to challenge:

> *'actually the nurses, maybe the nurses just need to be a little bit more sort of like you know, I can't think of the word, forthright in saying yeah you're going to have to wait,'* (Physiotherapist 1, lines 161-163).

Nevertheless, this concept of improved confidence and challenge was supported by three Registered Nurses (Sister and Junior Sister). They described a nursing ownership of the medication process:

> *'but most of the time they just actually turn around and say no no I'm doing the drugs you have to stop. I'm doing the drugs I can't do that now'* (Survey 9 (Sister),47-48)

This concept of owning the situation was also echoed when Medical Consultants and Pharmacists were describing the prescribing process. This concept was linked to engagement with interventions and processes:

> *'but actually, it is down I think to prescribers to actually do it, if that makes sense and the ownership has to come from them.'* (Pharmacist 2, lines 488-489).

This demonstrated the importance of the individual believing and valuing the actions within the process or intervention. If this was not present, they would be unlikely to use or follow the intervention. This was supported by the data in survey two, which described increased engagement if professionals chose to use the intervention within that ownership:

> *'it is not mandated erm but strongly encouraged, the reason for that again is that we want them to do it because they value it as opposed to because they have to, because we think they'll be better engaged in that process'* (Medical Consultant (Interview 2), lines, 342-345).

It was also noted that without engagement from the team, interventions were perceived to be limited:

> *'but it has to be, it only works where you've got motivated doctors and therefore actually the sustainability of it as an intervention erm is limited for that reason.' (Pharmacist 2, lines 496-498).*

To counteract this lack of engagement, participant two described a strategy where they tried to engage professionals into using interventions rather than push and enforce its use:

> *'not to say you must use it but em to avoid interruption but er more which I see as a falsely functional, a mandatory push or as the other way round as a pull; colleagues of yours who have been involved with incidents have wished that they had used em the prescribing area or had wished they had prioritised*

> *medication safety more because they are em mortified they have been involved with an incident' em and em er you know descriptions strong descriptions for the second victims of people losing sleep over, over not necessarily that significant incidents but just the fact that something they were involved with potentially caused harm to a patient'* (Survey 2 (Medical Consultant), lines 164-171).

Alternatively, the unit culture may have exerted more power or influence over individual actions than the intervention was able to. Six participants (three Medical Consultants and three Registered Nurses, Sister and Junior Sister) within both surveys and interviews noted the power of culture. They recognised that culture could influence feeling safe and not being blamed. In addition, culture was also noted to affect rates of reporting, rates of interruptions, and the measuring of impact of interventions. The following Registered Nurse acknowledged the power of culture:

> *'it makes me feel, it's frustrating to begin with erm it and I think, unless people know you are doing it and it's clear that you're doing medications, it should be but sometimes people don't erm then you shouldn't be interrupted and it's I think it's a cultural, it's possibly a cultural thing?'* (Sister (Interview 7), lines116 -120).

In addition, the concept of 'busyness' was highlighted as important within unit cultures by four participants. This culture was seen to contribute to the acceptance of interruptions:

> *'because when it is really busy there is almost an unwritten culture that it is ok to interrupt because it's busy' (Pharmacist 2, lines 115-116).*

It was suggested that 'busyness' could be offered as an excuse for making and allowing interruptions to occur. This was initially suggested as a potential reason for it happening by the Pharmacist:

> *'I think that some people would put it down to stress and whether it is that you know it's kind of almost that busyness, does that become an excuse for interrupting slash being less mindful?' (Pharmacist 2, lines 107-109).*

Furthermore, being busy in an intensive care environment enabled staff to justify interrupting. Interruptions that were linked by participants to emergency situations appeared to be justified and accepted:

> *'sort of asking a particular member of staff you know, oh actually we need adrenaline, or we need this drug or is this drug coming cause we're about to arrest or (laughs) you know that kind of thing'* (Consultant (Interview 5), lines 73-75).

Alternatively, it may not be an excuse, the comment by Pharmacist 2, that professionals become less mindful when busy, may lead to the suggestion that individuals may become overwhelmed by the number of procedures and care required by the child. This may suggest that they are unable to respond to or do not see the task of medication administration in this situation.

The outcome of the feeling of 'busyness' was a change in priorities for staff. It was seen to impact on the professional's priorities as a reduction in available time which affects their choice and could result tasks becoming less important:

> *'because people don't take the time to do that, I think, I think that's one of the things that I've identified is that because people don't think it's, they haven't took the time to do it, they don't think that it's necessarily important'* (Junior Sister (Interview 14), lines 67-69).

Time was also described by 17 participants as a critical resource that could impact on behaviour; '*I think a lot of the time people feel that time is, they're under pressure with time'* (Sister (Interview 7), lines 40-41). This lack of time was experienced by nurses and could result in the cutting of corners especially if another patient was felt to be vulnerable whilst the process was taking place:

> '*how it works practically is that a nurse will come and check the drug chart, check your name band erm and then will go back to there and check that the drug has been prepared and then will leave the bedside er to go back to their own patient because there isn't anyone free and you're leaving your own patient on its own, that's ventilated and turn your back on them to go and check a drug for someone else. So, I think in practice it is really hard to have a very rigid medication checking process erm but and corners are cut which unfortunately is what happens when we have medication error.'* (Junior Sister Interview 14), lines 18-24)

Pressure to be efficient and quick in the delivery of care was also perceived to be applied by wider members of the multidisciplinary team:

> '*and I think sometimes we do have some pressure from medics and other people to be quick at doing our medication because the next task is ready, we need to do the next task, we need to be ready for the next task and we should be slowing down really'* (Sister (Interview 7), lines 73-76)

Another issue extra to the lack of time, was the awareness of the task of medication administration. This was described by two participants who described a lack of awareness of what task or role nurses were performing; *'and then probably lack of awareness of what someone's doing maybe?'* (Medical Consultant (Interview 5), line

80). This demonstrated a lack of situational awareness at times and was amplified within an emergency:

> *'so, I suppose if you've got a deteriorating patient in front of you (laughs) er and maybe you're not quite aware of what everyone's doing around you,'* (Medical Consultant (Interview 5), lines 69-72).

Ultimately, the medication administration process was affected by staff 'being busy' or 'short of time'. These factors resulted in increased pressure to interrupt and decreased adherence to medication policy. Participants demonstrated that these both impacted on individual actions and unit culture. The impact of 'busyness' had not been considered within the design of any intervention to reduce interruptions to medication administration.

Overall, this theme has identified several factors that have influenced the impact of interventions to reduce interruptions to medication administration. Professionals identified that there were specific rules within administration within PICU that the interventions do not comprehend. In addition, participants noted that individual actions and engagement were influenced by both positive and negative thoughts and feelings generated by the interventions. Nevertheless, these could be overpowered by the culture of the unit when factors such as lack of time and resource encourage professionals to cut corners and potentially compromise safety.

5.4 Theme 3 - A patient led service?

This theme related to whether the design of interventions was driven by patient or professional needs. Concepts that emerged from the data that related to this theme also examine whether the effectiveness of interventions was affected by patient or professional need. The theme will examine the issues surrounding the interventions in relation to communication, team working, decision-making and leadership.

5.4.1 Communication

As previously identified in section 5.2.2 the PICU nurses were always present at the bedside of the critically ill infant or child. The location of the nurse at the bedside contributed to them coordinating the care for that child. An important part of this co-ordination was the communication between teams that was described by nineteen participants (nine surveys and ten interviewees):

> *'an example would be whether the physio team came round in the morning and decided is it a good time, you know 10 o'clock and your medications let's see the patient at half past nine for example or half past ten when you're finished if that's possible, maybe?'* (Sister (Interview 7), lines 249-253)

Communication appeared essential in the organisation of the delivery of care. This was particularly evident in the communication between AHP's and Registered Nurses who negotiated the most effective way to maximise time and routines for the patient:

> *'or you know so there's always a way round it and trying to negotiate the best time to do it and if the time isn't right then for whatever reason, then we'll try and come back, so I suppose it's just on a bit of a case-by-case kind of, work out on the day what's going on and what we can fit when. Yeah'* (Physiotherapist 1, lines 110-113).

This negotiation process was acknowledged by the AHP's within their interviews, to create *'an awful lot of conflicting priorities'* (Pharmacist 1, line 211) as they balanced their workload within and outside of PICU:

> *'And try to plan times and slots with them wherever we can but then that's dependent on our workload, what's going on with the patient and trying to fit it in with everything that's going on with the rest of our caseload as well. Yeah, generally ok.'* (Physiotherapist 1, lines 96-99).

In the wider organisation of PICU, plans and strategies were reported to be developed between the nurse in charge and the medical team to organise patient flow in and out of the unit. If the nurse in charge was involved in medication administration both the Medical Consultants and Receptionist acknowledged that the nurse in charge would be interrupted for this information:

> *'I think that reflects on the amount of interruptions that take place so that usually I'm asking things like is there a bed for patient X or can we bring patient Y in from theatres, or whatever it is'* (Survey 10 (Medical Consultant), lines 157-159)

Communication was also described by six participants as an influencing interruption itself; *'I think that people do talk while they're checking drugs'* (Sister (Interview 4), lines 172-173). These non-essential communication interruptions were acknowledged in the interviews by Registered Nurses, Medical Consultants and Pharmacists. Furthermore, they were reported within units where time had been invested in embedding interventions as well as those where none had been tried.

In contrast, 13 participants (seven surveys and six interviewees) acknowledged that essential communication between the multidisciplinary team also created

interruptions. These essential communications were pre-dominantly classified as being urgent or an emergency:

> *'but yeah, if there was something life threatening then obviously, you'd interrupt somebody'* (Survey 10 (Medical Consultant), lines 130-131)

Five participants from both the survey and interview dataset highlighted that Medical Consultants were frequent interrupters suggesting a lack of awareness or respect for the medication process:

> *'as in you get interrupted when you're doing checks, the doctors will just walk over to you and start talking to you and you're in the middle of doing checks, checking the medication'* (Sister (Interview 7), lines 105-107)

Furthermore, two Medical Consultants and two Pharmacists openly admitted that they did cause interruptions to the medication process. These interruptions were commonly justified by the need to communicate essential information about safety issues for the patient. One Medical Consultant acknowledged that he respected the red apron and would not interrupt if the issue was not an emergency as indicated below:

> *'if it's urgent I will interrupt say you need to stop, but most of the time I'll you know apologise'* (Survey 5 (Medical Consultant), lines 74-75).

The expectations of the nursing role in medication administration in PICU were communicated primarily during the induction phase. In contrast to all the other participants, two described a very structured approach to new starter medication administration programmes:

> *'so, on PICU we have a very strict education programme with regards to drug administration. It matters less where you come from or what your experience is, so I came to PICU as an experienced nurse, I had 9 years' experience of nursing em and I couldn't even give Calpol for 6 weeks we had to be, they don't even allow you to be a second checker for the first 6 weeks erm as an experienced nurse.'* (Junior Sister (Interview 1), lines 117-121)

During this time new staff starting on PICU were supported by more experienced nurses and standards could be communicated:

> *'I think the new people that come through you can tell they've had a bit of a erm a better training I suppose cause they're a bit, they're doing it properly'* (Junior Charge Nurse (Interview 12), lines 119-121)

However, during this period when standards and practice could be influenced, no one in either the survey or interviews described any education or training sessions about preventing, challenging or managing interruptions. Although, five Registered Nurses described an ongoing mandatory medication education day in their unit:

> *'so, we have yearly study days for our teams and on that we take themes from the year or the six months prior to that, for things that we feel are important that we should bring up erm and talk about and discuss.'* (Sister (Interview 7), lines 261-263).

This type of education included mandatory sessions such as calculation tests (Junior Sister), feedback from audit (Staff Nurse) and thematic analysis of incident reporting (Sister). Similarly, to new starter training, no one outlined any sessions about interruption management. Attendance at these study days was not multidisciplinary, although three interviewees described a multi-professional faculty. Therefore, education on these days would be limited as it would be important to deliver interruption sessions to the whole team.

There were two units that had patient safety teams and one that had a clinical governance team embedded within their clinical unit. These units frequently described multi-factorial communication in response to incident reports. It was in this method that participants described interruption management communication and education occurred:

> *'Erm and then in every morning and for the ward round, for the nursing handover both morning and night and they say what the big 4 for November and it'll be you know ok drug checking, making sure we don't do errors, what are the big four and then somebody'll read them all out you know so they're, they're dotted around the room and you've got to find where they are on the wall and then somebody reads it out so sometimes you get prizes if there's you know different questions you know why are we doing it and there's different things like how many incidences have we had that's drug related this month you know what was the worst one we did and so on'* (Survey 9 (Sister), lines 116-124).

Regrettably like the mandatory training days, this communication often occurred in professional silos, only two participants described nursing and medical staff having a joint handover. Therefore, it was possible that discussion and learning were focused on one viewpoint and the impact of interventions on colleagues less understood.

In summary, this section has explored the importance of communication within PICU in the delivery of medication administration. Consequently, communication is often a

cause of interruptions and some units have tried to minimise the impact of this but with limited success. Education and communication about interruptions in medication administration and their management was reported to occur in silos and overall multidisciplinary understanding of the impact was limited.

5.4.2 Teamwork

It was acknowledged within eight surveys and all the interviews that there were multiple different teams working within the intensive care environment. The teams that were acknowledged were nursing, medical, leadership, pharmacy, education, safety, clinical governance, visiting or specialist and physiotherapist. At times professionals from each would combine to deliver a multi-professional team working together to deliver day to day care. It was acknowledged that was fluid in composition as team members changed daily:

> *'so, I mean I would I guess I would consider our team to include the sort of allied health professionals, physios, pharmacists, etcetera as well as all the staff who work on PIC all the time'* (Survey 5 (Medical Consultant), lines 35-37)

There was an expectation that these teams worked together to provide collaborative care to the critically ill child:

> *'because we all know where we are on the page and the nurses know what the doctors are doing and the doctors know what the nurses are doing, we can we, we can, we are safer as a cohort.'* (Medical Consultant (Interview 2), lines 433-437).

A role that was acknowledged in the interviews with the larger PICU participants was the role of a float or resource nurse. This nurse was described as not having a patient allocation and being able to support other nurses in the delivery of care. It was a role that was highlighted by one Medical Consultant, three Registered Nurses and the Receptionist:

> *'but you know we're usually well-staffed, we usually have one nurse per patient erm and so you know and there's somebody around to float or something to keep an eye on what's going on'* (Survey 9 (Sister), lines 155-158).

The extra 'float' nurse was important for increased support or to facilitate two to one nursing for an unstable patient allowing for one person to purely focus on medication:

> *'when they are poorly and there's lots going on then you tend to have another person that's there working with you who is actually doing the drugs with you,*

> *you know doing the drugs so that you can get on and do other things and they then pull somebody else out to help them do the drugs'* (Survey 9 (Sister), lines 323-326).

Although it may be argued that they are no longer a float nurse if the dependency of the patient requires two nurses to deliver the care. Increased staffing ratios were described by participant nine offering the opportunity for one nurse to focus purely on medication administration; *'so you can prepare your own drugs and somebody else is watching the child'* (Survey 9 (Sister), line 329). This may then result in less interruptions as the nurse involved in medications would not have to provide the continual observation and respond to the critically ill child as highlighted in the following:

> *'there's somebody else there to watch them so you're not going to be distracted, you know move away from the bed space, you know turn the erm go to the IV checking trolley you know and turn it slightly away so that you can't see actually see what's happening with the patient and you're not distracted cause you've already got somebody else there erm now put the gloves on, let people know erm and then you know if people ask you questions and that then you know just say 'I'm just checking these drugs I'll be with you in a minute' you know 'can you just hang on I'm just checking these drugs'* (Survey 9 (Sister), lines 106-112).

Conversely, if staffing levels decreased and a 'float' nurse (see glossary for definition) was not available there was a risk that the nurse in charge would have to provide care for a patient in addition to managing the unit:

> *'I suppose the only other thing, it probably relates to sort of staffing numbers so when I have to interrupt or when I need something from a nurse who is wearing a red apron and you know preparing drugs for administration then it's normally the situation that it's the nurse in charge who has had to do that job because there isn't anybody else'* (Survey 10 (Medical Consultant), 153-157).

This situation required the nurse in charge to provide clinical care for their patient, including medication administration. No additional interventions appeared to be in place to support the nurse in charge to manage the unit and deliver medication administration:

> '*I mean the appearance to me is that the nurse in charge just looks after a patient and checks drugs in the exactly the same way as if they were just another member of the shift'* (Survey 10 (Medical Consultant), line 173-175).

In addition to the medical and nursing team members, AHP's were part of the team delivering daily care. Within the PICU team, the important role of the pharmacist was highlighted. This was identified within three surveys and four interviews:

> *'I know from documents like Safer Two erm in the US erm you know the whole process of 'to err is human', that having it that suggests that having a pharmacist present is a as an intervention is beneficial'* (Medical Consultant (Interview 2), lines 425-427).

The presence of pharmacists on ward rounds was described as having a positive benefit on prescribing behaviour and standards; *'their presence seems to help, just for sort of general awareness of er sort of etiquette around drugs'* (Survey 5 (Medical Consultant), line 104). In addition, participants described a positive impact from the inclusion of pharmacists in teaching and audit:

> *'we have a pharmacist who comes on the round almost every day so they er check the drug chart and they make a note of any errors and as I said they put, put it in an audit'* (Survey 7 (Medical Consultant), lines 73-75).

Pharmacists also identified that they were interrupted and the impact of those, particularly when they felt they had no control over them:

> *'and then you've kind of got distractions of bleeps and that sort of thing which obviously are less easy to control as well.'* (Pharmacist 2, lines 298-299).

This may be helped by having freedom to leave the clinical area. That freedom enabled them to seek out quieter spots, therefore potentially reducing the rates of interruptions:

> *'but I guess I'm in a relatively fortunate position that I'm not you know a bedside nurse I can wander off and do that, you know I don't have to, I'm less tied to the bed side than some people might be.'* (Pharmacist 2, lines 433-435).

The AHP's acknowledged that their actions were not always time critical. At times they were able to negotiate and work around the administration of medication:

> *'I probably include myself in that as a general pharmacy point of view that em I am on the unit every day and I am providing patient care but in a very different way, so it's relatively easy for me in many respects for me to step back cause most of what I do is, isn't really, really time critical if that makes sense?'* (Pharmacist 2, lines 95-99).

Although, there were occasions when they were time limited as they needed to be elsewhere. On these occasions it was noted this contributed to an increased pressure on them to interrupt:

> *'As a pharmacist annoyingly, I am one of those big distractions because I'm working in a time, I'm quite time poor at work so I don't have, I'm not on the ward all day, I basically have 2 or 3 hours in the morning when I can do the ward round and I can run round and do all my essential checks and things so I don't really have the time to allow a medication administration process which*

can take up to 40 minutes erm because them I'm not going to be able to review that chart if that makes sense?' (Pharmacist 1, lines 205-211).

The impact of time was echoed by the physiotherapist who described interrupting the medication process to perform a treatment session:

'I suppose as physios we can be guilty of the interrupting because we could come to bedside to do a treatment session and the nurses are preparing medication at the bedside em and then we're there to start the treatment em' (Physiotherapist 1, lines 65-67).

A consequence of this treatment was that on occasion the treatment could then make the patient unstable, and the nurse would be required to respond and abandon the medication process:

'*I suppose there's been the times when mid treatment if I've then needed a nurse to support me with a treatment and they've been to the side of me doing that, but I've needed the nurse immediately then I have just had to interrupt to say I need some help or whatever, but in more of an emergency situation then.'* (Physiotherapist, lines 81-85).

The survey data indicated that healthcare professionals did not always perceive that support staff were important within the medication process; '*yeah, so they wouldn't help us with drugs'* (Survey 9 (Sister), line 382). In contrast, the interview data highlighted an important role for support workers in preventing interruptions:

'this is often difficult when you've got somebody on the phone who finds their situation more urgent than the what the checking the CDs are, so they often ask me to find out and try and get round it someway.' (Receptionist 1, lines 32-35).

In addition to the team based within PICU, participants identified visiting multi-professional teams from other specialties who work with the intensive care team to deliver care to the individual patients. An observation made by a Pharmacist was that visiting teams who were less involved in the delivery of intensive care noticed the task of medication administration and were less likely to interrupt:

'I say some people are probably better than others, probably erm in some respects they probably some of the visitors to, relative visitors to the unit so pain nurses is one example that I can think of certainly you know one of the pain nurses is particularly good at not em kind of not interrupting if that makes sense I know one of the site matrons do it again I think, I think that people who are based on the unit all the time if they're, whether they're medics or nurses I think they're a little bit possibly less mindful in many cases.' (Pharmacist 2, lines 78-85).

Conversely, in one survey the participant questioned whether information about the use of red aprons had been shared with wider visiting teams. This suggests that the intervention had been applied to the unit rather than across the whole hospital:

> '*Outside the team so visiting professionals from other teams I've got, I actually don't know how aware they are of the red aprons cause I'm not even sure if it's something that's used across the trust*' (Survey 5 (Medical Consultant), lines 39-40).

This limitation of a unit-based intervention indicated the importance of team communication in the development of interventions to reduce interruptions. The survey and interview data showed wide engagement within PICU's but limited input from visiting teams. It was noted by eight participants in both surveys and interviews that engagement from within the whole PICU team was important for the intervention to have any chance of success.

> *'Erm but in terms of whose ideas they were I think it was just kind of team, you know speaking to the whole team about what the issues were and what could be done to improve it rather than anyone person erm yeah.'* (Medical Consultant (Interview 5), lines 248-251).

The data provided by the receptionist highlighted the importance of understanding issues from multiple viewpoints, this may allow the development of an intervention which comprehends the needs of other professionals within the team:

> '*erm but if you're not trained then you're not used to that environment you don't really know when it is the right time and the wrong time to interrupt.'* (Receptionist 1, lines 171-173).

Furthermore, investing time in promoting equality between professional groups within medication administration was described as having a positive effect on relationships and widening the impact of the culture by involving the multidisciplinary team:

> *'there was a disparity of the way that doctors were treated to nurses, and we tried, we tried to remove that by saying that medication is a priority'* (Survey 2 (Medical Consultant), lines 117-120).

Participant 2 (Medical Consultant) described a culture within their unit where equality between nursing and medical staff was developed. These actions were implemented in response to differences in the management of PICU staff after a medication error had been reported.

> *'so, it was er one of the important elements of it was that it was equitable, so there was a disparity of the way that doctors were treated to nurses'* (Survey 2 (Medical Consultant), lines117-118).

Inequality was also identified by two participants who highlighted those interventions aimed at the medical team, such as prescribing zones were implemented officially in contrast to informal encouragement not to interrupt the administration process:

> *'a prescribing desk which is in a separate area of the unit and um doctors aren't allowed to be interrupted while they're prescribing unless it's an emergency.'* (Survey 7 (Medical Consultant), lines 22-25).

Input from each member of the team is required for the delivery of quality patient care, participants identified that there is a risk that professions can work in silos without consideration of each other:

> *'And also recognised that you, we all work in silo teams so whether that's doctors or nurses or em ward A versus ward B that we, that we that there are, we think our own team is great and those outside the team em we may, there's the teams work with maybe slight sharper edges'* (Medical Consultant (Interview 2), lines 272-275).

In summary, this section concerning teamwork has highlighted the impact that individual roles within teams can have on both interruptions and the interventions that aim to reduce them. It has highlighted the difficulties faced by professionals who are expected to deliver services outside of PICU whilst also being an integral member of the team delivering care to critically ill children.

5.4.3 Decision making

The data obtained from the surveys and interviews indicated that there were several factors that influenced actions when choosing to interrupt or accept an interruption. Some of those factors were patient focused such a prioritising care or responding to unpredictable patients. Other factors were centred around the individual professionals, who were influenced by prior experiences and their priorities. Furthermore, the culture of the unit may encourage professionals to challenge interruptions or alternatively accept them as a necessity.

Focusing on a single task in the intensive care environment was seen as extremely difficult. The implementation of interventions to reduce interruptions to medication administration within the intensive care environment resulted in the healthcare team

frequently basing their decision making on an assessment of urgency; *'if it's urgent, I will interrupt say you need to stop'* (Survey 5 (Medical Consultant), line 74).

All units included within this study were responsible for the provision of intensive care to critically ill children. The nature of this work at times, is extremely unpredictable requiring the healthcare professionals within the teams to make reactionary decisions in response to the clinical need of the child:

> *'as you know on PICU things can change very quickly and sometimes you just have to do something else cause something is happening with your child'* (Survey 1 (Junior Sister), lines 79-81).

Twelve participants described situations when nurses may be required to respond to the infant or child. Examples such as an acute deterioration resulting in an emergency (Medical Consultant, Interview 5) or a child suddenly waking up (Sister, Survey 9). One Registered Nurse described how those events could impact on the healthcare professional's concentration:

> *'but it's, it is very tricky you know you do get distracted the alarms start going off and you know you can see that they're trying to turnover in the bed, or they're getting suddenly getting very bradycardic then you do sometimes get distracted yeah'* (Survey 9 (Sister), lines 58-60).

The data from both surveys and interviews highlighted that the potential instability or unpredictability of critically ill children created a need for nursing teams to be continually present at the child's bedside (see section 5.3.2). In addition, the nurse was required to be continually cognisant of the child's physical condition:

> *'you still have to be able to run back and get them you know, you, you can turn your back slightly and you can turn the trolley slightly but erm you have to be able to still get to them quickly, so you know and be aware of what's going on'* (Survey 9 (Sister), lines 150-153).

This awareness of surroundings demonstrated how the environment resulted in the nurses multi-tasking. Seven participants from both interviews and surveys described episodes of multi-tasking. Four Registered Nurses were aware of the need to multi-task and two Medical Consultants, and a Pharmacist reported their observations of it occurring. Registered Nurses reported that it was likely to occur if the child was unstable and requiring multiple treatments at once. They also felt that sometimes the medical team had reduced awareness of the current task, pressuring them to take on new ones.

It was acknowledged by 10 participants that medication regimes were at times complex and time consuming. This was acknowledged within the surveys and discussed in detail in the interviews. This data indicated a need for long periods of concentration:

> *'especially with a er sick child you are continuously doing something to do with infusions or drugs or stuff'* (Survey 8 (Medical Consultant), lines 45-46).

Within surveys five (Medical Consultant) and nine (Sister) it was noted that the nursing teams were involved in significant volumes of medication administration that filled their time within their shift; *'It's like, it's a major part of their day'* (Survey 5 (Medical Consultant), lines 131-132). In turn, this created problems with conflicting priorities, the following highlights the issue of being continually available to staff and parents/carers:

> *'but we don't have that because we're always at the bed space, you're always there to be asked a question, aren't you? Parents do it, other staff do it you know'* (Sister (Interview 11), lines 131-133).

Furthermore, the Physiotherapist described how their treatments can cause patient instability. The outcome of this was an expectation of availability as she felt that the nursing team needed to be aware of and be able to respond immediately:

> *'I suppose there's been the times when mid treatment if I've then needed a nurse to support me with a treatment and they've been to the side of me doing that, but I've needed the nurse immediately then I have just had to interrupt to say I need some help or whatever, but in more of an emergency situation then.'* (Physiotherapist 1, lines 81-85).

This section has illuminated how the decision-making process was influenced during medication administration, suggesting that interventions were required to comprehend workflow patterns that could affect the delivery of patient care. However, it was important to the professionals within the sample that they were able to deliver holistic patient care:

> *'because you're becoming task focused rather than actually responding to the change in the needs of your patient or erm you know you just become sort of focused on that one task'* (Sister (Interview 11), lines 200-203).

Furthermore, the impossibility of isolating a task within the intensive care environment was identified by one of the Pharmacists:

> *'And it's how do you, it's how do you isolate, how do you isolate the person from the environment? When they need to be aware of what's going on in that environment?'* (Pharmacist 1, lines 193-195).

The organisation of services within intensive care was also highlighted as creating conflicting priorities as the three AHP's identified that they were commissioned to deliver care within different environments. Furthermore, each environment created equally important priorities:

> *'So, there's an awful lot of conflicting priorities I think and that's a cultural issue that is about operational and operational management and leadership and the way services are structured to this environment is that'* (Pharmacist 1, lines 211-213).

These conflicting priorities influenced reactions to interventions to reduce interruptions to medication administration. The impact of visible interventions such as aprons or gloves depends on the interrupter to decide whether the interruption is more important than the preparation of medication. Pharmacists noted that there was a risk of elements of care being missed or forgotten if they were unable to deliver their message:

> *'then if I don't interrupt it's likely that I won't then get the chance to come back and do that. And then you end up missing something or it gets forgotten.'* (Pharmacist 1, lines 276-279).

In addition, these interruptions were associated with higher levels of worry and concern from the individual interrupting the process. Nevertheless, the internal feelings of worry were overridden by other external priorities:

> *'it makes me feel awful because it, I know consciously I know I'm interrupting because I've got to go and do something else erm*' (Pharmacist 1, lines 281-282).

Members of the multidisciplinary team interviewed, who were not nurses, described the importance of being able to identify when nurses were involved in medication administration. Strategies such as recognition of body language or actions were used to inform when nurses could be interrupted:

> *'one checks the book and the other one checks the cupboard and you can see they're both working together doing that er if they're not erm looking at the drug cupboard or they're not in progress and they're standing talking to each other erm then they're not facing the drug cupboard, they've not opened the drug cupboard or they've not erm or opened the cupboard but not actually started er so I might open the door'* (Receptionist 1, lines 45-50).

A strategy used by the MDT to help with the decision-making process was to stand back and observe for an appropriate time to interrupt. Six participants (Registered Nurses, Medical Consultant, Pharmacist and Physiotherapist) described taking the time to understand what was happening at the time:

> *'I think possibly waiting, possibly erm keeping out of the way I think erm a little bit more so actually maybe approaching someone then realising that they're actually engaged in kind of you know drawing up medicines or administering medicines and then kind of backing away a little bit without necessarily asking the question that they went there to ask erm so I think it is, it's kind of that sort of situational awareness thing I guess'* (Pharmacist 2, lines 73-78).

In addition, they acknowledged a need for the nurse to have an awareness that they were waiting otherwise this became a problem:

> *'but then its but then it's difficult cause then if you're at, if you stand at the top of PICU and they don't even know that you're there, there's that many beds around, then that nurse doesn't even know that you're there for them,'* (Physiotherapist1, lines 208-211).

As previously highlighted the visibility element (see section 5.2.1) of the intervention aims to stimulate that thought process and promote actions that reduce interruptions to the medication process. Although, not everyone was recognised as responding to the intervention in the intended way; *'so there are people who will interrupt people wearing red aprons'* (Survey 10 (Medical Consultant), lines 43-44). This was evidenced by data that described situations when they ignored the red aprons:

> *'but I'll only wait as long as I can because I have other duties that I need to perform so if I have to hand over that we're going to change a dose or if I have to go and write another prescription for something else that we've decided on the ward round, but I've got to be somewhere else at a meeting or a clinical appointment in 15 minutes then I'll interrupt.'* (Pharmacist 1, lines 269-273).

In summary, this section indicated that some decision-making surrounding interruptions was driven by patient need. However, there were a significant number of influencing factors that were driven by the individual's feelings, experience and priorities. Furthermore, the actions of professionals are also influenced by the environment and in turn this can affect engagement with and the effectiveness of the interventions.

5.4.4 Leadership

The final section of this theme concerns the use of leadership. This was noted as an influencing factor, especially within the survey. Participants discussed the role of

senior members within the team, role modelling, flattened hierarchies, safety champions and safety leaders.

The senior nurse role was commonly perceived to be associated with increased levels of interruptions. Participants described needing to ask for information from the nurse in charge (Medical Consultant and Receptionist), share information with them (Medical Consultants and Junior Registered Nurses) or ask for advice (Junior Registered Nurses):

> *'this is why it's so difficult when the nurse in charge checks the drugs because or does anything that needs to be done at certain times because the nurse in charge is above all most in demand and erm she's needed for so many different things, if it's only to ask questions or pass messages on or keep her in the loop she, she is in the most demand'* (Receptionist 1, lines 135-139).

This role as nurse in charge of the intensive care unit was also perceived to have an increased level of knowledge about individual patients. They would then be approached if the bedside nurse was not available:

> *'I will see the nurse in charge because she's probably the only other person that knows as much about that patient as the nurse that's looking after them'* (Receptionist 1, lines 134-135).

Participants in both surveys and interviews described different roles within the nursing team. These were in addition to the bedside nurse and associated with differing types of responsibilities and levels of interruptions:

> *'but because I'm a team leader I have a responsibility for half the unit, so I could be making drugs up with a member of staff,'* (Junior Sister (Interview 1), line 212).

Nevertheless, participants indicated that engagement from senior members of the team was influential in the implementation of interventions. Eight participants (three Medical Consultants, one Pharmacist and four Registered Nurses) acknowledged that more experienced nurses would challenge and not accept interruptions. In contrast, it was noted that junior nurses were less likely to have the confidence to challenge an interruption:

> *'the older ones like you Rachel (laughs) I think I'd say that yes, I think the younger ones would be er more likely to er you know say 'what do you want?'* (Survey 10 (Medical Consultant), lines 66-69).

The sister in survey nine described the impact of the presence of a senior team within the critical care unit, role modelling behaviours that promoted decision-making and challenged interruptions:

> *'I just think that there's quite a lot of senior team and there's a lot of the RNP's which are like the ANP's that we have erm and they train up you know 'I can't talk now I'm just doing this, you know, let me finish this and I'll come and talk to you'* (Survey 9 (Sister), lines 315-317).

Participants described several strategies that had been implemented which promoted different cultures within the individual units. These strategies involved the role modelling to enforce a culture of challenge when interruptions occurred. This was role modelling was also highlighted within one of the interviews where the demonstration of consistent behaviour by senior staff was felt to be important:

> *'whether actually what would make a difference behaviour wise is whether actually there was a consistent em kind of example set by more senior staff but also that ability to challenge and not only if you're the person being interrupted to say no I need to finish this, I need focus on that,'* (Pharmacist 2, lines 134-138).

In addition, two participants identified the need for a consistent re-enforcement of the intervention even when they were not present:

> *'when I wasn't here, she was the one that would be pushing for the people to be sure they are wearing the red aprons.'* (Sister (Interview 7), lines 335-336).

In two larger units where safety and clinical governance teams had been present, a flattened hierarchy within the senior team was described. This contributed to a greater ownership of interventions within the team, that promoted the challenge of interruptions regardless of the profession or grade of the person interrupting:

> *'Em er and everybody was empowered to be able to say, as I said it doesn't matter who you were, what your grade was what your, it doesn't matter in any sense what matters was that we were prioritising medications safety'* (Survey 2 (Medical Consultant), lines 136-138).

In contrast, three participants described a strategy using juniors as leaders. Champions (see glossary for definition) were selected and trained to promote the intervention and influence the behaviours of others within the team:

> *'retrained 10 maybe 12 members of staff erm and they were sort of champions for that'* (Junior Charge Nurse (Interview 12), lines 52-53).

The effectiveness of Champions was described by one Pharmacist, who felt that they had to have very high levels of motivation:

> *'I think that erm it takes off ok, the wards on which this has been more successful er or areas in which it's been most successful is where there is a clear, a very motivated erm junior doctor often in the case of the wards an F1/F2.' (Pharmacist 2, lines 477-479).*

Whilst one Medical Consultant acknowledged that this use of champions could promote the benefits of whole team involvement and remove the need for one leader. It was perceived that the whole team worked together to deliver safer care:

> *'flatten the hierarchy, so it wasn't erm it wasn't the consultant seen as boss or the nurse champion who was seen as boss, it was seen as we are working together to learn from each other and to learn from other places other centres such as and that's the premise behind Making it Safer Together and the American equivalent or North American equivalent Solutions for Patient Safety of collaboration to learn from rather than compete,'* (Medical Consultant (Interview 2), lines 445-449).

Furthermore, seven participants described a need for the team to have a consistent, collaborative strategy to improve patient safety. To develop this, feedback from the wider team was required:

> *'er we created em what's app groups or telegram groups that erm discussed medication safety, so I would put questions on there saying, 'what does everyone, what does everyone think about this?' so rather than it being this is how we are going to do things and dictating and leading by er mandating erm to try to get discussions going to try to raise the profile of medication safety' (Medical Consultant (Interview 2), lines 441-445).*

It was more common for interventions and strategies to be implemented and discussed in a top-down manner. Fourteen participants within both datasets were able to describe occasions within medication where a management decision has implemented a change in practice:

> *'accept that it is ok to challenge and to be challenged erm but I think education and but also support kind of from top level down, sort of multidisciplinary medics and nurses would need to be involved as well. Erm to make that work.'* (Pharmacist 2, lines 420-423).

A required element suggested by one Medical Consultant to achieve the challenge of promoting medication safety, was trust between the whole team:

> *'the team learning survey which was the one that looked at psychological safety and looked at the work, that looked at, that recognised that the further*

> *somebody is either up the hierarchy or more distant from your local team the less, the less you trusted them.'* (Medical Consultant (Interview 2), lines 269-272).

Three units had roles where there had been an investment of time and resource in patient safety leadership. This investment was also identified as important within units with strong patient safety cultures:

> *'so, I was er I think I was probably I was certainly one of the leaders of safety generically including medication safety across ICU'* (Medical Consultant (Interview 2), lines 223-224).

These roles were key in leading and developing practice within their unit, particularly in relation to patient safety:

> *'but we have like a quality er lead nurse on critical care who's very much involved in service improvement* (Junior Sister (Interview 14), lines 154-155).

This section demonstrated the influence that leadership roles had over managing interruptions and using interventions. A minority of units had invested in patient safety roles. These leaders were focused on promoting interventions that were created by the whole team. This whole team approach was used to reduce the need for one person to lead and enforce the intervention on a day-to-day basis. In contrast, other units required the role model and enforcement of the senior leadership team to ensure interventions were adhered to. This was described as less effective, as engagement with the intervention was not always consistent.

Overall, this theme has considered the key influencing factors of communication, teamwork, decision-making and leadership. Although the actions and behaviours of staff are sometimes required by the critically ill infants and children, it is more common for staff to react to other professionals. The different roles and teams within PICU heavily influence the interactions between professionals and often the patient is not the primary consideration.

5.5 Healthcare professionals' contexts, mechanisms and outcomes

The previous three sections (5.2, 5.3 and 5.4) have presented a thematic analysis of the data gathered from healthcare professionals. The inductive thematic analysis allowed the participant voice to be presented without being forced into a framework but did not explore how and for when interventions to reduce interruptions to medication administration were effective. Therefore, an explanatory realist lens was

applied to assist in achieving this aim. The questions outlined in sections 3.7.8 and 3.8.9 were used within the realist analysis to explore how healthcare professionals' behaviour and actions were influenced within the medication administration process when interruptions occurred, or interventions were in place to reduce disruption. This additional layer of analysis uncovers the key contexts, mechanisms and outcomes (see Table 32associated with the medication administration process within PICU and the use of interventions to reduce interruptions to it.

Table 32 - Healthcare professionals' context, mechanisms and outcomes

Contexts	Mechanisms	Outcomes
• Patient factors • Expectations • Physical matters	• Feelings • Focus versus Risk • Team Interaction	• Rates of change • Timely and efficient care • Value

The information displayed in Table 32 identifies the situations or contexts that triggered any hidden mechanisms such as behaviours or actions that influenced any interesting outcomes. A more detailed explanation of the realist concepts of contexts, mechanisms and outcomes is in the glossary. The following sections will critically explore and discuss these contexts, mechanisms and outcomes in more detail as per overall framework of this thesis.

5.5.1 Context 1 - Patient factors

The requirement to deliver one to one nursing care was a key element described by healthcare professionals (Medical Consultants, Registered Nurses and Pharmacists). Any child who is ventilated and sedated has been deemed to require the complete attention of their own nurse. The healthcare professionals within this study indicated that this standard of being continually present at the bedside was delivered within the units they worked in (section 5.3.2 and 5.4.1). The inability to be able to leave the bedside for prolonged periods of time to prepare medications has resulted in the administration process being delivered at the child's bedside (section 5.4.1).

Participants described the delivery of the medication process at the beside being compounded by the volume and complexity of medication required by these patients (section 5.2.3). They noted that it was common for the sicker children to have larger

medication requirements, therefore creating prolonged periods of time where nurses were busy with medicine preparation. Participants described increased organisational strategies if the medication workload was complex (section 5.2.3). When medication workloads were large, interventions were noted to be less successful, as the nurse would always be inaccessible for prolonged periods of time, this was not acceptable to both nurses and surrounding MDT members.

A key rationale provided by all members of the multidisciplinary team within PICU for interrupting the medication process was the management of and response to the critically ill infant or child (section 5.4.3). Professionals described how their overall view narrowed to focus on the unstable patient. Therefore, the delivery of intensive care to unstable or unpredictable patients created a context where the bedside team were required to have high levels of situational awareness (section 5.2.1 and 5.4.3), however, this was difficult to maintain in practice.

If a patient was extremely unstable requiring multidisciplinary team input to keep them alive, the number of professionals delivering that care increased. If staffing levels were robust a more task orientated approach could be taken, as two nurses may be allocated to purely focus on medication administration (section 5.4.2).

In contrast, if the patient was stable but at risk of coughing or waking up the bedside nurse was required to deliver medication administration as well as observing the child. At this time the nurse was required to focus on medication administration whilst maintaining awareness and responding to critical situations such as desaturations. In this context, it was less likely that extra staff would be available to help the nurse manage the multi-tasking required, unless there was a strong team ethic to help observe the patient whilst the nurse stepped away from the child (section 5.4.2).

The concept of busyness (section 5.3.3) was identified by participants as influencing cultures where interruptions were accepted as normal. It was felt that busyness was used as an excuse to interrupt. On these occasions, professionals prioritised their own needs or the needs of another patient above a safe administration process.

5.5.2 Context 2 - Expectations and priorities

Participants within the study identified several different expectations and priorities within the processes delivered within the intensive care environment (section 5.2.3).

Each role within the multiple teams on PICU set different expectations and priorities. These were noted by the participants to influence the medication administration process, interruptions and the use of interventions.

The data from the multidisciplinary interviews described the variety of roles within the PICU team (section 5.4.3). The roles within the team created different expectations and priorities for the professionals within intensive care. The bedside nurse was expected to maintain continual observation and awareness of their patient's condition. Furthermore, medical teams, visiting specialty professionals and parents/carers expected current and timely communication with that nurse (section 5.4.1). Whereas the float nurse was expected to be knowledgeable and experienced to be able to offer support to those with increased workloads. In practice, this role was described as intermittent and depended on available staffing levels. The nurse in charge was expected to manage the flow of patients in and out of the intensive care unit. If they became involved in medication administration, they were increasingly likely to be interrupted by questions that required immediate answers.

The medical team were also expected to the plan the care for all patients and were identified as frequent interrupters (section 5.4.2). Although, some of their interruptions were noted to be urgent and needed prioritising. Whereas AHP roles were funded differently to other members of the team, they often needed to deliver services outside of PICU and this created external pressures that increased their need to interrupt. Finally, receptionists were described as gate keepers (section 5.4.2) for the nursing team, as they managed external interruptions for them. For this role to be effective receptionists needed to understand the actions or body language within the medication process and know when it was safe to interrupt.

The culture within each intensive care unit was identified as being important in influencing the expectations and priorities of healthcare professionals (sections 5.3.1, 5.4.2 and 5.4.4). In some units the participants felt there was a culture of acceptance, that interruptions were the norm. In contrast, other units with a strong safety focus actively implemented interventions that aimed to reduce interruptions. Alongside the use of interventions there was encouragement to challenge and manage interruptions by all professionals regardless of their grade or role. The presence of a safety culture

was demonstrated using safety or clinical governance teams and the presence of safety leaders.

The enforcement of following medication policy was highlighted within section 5.2.2 as an important context within the process, although not every unit described adherence to the medication policy as a priority. When the policy included an independent checking procedure and it was enforced, interruptions from the nurses involved within the process were reduced, suggesting that this was a beneficial addition to the intervention. If this process was not followed, then interruptions increased as the nurses talked each other through the process. This conversation may have contributed to other professionals perceiving that they thought it would be acceptable to interrupt if nurses were talking at that point of the process.

When using interventions professionals expected them to work within the normal medication process, and not require extra time or effort to use it (section 5.4.3). If the professional was expected to make extra effort to apply the intervention, they described a use of prioritisation. As long as they and their patient were protected, for example, using Aseptic Non-Touch Technique or the wearing of Personal and Protective equipment, they would not always go in search of a red apron if they were not at hand.

5.5.3 Context 3 - The PICU environment

There were some participants who described an ‘ideal world’ within the PICU (section 5.2.3). They acknowledged some physical factors that influenced the medication process and use of interventions. In the ideal world interruptions would not occur, short cuts would not be taken, resources (supplies and staff) would be abundant.

The lack of access to supplies or equipment required by the intervention was identified within sections 5.2.1 and 5.2.2. It was acknowledged in both the surveys and interviews that access to supplies was difficult, they were often unable to obtain the correct coloured apron or gloves. If the correct colour of apron was not available, it created confusion as team members were unable to see from a distance that the nurse was involved with medication. Alternatively, if the red medication apron/tabard was worn for bedside nursing care team members ignored the apron and its effectiveness

within the intervention decreased. Furthermore, several participants acknowledged that there were multiple-coloured aprons in use, creating a visual overload.

Alternatively, when interventions such as ‘No interruption zones’ were in use, its effectiveness required it to be well stocked (section 5.2.2). The medication resources required were calculators, medicine handbooks and information sheets. If these resources had been removed from the area, the intervention was less effective as the professional had to leave the area to find the equipment required.

5.5.4 Mechanism 1- Feelings

The professionals included within both the surveys and interviews described multiple different feelings when talking about interruptions and interventions to reduce them. These feelings were generated as a reaction to the intervention itself or its impact on the medication process, therefore these feelings may contribute to its success or failure. A fundamental conflict described by participants was the feeling of being torn as they balanced patient safety with a focused medication process (section 5.2.2). Both aspects were viewed as important but a patient safety issue such as a potential self-extubation (see glossary for definition) would always be a priority despite the potential harm from a medication error.

In section 5.3.3 participants described feelings of frustration that interruptions could generate, especially non-urgent ones. These interruptions could affect interactions between team members as interruption rates increased. Despite feelings of frustration, it did not result in participants increasing their adherence to the use of interventions to reduce interruptions.

In addition to feelings of frustration, participants described feeling pressured (section 5.4.3). These feelings of pressure were linked to other team members both within PICU and external to intensive care. Participants described an expectation that medication could be rushed in order to move on to the next task. Alternatively, the pressure could be generated by the workload associated by an unstable child as multiple medications or treatments may be required to ensure that child survived its critical illness. These pressures were identified by participants as contributing to increased rates of interruptions and lack of response to the interventions such as red aprons. In times of pressure, visual signs were not seen.

Finally, participants acknowledged that feelings of discomfort or embarrassment could be generated by one of the interventions (section 5.3.3). If these feelings were generated, then it was likely that professional engagement would be poor. Alternatively, if the intervention generated feelings of protection or empowerment, engagement would be increased, and the intervention perceived to be useful.

5.5.5 Mechanism 2 - Focus versus Risk

The rationale for the use of interventions acknowledged by participants was the ability to work undisturbed and focus fully on one task (section 5.2.1). However, within the PICU environment this creates conflict and risk between being focused and being available to deliver care. Section 5.2.2 identified a fundamental conflict within the design and use of interventions to reduce interruptions to medication administration. The conflict generated prioritisation issues between two opposing patient safety concepts. On one hand nurses had a priority to provide safe care to the child by closely observing them and responding to their needs that may be urgent. The alternate priority was to safely administer complex medications by reducing the nurse's awareness of their patients' condition and completely focus on one task. The evidence of medication being prepared at the bedside indicated that the observation of the critically ill child was top priority now in most intensive care units included within the study, as only one unit had moved medication away from the bedside.

A benefit of using an intervention such as a red apron was the protection offered to the medication task by its isolation. This could result in a change in mental attitude towards the task, as a beginning and end was identified. Participants acknowledged in sections 5.2.1 and 5.2.2 those interventions like wearing a visible red apron to try to reduce interruptions could create a protected time. This protected time was viewed positively by nurses as it allowed them to reset their mind and increase their focus on medication administration.

This isolation of task was accompanied by negative effects such as feeling cut off from the rest of the team and the patients (section 5.2.3). Furthermore, participants highlighted that it could lessen their awareness of patient condition, and this did not sit comfortably with them as they were responsible for the continual delivery of care.

An additional issue with the focused concentration were the risks associated with the balancing of priorities. These were particularly evident if the nurse in charge was involved with the medication process. They found it difficult to offer full focus to the task because of other responsibilities. It was noted that sometimes these interruptions could be delayed, and they had concerns that they may miss important information about a patient's condition that they needed to be aware of.

5.5.6 Mechanism 3 - Team Interaction

Interactions between team members were an important mechanism identified within the analysis. In section 5.3.3 the concept of what could be described as safety mavericks was discussed, identifying factors that may influence a professional not to adhere to policy or the use of an intervention. The factors that influenced these professionals were associated with team interactions and the culture of a unit.

The interactions between senior and junior nursing team members were significant (section 5.4.4). The senior team were important in the culture of challenging interruptions. Experienced nurses were noted to be more likely to be vocal and challenge interruptions even if no intervention was in use (section 5.4.4). Furthermore, the promotion and implementation of an intervention to reduce interruptions often increased the confidence of less experienced nurses. This increased confidence enabled the junior nurse to challenge interruptions regardless of who the interrupter was.

In addition, the interactions between different teams were important. Equality between nursing and medical staff within the medication process was highlighted within the analysis (section 5.4.2). The medication process can be broadly split into administration and prescribing, both of which can be affected by interruptions. If professionals are encouraged to respect the different elements there was a suggestion that this created mutual benefit as they themselves were less likely to interrupt others.

Trust was an important element within the teams at the bedside (section 5.4.2). If a nurse was to completely focus on the medication process and have less awareness of their patients' condition, they needed to trust their team. This trust required the rest of the team to deliver care to or observe the patient whilst the nurse was busy administering medications. In addition, it was highlighted that environments where

there were strong hierarchical structures were likely to have less trust within the team as senior leaders were seen to be less approachable. This could create an environment where interventions were enforced and engagement from the team reduced.

5.5.7 Outcome 1 - Rates of Change

The outcomes commonly acknowledged were the reduction of interruption rates and an associated decrease in medication errors. In addition, it was highlighted that it was also important to understand the type of interruptions that occur (section 5.2.1). The impact of understanding the causes of the most frequent interruptions was to ensure the most appropriate intervention was implemented. An example of this would be implementing a red apron without information for parents/carers, if they were the most frequent interrupters.

Despite there being different types of interventions, participants described a similar rationale for their implementation. This rationale was to create a time or area where interruptions were reduced (section 5.2.1). Associated with the reduced rates of interruption was often a decrease in medication errors (see section 5.2.1). Within the sample only two units had performed any measurement of interruption rates (one unit did not have the results available) and one unit had looked at medication error rates alone.

The analysis showed that the availability of resources was an important factor in the understanding and measurement of interruptions and their reduction. Within the intensive care unit there needed to be a structured process for patient safety and clinical governance (section 5.3.1). Time needed to be invested to organise this process and engage with the wider team. In turn, this process would contribute to the understanding of what was required for that unit and the monitoring of its impact. This process also created time for learning and discussion. Also required was the availability of trained and motivated individuals to lead this work. What was not evident from the data was the influence of the wider organisation. It was not identified whether the wider organisation expected these patient safety teams to be in place and report back on their work and results.

5.5.8 Outcome 2 - Timely and efficient care

The surveys and interviews with the multidisciplinary team in PICU indicated that the medication workload forms a significant part of the care required by a critically ill child. Additionally, it was also noted delivery of nursing care or treatments within the intensive care cannot stop every time the medication process occurs (sections 5.3.3 and 5.4.1).

Participants identified that the delivery of timely care was vital (section 5.3.3). Furthermore, it was essential that healthcare professionals negotiated, planned and worked as a team to ensure that happened. This negotiation is important to prevent the nursing team rushing medication administration when feeling pressure from the wider team.

The data presented within section 5.4.3 explored decision-making when interrupting the medication process. An outcome of the intervention was informing professionals when it was safe to interrupt. The visibility of interventions encouraged colleagues to wait to interrupt. Nevertheless, they were likely to wait close to the medication area, which was described as 'hovering', and noted to be an interruption. Participants noted that if they waited too far away from the process, nurses may not realise that they were needed and move on to the next medication, resulting in a prolonged wait for the other professional.

5.5.9 – Outcome 3 - Value

Creating value within the intervention was the outcome identified within the analysis. Section 5.2.1 highlighted that professional may value the intervention more if it worked to address the most frequent non-essential interruptions and fitted into the current process. In addition, it was also noted that the overuse or incorrect use of an intervention decreased its value.

Furthermore, professionals from the multidisciplinary team identified in sections 5.2.1, 5.2.2 and 5.3.2 that it was important that nurses owned the medication process. The creation of an environment or culture where nurses involved in medication administration actively managed the interruptions allowed them to deflect, delay, disengage or challenge interrupters. Participants acknowledged that the culture of the

unit was important, a flattened hierarchy enabled more nurses of all grades to own the process.

The analysis of data presented in section 5.3.3 indicated that engagement with interventions to reduce interruptions is essential for it to become embedded in practice. Furthermore, engagement with the intervention increased if professionals could see its value. This engagement was perceived to increase if professionals understood the value of the intervention as they were pulled into the process rather than being pushed by an enforced intervention.

5.6 Conclusion

In summary, this chapter has presented a thematic review of the data provided by the survey of PICU's within England and interviews with members of the multidisciplinary teams. The thematic analysis illuminated the multiple interventions that had been implemented repeatedly within PICU's in England. The lack of measurement of these interventions has resulted in the repeated implementation of designs that do not comprehend the complex workflows within PICU. Within the interventions there is a conflict within the maintenance of patient safety, the continual observation of child versus isolation of a task.

Finally, the chapter concluded by analysing the themes for contexts, mechanisms and outcomes that influenced the effectiveness of interventions to reduce interruptions to medication administration. Contexts such as role, culture, unstable patients and lack of supplies trigger mechanisms such as trust, feelings of discomfort and frustration. Ultimately these then impact on the outcomes associated with the interventions such as efficiency, interruption and error rates and creating protected time. This chapter has developed the knowledge generated in the Realist Review, by adding a rich analysis of PICU data. This will be developed further by adding parent/carer views in the next chapter.

Chapter 6 – Findings 3 - Parent/Carers

6.1 Introduction

The aim of this chapter is to present a thematic review of the data provided by parents/carers of critically ill children. The data was explored to illuminate and comprehend the critical issues identified by parents/carers of critically ill children, pertaining to medication administration. Furthermore, issues are evidenced throughout by parent/carer quotes. The critical analysis process, presented in chapter 3, identified three themes, namely, 'It's my child', 'Watching and waiting' and 'I am part of the team'.

Theme one, 'It's my child' illuminated the parent/carer role of protecting their child, whilst exploring the impact of admission to PICU and feeling safe within the intensive care environment. While theme two, 'Watch and wait', highlighted the prolonged periods of observation experienced by parents/carers. This exploration highlighted the extensive knowledge developed by parents/carers during their time on critical care and its impact on their decision-making. Finally, the last theme, 'I am part of the team' explored the involvement of parents/carers within the medication process and identified their requirements to enable them to feel part of the team.

The concluding section of the chapter explores the relationships between the themes. This exploration illuminated situations, thoughts and feelings that were noted to influence parent/carer actions when medications were being administered to their child within the intensive care environment.

6.1.1 Participants

The study recruited parents/carers whose children were current PICU inpatients from four units within the Midlands region of England. The clinical teams involved in the study approached 60 families (see Chapter 3 for recruitment process) of critically ill children and fifteen interviews were organised that included 19 parents/carers. The data displayed in Table 33 summarises the demographic information of the parents/carers and children included within the study.

All families were offered the choice of one or both parents/carers taking part, and four couples chose to be interviewed together. The sample contained a significant number of white British females (n=10), but the study did not aim to recruit a representative

sample due to the qualitative methods used. Although, it does include the views and experiences of males (n=6) and participants from an ethnic minority (n=4) adding a degree of credibility to the study.

The parents/carers were offered the choice of conducting the interview by phone or a face-to-face conversation in the intensive care unit caring for their child. In this sample, the first and last parent/carer chose to conduct the interview by telephone. The interviews lasted a maximum of 56 minutes and a minimum of 13 minutes, with a mean time of 30 minutes. The final interview was shortened by the unexpected early arrival of an ambulance to transfer the child and their family to a hospital closer to home.

The inclusion of four units enabled the sample to contain a variety of reasons for admission to PICU as each unit was commissioned to provide different specialist care. It was anticipated that the sample would include at least one child from each of the common diagnostic groups; cardiovascular, neurological, respiratory, renal, infection and musculoskeletal. The data displayed in Table 33 indicates that the sample did include children from the common diagnostic groups admitted to PICU. Furthermore, the sample included a variety of age ranges, however, a significant number (n=9) included were aged one year and under. This aligned with the demographics of the national population as the annual report for the audit of paediatric intensive care delivery indicates that over 50 percent of admissions were aged one year and under (Paediatric Intensive Care Audit Network, 2020;7). In addition, the sample contained a significant number (n=12) of children with long-term complex medical conditions, similarly, this was reflective of the national population of children's intensive care admissions (O'Brien et al., 2017).

Table 33 - Demographic information parents/carers

Participant number	Parents/Carers	Length of interview	Gender of child	Age of child	Speciality	Length of stay/prior admissions to critical care
	Unit A					
1	Female White British	40 minutes	Female	2 months	Renal	Hospitalised since birth, inpatient on two units (NNU and PICU) Interview conducted towards end of PICU stay and infant extubated
2	Female White British	26 minutes	Male	18 months	Infection	Emergency admission (non-survivor sibling experience of ICU) Interview conducted towards end of PICU stay and child extubated
3	Female White British	26 minutes	Male	16 years	Neurological	Emergency admission (Second critical care admission) Interview conducted towards end of PICU stay and child extubated
4 5	Female White British Male White British	25 minutes	Female	4 years	Neurology (Complex medical history)	Acute admission (several previous admissions to critical care) Interview conducted whilst child still intubated and ventilated
6	Male White British	15 minutes	Male	12 months	Respiratory	Acute admission Interview conducted towards end of PICU stay and child extubated
7 8	Female White British Male White British	27 minutes	Female	10 years	Renal	Acute admission Interview conducted whilst child still intubated and ventilated
9	Female White British	29 minutes	Male	6 months	Cardiovascular	Repeated admissions to critical care since birth Interview conducted whilst child still intubated and ventilated
	Unit B					

10	Female White British	33 minutes	Female	16 years	Musculoskeletal (complex medical history)	Acute admission (prior admission to critical care) Interview conducted whilst child was still intubated and ventilated
11 12	Female White British Male White British	34 minutes	Male	2 years	Post-op renal transplant (complex medical history)	Acute admission Interview conducted whilst child intubated and ventilated, 3 days post-surgery
13	Male Asian	56 minutes	Male	3 months	Cardiovascular	Hospitalised since birth (inpatient in two units) Interview conducted whilst infant intubated and ventilated
14	Female Asian	30 minutes	Female	1 year	Cardiovascular	Hospitalised since birth Interview conducted whilst infant intubated and ventilated
15	Female Asian	30 minutes	Male	4 months	Cardiovascular	Hospitalised since birth (inpatient in two units) Interview conducted whilst infant intubated and ventilated
	Unit C					
16 17	Female White British Male White British	22 minutes	Male	3 weeks	Cardiovascular	Hospitalised since birth Interview conducted towards end of PICU stay after infant had been extubated
18	Female White British	37 minutes	Female	6 months	Cardiovascular	Planned admission Two PICU admissions since birth Interview conducted towards end of PICU stay after infant had been extubated
	Unit D					
19	Female Asian	13 minutes	Male	18 months	Respiratory	Acute admission (one prior admission) Interview conducted towards end of PICU stay after child had been extubated

6.2 Theme 1 - 'This is my child'

The analysis of the data provided by parents/carers identified a theme that encompassed an important driving force in their reaction to medication administration; the need to protect their own child. Although the need to protect their child was important, parents/carers acknowledged the difficulties and challenges of doing this in such stressful circumstances. Parents/carers reported an understanding that errors can happen but were clear about the influence that nursing behaviours on their actions.

6.2.1 Admission to PICU

All the parents/carers described admission to intensive care as a frightening and intimidating experience. Four parents/carers reported that this could be worsened by extended periods of illness prior to admission due to a lack of sleep. This was highlighted by a parent/carer who had been admitted after their child deteriorated at home with an infection:

> *'when you're a new, a newer parent and you're new to an intensive care ward or you're new to hospital everything is just so daunting, you've got no idea what's going on, you're in shock, you've probably not slept for a couple of nights you're terribly worried so it's different,'* (Mother (participant 2), lines 227-230).

Even when admission to PICU was expected a process of shock was also described, one parent/carer whose child had been admitted to PICU post planned surgery, acknowledged it in the following quote: *'obviously seeing **** straight after erm surgery in there was a shock'* (Father (participant 12), line 180). Additionally, all parents/cares also acknowledged how important the equipment and treatments were in order to sustain their child's life:

> *'she was actually put on dialysis; so she was put on haemodialysis when she came over which I erm understand is quite unusual for a baby of her size and age cause I don't think it's actually licensed for children under 8 kilos and she was a lot smaller than that'* (Mother,(participant 1), lines 22-25).

Furthermore, eight parents/carers described periods where they were unsure whether the child would survive, and their condition is extremely unstable *'we just wanted to make sure **** was still alive'* (Mother, (participant 18), line 124). Additionally, the instability of the child's illness caused worry to all the parents/carers:

> '*sometimes it's, sometimes I think most of the time it's fine, I think sometimes if you're maybe, if we're maybe having a bad day or ******'s not quite right I think*

sometimes that makes you, puts me on edge a little bit just because, just because it does,' (Mother, (Participant 18), lines 318-321).

It appeared that this data indicated that parents commonly found admission to PICU a traumatic and frightening experience. They found the environment to be daunting, especially when it was their first admission to PICU, and the unpredictability of their child's condition caused them to enter an initial period of shock. However, parents/carers identified that alongside these traumatic experiences they continued to act as protector of their child.

6.2.2 Protecting my child

Whilst all parents/carers described being in stressful and frightening situations, three mothers described challenging nursing care. One mother identified a situation where she needed to express concern about medication and the planned care for her child:

> *'I've not seen the wrong medicine, but I've seen with my child that some of the medicines might have been stopped too soon, so that was my one concern that I've had with medicines which was I think morphine'* (Mother, (participant 15), lines 205-207).

This expression of concern was developed further as a role of protector was described. Interestingly, this role was only highlighted in the data from mothers as two of them described occasions when they needed to intervene and question the PICU team:

> *'I like to know what things, what they are doing cause it's your child at the end of the day, I do trust them, but you still have to know what's going on'* (Mother (participant 4, lines 205-207)

The narration of this role was developed further as another mother explained that there was a difference between caring and protecting. Within her explanation she clearly identified a legal framework to underpin her rationale:

> *'I feel quite upset because I think she's my child you're just caring for her I'm her parent you need to tell me I'm not stopping you, but you need to talk to me first because I'm her parent I've got PR (parental responsibility) not you, so you're just caring for her'* (Mother (participant 14), lines 130-133).

Furthermore, this role as '*protector*' was acknowledged by one mother (participant nine) within the medication process. She described situations where the role of protecting her child stimulated her to query and challenge medication processes:

> *'well I think there's always that bit as well about you protecting your children you know it's that I think perhaps if somebody hadn't have told me that the*

> *captopril may have been implicated in the arrest then maybe I wouldn't have been so wary of it but I know because it has such an effect on ***** and it does drop his blood pressure that it's something that I'm really wary of.'* (Mother (participant 9), lines 87-91).

Knowledge was illuminated as an important element within the role of protector. One mother outlined the depth of knowledge about the medication and its side effects that they needed to continually help to protect their child:

> *'So I do ask, cause I have to keep an eye on her blood pressure, she's on, she has chloral sometimes as well so because her blood pressure drops so I need to know what are you giving her how much, especially the sedation ones, she's very sensitive, she had like 15mcgs/kilo and it drops her blood pressure so I need to know and I'm like you know because not all the nurses know but she's, now she's roc-ed (rocuronium, a paralysis agent administered) and she's got midazolam I say to them can we reduce the clonidine cause if you give her that she's going to drop her blood pressure'* (Mother (participant 14), lines 107-114).

This data highlighted four mothers that felt driven to continue to offer protection whilst they were experiencing the trauma of their child being critically ill and admitted to intensive care. It appears within this study these feelings were gender related as none of the fathers' described actions or feelings of protection. Although, one father did describe his wife's worry and concern to protect her son. In order to deliver this protection, it was evident within the data that most parents required a detailed working knowledge of the medications their child was receiving, with only one father indicating that he found too much information overwhelming. Parents/carers of children with complex needs described a prior knowledge of medication, whilst those admitted for the first time reported developing this understanding during the admission. This knowledge appeared to develop over time, once the initial shock of being admitted to intensive care subsided. Parents/carers whose child had been admitted for less than a week were able to describe common medicines such as sedation and pain relief.

6.2.3 Prior knowledge

Unsurprisingly, parents/carers who described in-depth knowledge of medications had either been resident in PICU for significant periods of time or their child required long-term medication administration at home. Therefore, it appeared that some parents/carers enter the intensive care environment with life experience that can influence their actions and behaviours when medication was administered to their child:

> *'yeah the morphine, we knew what that did and we knew midazolam, we'd been in that position before when it's been needed'* (Father (participant 5), lines 65-66).

Furthermore, prior experiences led to parents/carers describing the impact of medication administration had on their life at home. This was demonstrated by one parent/carer as they acknowledged that medication had become a normality within their life:

> *'so, for us it's like it becomes normality, it's become normality seeing drugs being made up or you know cannulas being put in, it's not particularly a nice thing, but you become immune to it'* (Father (participant 12, lines 181-183).

Within this sample, three parents/carers had been involved in the administration of complex medication routines to their child at home. While six parents had experienced intensive care medication routines with prior admissions. Two parents/carers disclosed that they were healthcare professionals which created unique complexities in their understanding of medication administration as a parent/carer. These professionals worked within environments that cared for adult patients, so were aware of the medication process but not the specific knowledge and skills demonstrated by the PICU nurse in the process of medication administration:

> *'I think it's really interesting being a parent and a nurse because you're seeing a whole process and you perhaps see a little bit more'* (Mother (participant 9), lines 94-95)

In contrast, eight parents/carers had had minimal prior exposure to medications in relation to their child. The parents with minimal experience reported a different experience of gaining knowledge. One parent called it *'a process of osmosis'* (Mother (Participant 1), line 198) as they learned about what medicines are being prescribed for their child and how medication was administered. Interestingly all the parents/carers who had not had prior experience of medication were able to describe the medicines their child had received and often an understanding of why it was needed:

> *'she's had vitamin K injections she's had calcium carbonate as medication, just to try and reduce her phosphate erm she's had erm nor-adrenaline for her blood pressure erm cause her blood pressure's gone from one extreme to the other so she's had stuff to kind of hold her blood pressure up and then to kind of bring down again erm she's been on all manner of medications for the duration that she's been alive basically'* (Mother, participant 1, lines 59-64).

The level of knowledge reported by these parents/carers was considerable, suggesting that the process of learning described by Participant 1 worked. Prior to this admission this mother stated she had no knowledge of any of these medications. Furthermore, this process of learning appeared to occur through conversation and discussion, as no parent/carer in this sample had received written information about the medication process or their child's medication.

6.2.4 Human error – wanting to feel safe

Although five parents/carer described a need to protect their child, they were understanding of the risk of human error. One parent/carer was aware that workload was a possible reason for error:

> *'and people make mistakes, everyone's human and I suppose if like, ***** was on so many* [medications] *it's probably quite easy to make mistakes' (Mother (participant 18), lines 214-215).*

Alternatively, personal well-being was recognised as a possible contributory factor to the mistakes occurring. The factors identified by one parent/carer were tiredness and feeling unwell. In addition, they also recognised some human factors such as the possibility of reading prescriptions incorrectly:

> *'we all make mistakes, we can all be tired, not feeling quite right, just, we've all looked at something and looked at it wrong'* (Mother, (participant 3), lines132-133).

Nevertheless, seven parents/carers acknowledged that a robust two-person check of the medication contributed to them feeling reassured that this fallibility could be minimised:

> *'it makes me feel at ease cause they're human beings they can make a mistake and you hear stories of wrong medicines being given so em it made you feel at ease yeah I'm happy with it'* (Mother (Participant 15), lines186-188).

Furthermore, it was recognised that the presence of a second check at some point in the process offered reassurance to parents/carers; '*yeah I think you know I mean at least then you're reassured that's they've both checked it and they're both happy.'* (Mother (participant 7), lines 266-267).

It was acknowledged within section 6.2.3 that some parents had extensive experience of administering medication at home. Within this group three parents acknowledged that there were risks of human error with medicines at home. Three parents had

experienced interruptions at home when preparing medication and acknowledged that this could lead to mistakes. One mother described how she found the medication administration process challenging:

> *'we've definitely had a moment at home when ****** drew up the meds, it was very close, we'd not been long home, and he, everything was in the big 2.5ml syringes and I think ****** the only thing that ******* ever had was, I draw the domperidone which is 1.2mls, she has in that in 2.5ml, but I wasn't even doing that at that point and erm cause she wasn't on 1.2 she was on 1. And he brought up loads of syringes, he was doing the meds, cause er my little girl had hit her head and I told him to stop cause she doesn't have anything in that size (syringe), she wasn't on paracetamol that was only if she was em had a temperature or anything erm so he'd given her too much I think it worked out at ranitidine but he had thought it was digoxin we'd only been home a few days, he didn't know the difference between the colours and stuff so that's how easy it's done he's never touched the meds again, mind you' (Mother (participant 18), lines 245-256).*

Furthermore, two sets of parents/carers had experienced the impact of being interrupted at home by other children. They reported implementing measures to counteract distractions:

> *'yeah big time (laughs) em yeah cause, we've got, they know now that if I'm doing medicines they try and stay away cause you can go wrong and sometimes I've gone to give it and I've thought oh there's a bit too much in there but you learn by your mistakes and they do know not to interrupt when I'm measuring things'* (Mother (participant 4), lines143-146).

Although parents/carers were understanding of human error, all participants acknowledged the importance of consistent and professional behaviour within the medication process. All parents/carers reported being reassured by a consistent delivery of medication administration.

6.2.5 Maintaining consistent and professional behaviour

All the parents/carers in the sample discussed the impact of professional and consistent behaviour by nurses and its positive impact on making them feel safe within the intensive care unit. The following quote highlights parental expectations of the nurse within the medication process:

> *'well this is where the worry is cause what should happen, they've got the 5 rights they have to follow the right patient, the right time, right dose, right something else and the right route. Now because *******'s been here a long time I don't know about others, they just quickly sign it sometimes they just don't check it'* (Mother (participant 14), lines 162-166).

One mother described a lack of consistency in nursing behaviour when administering medication. These observations led to them question the professionalism of the nurses involved:

> '*I do think it's er an attitude, personality type of thing and erm and their attitude to the job I think more than anything else, I think that's the impression I've got anyway from it'* (Mother (participant 10), L196-199).

All parents/carers reported observing a double-checking procedure; *'they will go back and check the drug card and do the calculations themselves and make sure everything is spot on'* (Mother (participant 1, lines 100-101). As well as offering reassurance (section 6.2.4), this second check was associated by one father with an increase in their confidence:

> *'well it gives you confidence that everything's being checked multiple times by you know a nurse, another nurse, a more senior nurse and then the doctor as well you know it's I think that's really what in PICU you want to be, you want to be reassured feel confident that there aren't, well mistakes are going to be absolutely minimized cause that's what, well you don't want mistakes do you? em so yeah I think it gives you confidence'* (Father (participant 12), lines 257-249).

In addition, two parents/carers perceived that the second check was an embedded part of the routine; *'they have them checked by someone I've never seem them not be checked, they're always checked.'* (Mother (participant 18), lines 115-116). In contrast two parents/carers felt the process could be improved as they commented on the need for the second checker to be present for the whole process making it more rigorous. Interestingly, one mother used their experience of being a palliative care nurse to question why the process was not second checked from the moment the medication left the cupboard to the observation of administration as was her experience:

> *'I think as a general rule coming from you know I'm incredibly used to doing lots of controlled drugs and even you know in the adult world we don't double check except when we're doing controlled drugs so that process from right from getting it out the cupboard to administering to the patient is always a 2 nurse process right the way through you know where as I think the two nurse checking thing is to check the drug but not necessarily to always check the administration.'* (Mother (participant 9), lines135-140).

Consistency was a second factor that was identified by five parents/carers as contributing to them feeling of safe. This was especially important within the process of checking medication:

> *'I know they always have to do a check, they always say can I have a check, can I have a check em which sometimes seems quite serious between some nurses but other times seems very laxadazy between some nurses so again there doesn't always seem consistency with that if I'm honest with you.'* (Mother, (participant 10), L176-180)

In contrast, the lack of consistency was perceived negatively by one mother, '*you need to make up your minds because there needs to be consistency, you're confusing me as a parent.'* (Mother (participant 14), lines 178-179). Furthermore, inconsistency contributes to increased rates of interruptions, as parents/carers seek clarification as to why practice had changed; '*if we seen something out of the ordinary I would, I didn't see you do that before I might just say; is there a reason you're doing this differently?'* (Mother (participant 7), L322-323).

In summary, this sub-theme has highlighted the impact nursing behaviour has both on parents/carers feeling safe within the unit and contributing to interruption rates. In addition, the in-depth knowledge described by parents/carers about the medication process, indicated that nurses were conducting the task within an observable distance of their child.

6.2.6 Eyes on my child

In Chapter five (section 5.3.2) the professionals working within PICU acknowledged that they were required to be continually present at the bedside due to the risk of unexpected deterioration or instability. This was echoed within this data where 12 parents/carers noted that the continual presence of the nurse was a requirement of the environment; 'On PICU they don't move from that bed space unless someone else is there' (Mother (participant 3), lines 194-195). Consequently, four parents/carers reported that presence of a nurse allowed them to feel safe:

> *'I know they are there if there's an emergency, I know they've got their eyes on the baby'* (Mother (participant 15), lines 298-299)

Most parents/carers (n=11) identified that this continual presence was required because of the risk of an acute deterioration at any point and the need for the nurse to be able to respond to this; 'c*ause obviously they know if something's flashing red continually and it'll bleep loud, they'll obviously go and have to intervene'* (Mother (participant 4), lines 231-232).

The need for this presence caused by the instability of the patients and the delivery of continual observation, created a challenge for nurses when they needed to leave the

bedside. This would occur if they needed to collect supplies, have a comfort break or prepare medications:

> '*often you can be left for an hour sometimes at a time with just two nurses to 4 beds which then means that erm you know if alarms are going and a child desatting to 70's or whatever, a nurse could be in the middle of doing drugs and actually has to leave it obviously to go and suction or sometimes bag a child you know when they are in the middle of drawing up something'* (Mother (participant 10), lines 127-131).

Eight parents/carers recognised that as a result of this continual presence, the preparation of medication was required to be performed at the bedside. This created situations where the nurse was expected to concentrate on the preparation and administration of medication, whilst having a background awareness of changes in patient condition, and of the equipment delivering life-saving therapies to the child; '*obviously cause it's PICU and they need to be, have their eyes on their patient*' (Mother (participant 15), line 283).

In these situations, parents/carers noted that nurses were required to make plans to ensure that close, continual observation occurred whilst they left the bedside. These plans may require asking another nurse to observe their patient or organising equipment to be brought to their bed space. An example of this was highlighted by one mother: '*but if they do leave to go to do anything like that, they always get somebody else to watch over the child they are looking after while they go and do it.'* (Mother (participant 16,) lines 137-139). This organisation and planning as described by parents/carers highlighted how teamwork was an essential mechanism required to enable the nurse to deliver continual presence at the bedside:

> '*sometimes when they go to the medicine thing though they'll get someone next to them to keep an eye while they're doing the medicine so then they don't get distracted'* (Father (participant 17), lines 171-173).

In two of the units (A and B) involved within the study, teamworking strategies were less formal; *'just before, [she] shouted for somebody else to go and get something'* (Mother (participant 11), lines 172-173). In contrast, in the other two units' parents/carers were able to clearly describe clear processes of how the team cooperated to provide continual care for their child:

> '*they always say in there all of them, whatever nurse you have always says you don't have to wait for your specific nurse if there's one next to you, you can just ask them so that's what we do yeah'* (Mother (participant 16, lines 234-237)

Ten parents/carers acknowledged that the continual presence of the nurse at the bedside was important to them. These parents/carers noted that having a nurse with them offered reassurance and made them feel safe:

> '*them being able to do it at the bedside obviously means that they are at the bedside with you and I think in intensive care that's probably the most reassuring thing is that there's always someone there, that is really reassuring'.* (Father (participant 12), lines 213-216).

Furthermore, it appeared that increased reassurance contributed to parent/carer confidence within PICU. It is possible that this also contributed to a relationship of trust between the parents/carers and the PICU team:

> '*in the beginning when we were first here, we probably didn't notice much because we know that she was being watched quite closely she was really quite poorly erm so therefore our confidence grew'* (Mother (participant 18), lines 316-318).

Although, this increase in confidence and assurance required an element of responsiveness. One mother commented on the immediate response nurses had to any alarm or deterioration:

> '*I think it's quite good cause then it, they're always watching as well so if anything bleeps or they're able to go straight away so yeah I think it's quite good the way it works yeah'* (Mother (participant 16), lines 127-129),

Although, it was highlighted by another mother that the delivery of care by the wider team could be unsettling and increased worry for parents/carers:

> *'she was an HDU patient for such a long time she did share a nurse, initially that was quite scary,'* (Mother (participant 18, lines 328-329)

In this situation, when the presence of another member of the team was required to provide care, it was appreciated if the nurse remained close to the bedside rather than observe from another bed space:

> '*but most of the time some people if, if someone's covering so from, like a break erm they're I think they're quite good if the person in charge will actually come and sit at the (bedside) desk'* (Mother (participant 18), lines 321-323).

Communication was identified by six parents/carers as essential within the team to ensure roles were clearly allocated. This resulted in the team pulling together to deliver care to their child:

> *'and the way they are with each other I think that's even involving the medicines like I say cause they all, they all just work together so if someone is busy doing that then there's someone else there as well'* (Mother (participant 16), lines 367-369).

In contrast, when the team failed to deliver the close nursing care, three parents/carers described feelings of discomfort. The father in the following quote had experienced this in the ward environment:

> *'you know if you are on a ward erm like say we're on a ward and we go to get something to eat yeah, yeah we'll keep an eye on him but they won't go and sit in the room with him and stuff they'll just have the door open and listen'* (Father (participant 12), lines 216-218).

However, the use of interventions to isolate the medication task were described as reducing the effectiveness of teamwork. It was described by one mother who was a healthcare professional as isolating the task and the nurse, reducing their availability and removing holistic care:

> *'I don't know whether there's anything that I think would make it safer you know unless you could have somebody just doing drugs but then that takes away that part of holistic care then doesn't it?'* (Mother (participant 9), lines 250-252)

In summary, the data in this theme illuminates the factors, behaviours and actions required by the PICU nursing team to help parents/carers feel safe. Parents/carers identified strong feelings of needing to protect their child. The presence of a professional nursing team delivering consistent standards of care was influential in its ability to make parents/carers feel secure and that their child was cared for in a safe environment. Feeling safe and assured was important as they were often present on the PICU for prolonged periods of time.

6.3 Theme 2 - Watch and wait

This theme developed out of the data pertaining to the times in intensive care where parents/carers felt that they needed to wait to allow their child to recover from their illness. During these extended periods of waiting, eight parents/carers described having the time and ability/permission to watch the care being delivered to their child, one parent/carer described prolonged periods of observation:

> *'watching *****, watching the monitors, watching them draw up the different medications'* (Mother (participant 1), L153-154).

Observation of nursing was an activity that parents described taking part in; *'you can just see what they were doing'* (Mother (participant 3), lines 207-208). Alternatively, parents/carers described activities to keep busy, but these were focused in the bed space allowing them to remain close to their child:

> *'it could vary erm cause she's sleepy now sometimes I sit there, sometimes I can be praying, sometimes I could be on my phone, sometimes I could clean the bed space,'* (Mother (participant 14), lines 324-326).

This data indicated that parents/carers spent prolonged periods of time observing actions, behaviours and routines within the PICU. Therefore, this prime bedside seat allowed them to frequently observe the medication process that occurred within their bed space. This observation enabled parents/carers to learn about the process and identify any differences in behaviours, actions and communication when medicines were being prepared or administered.

6.3.1 Parental observation of the process

All parents/carers interviewed were able to describe the medication process in detail, noting the different phases of medication administration, key pieces of equipment associated with the task and the different ways medication may be administered:

> *'I know they've got a chart in front of them, well first of all a doctor has to write it, or prescribe it and they have a chart in front of them it's all written down erm they have to put gloves on, aprons on they draw it up using a syringe and a very sharp needle and it comes out of a bottle, another nurse has to check it, they do the weight they calculate his weight so 10.6 kilograms and it all calculates down on how many mls or how many whatever per weight, they both work it out together the nurse and the secondary nurse do it together, they check it they write it down they plot it on another bit of paper they put it on the administer er thing with all the syringes, the pump yeah they put it on the pump plug it in the pump check it again I think erm it seems very very thorough I think anyway.'* (Mother, (participant 2), lines 46-47).

Parents/carers within two of the units (A and B) described a medication process that occurred at the bedside and involved two nurses following a set routine to check that the medicine had been prescribed, prepared and administered correctly. In contrast, in the other two units (C and D), parents/carers reported nurses had moved away from the bedside and performed the same checks at a central medication station. Colleagues were asked to observe and support parents/carers whilst they followed the same checking process as previously highlighted.

Fourteen parents/carers commonly associated the start of the medication process with the discussions held and plans made during the medical ward round, suggesting an understanding of the multi-disciplinary team within the delivery of medication:

> *'you know the sort of the ward round, they come round and the doctors prescribe don't they, so they have a little chin wag and they prescribe and that goes on the drug card'* (Mother (participant 1), lines 81-83)

All of the parents/carers interviewed indicated that the medication administration process began with some clearly recognisable cues, these were either visual or verbal. Three parents/carers associated the start of the process with the hunt for the keys for the medication cupboard, this had a very clear verbal cue associated with it, *'so, the first step of the journey; have you got the keys?'* (Mother (participant 9), line 95). Whilst eleven parents/carers associated the start with the use of specific equipment, commonly the use of trays and syringes *'then you see the trays come out'* (Mother (participant 3), lines 106-107). In contrast, two parents/carers noted the process began with nurse checking the drug chart '*I know they've got a chart in front of them,'* (Mother (participant 2), line 47).

Within the process itself, all parents/carers recognised the different stages within the process of preparation, calculation and administration:

> *'so what they seem to do is they start off, they get their little trays out and give them a nice wipe down with erm I guess antibacterial wipes or whatever, they get the drugs out, if they're controlled drugs I think they go and get them from, and they're always after the keys to go and get them out of a cupboard and they get them, em they draw them up, they check to whether or not what the method of administration is so if they're going down the NJ or the NG tube or they're going to be as a bolus or then they, well sometimes if they're going into the line they'll do like a flush'.* (Mother (participant 1), lines 88-95)

In addition, two parents/carers noticed the phase of calculation due to the actions, body language and use of specific equipment. In addition to this observation, they realised it was a vitally important stage within the process:

> *'they will always kind of calculate, they get their phones out they calculate quite a lot just to check the dose'* (Mother (participant 1), lines 95-96).

Whilst all parents/carers acknowledged that the medication process began with specific actions, seven parents/carers also noted that the procedure had a verbal process that accompanied the visual cues. This conversation between nurses was primarily associated with the verbal double-checking procedure:

> *'and you see them prepping it all and then they bring it all over, and they'll see each one go through and it'll be oh this is this and this is that so I mean I don't stand there watching them but you can see that they're getting ready,'* (Mother (participant 3), lines 107-110).

The detailed awareness that parents/carers had of the medication process appeared to help them understand the importance of allowing nurses to focus on the medication process. Four parents/carers described a transference of their own personal feelings and experiences as they envisaged that they would not want to be interrupted when concentrating and their actions were influenced by this understanding:

> *'I just don't interrupt cause I just think that if it was me I wouldn't want to be interrupted so I erm just the fact that they're doing that at that time would stop me from interrupting them,'* (Mother (participant 1), lines 294-296).

Two parents/carers were aware that nurses need to have time to focus on medication calculations without interruptions. These parents/carers appeared to have an awareness that the medication calculation phase could be complex:

> *'if they look like they are concentrating, well obviously they are concentrating all the time, but you know if they look like they are working something out now'* (Father (participant 12), lines 153-155).

Furthermore, two parents/carers were acutely aware of the nursing workload, this also encouraged them to sit back and keep out of the way:

> *cause I know they've got lots to do in their set amount of time and I just usually, quite often sit and watch them do it and make sure I stay out of their way, it's all you can do.'* (Mother (participant 3), lines 142-145).

The section has explored the data that illuminated the impact of parent/carer observation. The close attention parents/carers paid to the process enabled them to recognise the visual cues that identified medication administration. However, no parents/carers reported that they were informed by a professional not to interrupt. Ultimately, parents/carers chose to minimise actions and communications that they felt may distract the nurse from medication administration.

6.3.2 Medication is part of the plan

Four parents/carers reported that the medication process was perceived to be integral to the delivery of the plan of care that was devised for each child. It was closely monitored by parents/carers as they sat by the bedside and watched as their child received the care that they required to treat their illness:

> ‘*they have like a plan in front of them every day they have the sheet and then when they come in in a morning then they have a plan so on there they always know what times their medicines are due’* (Father (participant 16), lines 159-162).

In addition, fourteen parents/carers noted that plans were generated by the medical team on ward round. These parents/carers often reported the importance of being present at ward round as it ensured they were kept more abreast of the plan of care for the upcoming day:

> *‘if I have been there for ward round erm I feel like you get quite a good kind of summary of what the plan is for the day is anyway’* (Mother (participant 1), lines174-176).

Furthermore, parents/carers perceived that nursing care was developed from a medical prescription. The following quote indicates how parents perceive their child’s care was planned medically but delivered by the nurse:

> *‘obviously the doctors come and they tell her what’s the plan for the next hours, or 10 hours or 8 hours, like the doctors come in night-time and then they tell her what’s the plan for the whole night and then they come in the morning and they tell them the plan for the evening and the evening one tells her the plan for the night’* (Father (participant 13) lines 311-315).

Although, half of the parents/carers within the sample did recognise the skill and knowledge of the nurses involved. One father recognised the role nurses had in the safe delivery of the medication:

> *but that’s in their knowledge how much medicine to give and how to give and when to give’* (Father (participant 12), lines 315-316).

In summary, it was evident that parents/carers clearly identified the important role medication administration played in the intensive care environment. They also recognised the involvement the medical team had in determining the medication plan for their child. Nevertheless, parents/carers acknowledged that nurses had a unique skill and knowledge in ensuring that the plan is implemented correctly and safely.

6.3.3 Expecting parents to understand interventions

Parents/carers described a lack of information about any intervention to reduce interruptions to the medication process. No one recalled receiving any verbal or written information about any intervention. Although, ten parents/carers described occasions when they observed nurses wearing red aprons or tabards during medication administration. In addition, two of the parents/carers had exposure in other units

outside of PICU and used this knowledge to inform their decision making within the intensive care unit:

> *'like it was red there so when I came here I knew that was what it was for and then you see them wearing it when they are doing the medicines so you just know but I don't know if I would have picked it up as quickly but I probably would have at some point'* (Mother (participant 15), lines 264-267).

Nevertheless, most parents/carers did note positive benefits to wearing red aprons. The red aprons and tabards were described as a visual cue to inform parents that the medication process was commencing:

> *'it's something you notice whenever anyone's at the medicine cabinet it was always a red apron they'd got on'* (Mother (participant 16), lines 263-264).

Although, parents/carers also described other visual cues that were equally effective at identifying the start of the process such as blue trays, syringes, needles, prescription charts and Personal Protective Equipment (PPE):

> *'they have a chart in front of them it's all written down erm they have to put gloves on, aprons on they draw it up using a syringe and a very sharp needle and it comes out of a bottle,'* (Mother (participant 2), lines 48-50)

Nevertheless, when red aprons or tabards were in use, they were perceived to be more effective if a printed message of 'do not interrupt' was visible to parents:

> *'I saw what they were wearing, and it says on there; administrating medicines please do not disturb so it doesn't get more clearer than that'* (Mother (participant 14), lines 307-308).

Aprons and tabards were not always seen to be beneficial by parents as they acknowledged negative aspects of their implementation. One mother described the impact that they had on parental feelings of involvement:

> *'But I think they're also, they're a bit of a sort of erm deterrent so as parent if you want to be involved in your child's care and you want to understand what's being administered and why erm you felt like when they had them those tabards on you couldn't really speak to them and often they would go round and do a lot of the babies so they could be quite a long time in giving the drugs so if there's something that you wanted to ask your nurse during that time you didn't feel like you could'* (Mother (participant 1. Lines 132-138).

Aprons and tabards add to the visibility, but as previously identified they are not the only visible cue described by parents/carers. In addition to these visual cues, the repeated use of a routine was recognised by parents/carers as being associated with

medication administration that also ensured that it was easily identified; *'the nurses erm tend to have quite a set routine in terms of administering the drugs'* (Mother (participant 1), lines 84-85).

6.3.4 Stepping away from my child

Two parents/carers discussed within their interview together the importance of understanding body language and the atmosphere at the bedside. They would choose not to interrupt if the body language of staff appeared to be frantic as this would indicate that the preparation of that medication was essential for the safety of their child; '*it just feels a bit more frantic doesn't it I suppose? A bit more urgent'* (Mother (participant 11), line 152). Similarly, if increased numbers of healthcare professionals were present, they would stand back and not interrupt until the situation appeared to settle, they described it as:

> *'and then actually probably if there is more than one nurse appears (laughs) if like if her friends appear then it's like step away from the baby'* (Father (participant 12), lines 147-149).

It was evident that these parents/carers were tuned into the atmosphere within their child's bed space and reacted to this as an audience may at the theatre. The data within this theme identified parents/carers can be viewed as an audience at the edge of the stage, with nurses seen as actors and Medical Consultants as directors. They identified that within their role, nurses often had an individual method of delivering medication, which is similar to an actor's interpretation of the part they are playing. In both cases the individual interpretation stimulates feelings and reactions in the audience. The nursing role of medication process within the intensive care environment can lead to feelings of safety and reassurance, but these are easily lost if behaviour is not consistent and professional. The Medical Consultant's part as director indicated the intermittent nature of their role. Just as the director is not present on stage during the play, the medical team were never identified as taking part in the physical process of medication administration. However, the director should be recognised as important as the inclusion of parents/carers within the planning of medication can empower parents to be more involved within the process.

The overall theme of 'Watch and wait' unpicks the parent/carer experience of being present at the bedside of their child. The prolonged periods spent at their child's side provides opportunities for them to observe actions, behaviours, processes and

interactions. These observations contribute to the development of their knowledge and can inform their reactions.

6.4 Theme Three 'I am part of the team'

The discussion in the previous theme identified that parents/carers described times during their time on PICU where they were a passive outsider observing the delivery of care to their child. In addition to the periods of passivity, parents/carers also described situations where they were active members of the team. This began with a detailed process of sharing information about medication within PICU:

> *'so they've always told us what medications are going on erm and if we have questions about it, they'll answer that erm the adrenaline obviously we didn't know what that was so they explained what it did and what it's about er the other two were given before'* (Father (participant 5, lines 60-63).

All parents/carers identified that information sharing was important within the critical care environment:

> '*And for somebody like me who is quite detail orientated and finds it important to be informed of what's happening that suited me a lot better'* (Mother (participant 1, lines 345-346).

All the parents/carers interviewed acknowledged the importance of being informed, without this they were unable to take an active part within the team. Information sharing created knowledge which was viewed by one father to as power. Being informed was an important power as it allowed him to have the knowledge to understand and remain calm:

> *'yeah it keeps you a bit calm and not you know very sensible isn't it? Information is power erm yeah when they share the information then you understand more, it's not as a stressful a situation as if you're just sat there and no one's talking to you and erm* (Father (participant 12, lines 353-356).

Although, the level of understanding of this information was reported to be affected by both language barriers and the use of technology.

6.4.1 Help me to understand

Parents/carers described a fundamental need to understand what was happening with their child and the treatment they were receiving. The data analysis highlighted that the rate of interruptions would be likely to increase, if parents did not receive information in a format and language that they understood; *'so it might be erm so if*

they haven't said specifically, we're just giving a dose of …. I'd be like ah is that the…,' (Mother (participant 1), lines 161-162). In addition, if this knowledge is not updated on a regular basis, interruptions would also increase:

> *'what the drugs are for, what the side effects are, cause most drugs have always, they've always got side effects that they then need another drug for and then that drug's probably got a side effect which you need another drug for so it's just a vicious circle isn't it, I don't want to use the word vicious circle but it's a circle of trying to combat the illness and the side effects of the drugs so I just ask questions like that how many doses, how long's he on it for, what does it do?'* (Mother (participant 2, lines 64-69).

These situations resulted in a need for parents/carers to raise questions and this commonly occurred at the time of administration as this is when they realised that they were not aware of changes in the medication plan for their child.

Furthermore, parents identified factors that affected parent/carer understanding of medication information. One factor was the language used, particularly by medical staff. Three parents/carers described how they found the generic names of medicines difficult to understand and remember. They preferred healthcare professionals to describe medicines by their classification such as sedation or muscle relaxant:

> *'it's what throws me off is like when the doctors explain it at a perfect level but as soon as they mention the long names of the medicines that's what throws me off but at the same time I know they've got to mention the long names and I've asked the doctor's when they talk about medicines just to like call them sedatives to me rather than actually calling them the medical, the medication name cause it's that what throws me off. It's when they use big words, when they're using medicines and trying to explain the medicines to you, they have to use big words'* (Father (participant 6), lines 138-145).

Conversely, nine parents/carers wanted to know the correct names for medication so that they could search for further information at their own pace:

> *'it would be useful I suppose to have like a little leaflet so basically I suppose you've got your typical ICU drugs, haven't you? and the drugs to be intubated with the midazolam, morphine, furosemide that's probably a typical ICU drug em I don't know any more, but the ones I'm familiar with you know what I mean it might be useful to have leaflets about them, you could just a little black and white leaflet you could give that to a parent and say or roc you know this is what this does, this is what this does, this is the reason we're giving it your child'* (Mother (participant 2), lines 267-273).

This was actioned by one mother who listed her child's medication on a day-to-day basis within her own diary, as this helped her to measure their progress within PICU:

> *'cause you can't remember all the medicines and sometimes it helps to know that some of the medicines have been knocked off like you know that he's not on everything even the wires and the medicine, it's a lot so you don't know unless you actually have it written down now he's on 3 less things than he was maybe a week ago so it does help me like that,* (Mother (participant 15, lines 75-79).

In addition, another factor that affects parents/carer's ability to understand medication information was their position in the child's pathway. On admission parents were less likely to pay attention or seek information about medication as they were in a state of shock:

> *'I think we do but again we kind of, how I understand things and how I learn and how I've dealt with our time in here is by just understanding everything so I'm, I would ask after the first couple of weeks once our heads were round what was going on, we would then ask'* (Mother (participant 18), lines 347-350).

All parents/carers were able to direct the level of information they received as they often described their search using questioning. It was extremely important to them that their knowledge was current and thorough within the limits they set. It was evident that some parents/carers wished to know a lot of detail both about medications and the process of administration:

> *'I know about the needles cause I ask a lot of like I said I ask a lot of questions, why are you using it so I know about the needles and I know about the different syringes, oral syringes and IV syringes they have to clean when they're giving IV they have to use you know the sterile wipes to wipe it down before they give it em what else do they use? That's it I think, they're the stuff that they use on *******'* (Mother (participant 14), lines 199-204).

Whereas other parents/carers were happy to keep their understanding at a basic level of information. It appeared that this level of understanding was affected by the length of time parents had been present within the environment. Parent/carer questioning increased the longer they were present on the PICU as they became aware of routines and were able to identify when they were not followed:

> *'I ask a lot of questions em, because we've been here a year, I need to know what goes on with my daughter's care,'* (Mother (participant 14), lines 79-80).

This analysis illuminated that the act of sharing information about medicines was important to parents/carers. The effectiveness of this information was dependent on the parental ability to understand it, this can be affected by factors such as language ability, thirst for knowledge and emotional status.

The parents/carers interviewed were divided as to whether information should be shared verbally or in written format. Seven parents/carers did not perceive that written information would be beneficial and one mother was adamant that it should not be displayed in poster format, as it should be a resource that parents can chose to read at a convenient time for them; '*Like having a display board with this is what Tazocin does and this is how it's given and I think that may be too much and quite overwhelming'* (Mother (participant 18), lines 366-368). Furthermore, too much information was perceived by some parents/cares to have a detrimental effect on understanding:

'but if they go into too much detail then I obviously I don't know but if they do talk about a few things then I do understand' (Mother (participant 13), lines 397-398).

The data from these eight parents/carers has illuminated that they require accessible and current information about their child's medication. Parents/carers noted that providing the correct level for everyone was difficult. Therefore, some parents/carers highlighted their use of the internet to supplement their knowledge of medications.

6.4.2 The use of Google

Seven parents/carers expressed concern about the depth of written information if it was provided. They felt that too many in-depth descriptions of medications and their side effects may stop parents/carers from reading it:

> *'and erm I think for some people it would probably be quite overwhelming I think erm the explanations as the drug's being given and why it's being given is enough because I think if you if you're really interested in what something does you can always go away and google it can't you? get a bit more detail that way'* (Mother (participant 1), lines193-195).

The seven parents/carers who expressed concern about the depth of information were very clear that any written information should only include the name and a reason for administration. The reason those parents/carers wanted that level of information was that it would allow them to search effectively on a web browser for more information if it was required:

> *'I like to Google, I know what she's taking, why she's taking it and the benefits of it so sometimes I'm can you just repeat that again so I know what it is, cause some of the, you can't even say them let alone spell them so I think sometimes*

> *it'd be nice to maybe have a list of right this is what your child is on'* (Mother (participant 4), lines 174-177).

However, the use of web browsers would be required if parents/carers felt they had not received enough information from the health care professionals looking after them:

> *'you just want to know like what is the effects of it long term you know but you don't get to know that unless go through Google'* (Mother (participant 15), lines 125-126).

The use of Google by parents/carers was not informed by medical professionals. One mother reported accessing the first website she located for information about her child's medication:

> *'just whatever that's why it's not good is it? Cause that's why we're better off with for parents to be provided with more em like reliable resources cause you just go on whatever comes up I don't really cause I don't know which ones are good and which ones are bad, there are too many possible I don't know so I just whatever comes up and looks like it's, seems like a legit website'* (Mother, participant 15, lines 134-138).

Parents/carers acknowledged that the availability of the internet allowed them to search for more detail about medications. This was especially important if they felt that professionals were not delivering the level of information required. However, professionals appeared to lack awareness of the type websites parents were accessing, therefore the reliability of information could be questioned. Nevertheless, having access to this information contributes to parents/carers feeling informed about their child's medication.

6.4.3 Informed but not always involved

All parents/carers described a sharing of information process that included an active element of questioning. Being able to ask questions was important to allow them to set the amount of detail at an appropriate level. It was highlighted that the nursing role was important as it allowed them to have questions answered whenever they arose:

> '*but because the nurses are constantly there then you can ask them later on and still get the answer'* (Mother (participant 16), lines 107-108).

Furthermore, if the information was shared in a way that included the parent/carer in a discussion about medication, they felt like they were included within the team:

> *'it makes me feel part of the team that I'm not just in the way sometimes cause you know they're very busy and flitting round the bed, makes you feel like you*

are part of the team that's helping him get better' (Mother (participant 3), lines 86-88).

This inclusivity as part of the intensive care team was beneficial as it was described by one mother as making them feel happy:

> *'I think it makes me feel you know nice and you know happy, not happy but you know you feel like you're being included rather than sort of sitting there and going what are they doing now, what's that you know,'* (Mother (participant 3), lines 92-95).

No parents/carers identified any proactive information sharing about the process of medication administration and when parents should or should not interrupt it. One mother identified that they were given a tour of the unit but not informed about the procedures that were completed at the bedside and important to the delivery of care to their child:

> *'it is like you give an introduction when you get given like a little tour where the toilet is, where the parent's lounge is but the most important thing is what's going on around your baby so to be given that kind of tour I think it will help about the different things that are happening and what the different things mean and do as well all the machines er that'll be helpful as well'* (Mother (participant 15), lines 337-341).

Furthermore, the involvement of parents can also be affected by the culture of the unit in which they are admitted. This is described by one mother when she refers to the enforcement of rules:

> *'and it just seemed a bit more stricter over at the **** in lots of other respects as well……. but I think that kind of follows right through to right into the kind of you know administration the medication and the opportunities that you have to ask questions about it. I feel like it's much more of a er its not a partnership cause I'm not involved in deciding what drugs **** gets but it's more of a sort of yeah you've got a different relationship I think over at **** than you would have with the staff at the ****. That's not a crit, that sounds really like a criticism of them em they did a brilliant job em but it is different, definitely there two different locations.'* (Mother (participant 1), lines 356 and 371-377).

This enforcement of rules was also described by another mother in relation to interruptions and their management. She felt senior nurses should challenge and enforce the use of interventions to reduce interruptions:

> '*but I think it can be re-enforced and I've always said it's the management level that if the band 7's and band 6's turn round and say you're doing medications, so if the bed space is here just say here, just sit there and do your medications and don't talk to anybody'* (Mother (participant 14), lines 287-290).

Furthermore, these cultural contexts can influence how parents/carers feel about asking questions about the medication being administered and the process involved. Two parents/carers reported that active discussions allowed them to question medication plans:

> *'I have on occasions challenged the cardiologist when they've wanted to change his doses and things I've always said are you absolutely sure this is the right thing to do what's the alternatives you know, I think I'm quite comfortable in having that conversation'* (Mother (participant 9), lines 80-83).

In contrast, another mother described a situation where there was limited involvement of parents/carers in the medication process; *'but if I'm totally honest most of them just tend to get on with it and do it without you'* (Mother (participant 10), lines 78-79).

Although parents/carers were able to describe the benefits of being actively involved within the team, others, acknowledged the variability of being included. The inclusion of parents/carers was sometimes linked to the culture of the unit in allowing parents to participate in discussions.

6.4.4 How much information is enough?

All parents/carers were able to demonstrate that they had been informed about their child's medication. This was evidenced by all parents/carers being able to describe the main medicines their child had received:

> *'she's had all sorts of medicines erm she's had erm obviously erm all manner of sedation, so she's had erm obviously fent, is it fentanyl? And erm rocuronium and to kind of keep her sedated and still from that point of view. She's had erm various diuretics to try and get her to urinate, so she's had furosemide, given a couple of other ones I think,'* (Mother (participant 1), lines 51-55).

The common theme within the information shared between health care professionals and parents was the type of the drug and the rationale for its use:

> *'I know they're giving for something we know they are giving for kidneys, giving for lungs, steroid for lungs and to keep his blood pressure normal and to keep his heart going.* (Father (participant 12), lines 270-272)

The medication administration process described by parents/carers, was one where healthcare professionals had very defined roles. Parents/carers described how information was shared by medical staff within the ward round. Primarily these discussions informed them about medication management plans. In contrast, nursing staff predominantly informed parents/carers of their actions at the time of

administration. Within this conversation they would share the name of the drug and the rationale for its use:

> *'erm we're, so there's lots of different times er at the doctors round when we're allowed in for erm the doctors round erm some of the time they'll talk through, you can, er they'll go through them with you erm some of the time you're involved in the conversation, sometimes they just go through it quickly erm when the pharmacist comes over to check what they are on erm, the nurse would if anything major's changing they tend to say erm especially when things are coming off or if any antibiotics are, that kind of thing are starting and then when they are put on and given they tend to let us know, most, I would say 99% of the time they kind of say this is what this is for erm'* (Mother (participant 18), lines 336-344).

In contrast to Chapter 5, where healthcare professionals identified that pharmacists were an important part of the multidisciplinary team, parents/carers rarely reported contact with them. Only two parents/carers described contact with the pharmacist based within their critical care unit. Those that did describe the pharmacist's role commented on their checking of prescriptions and medication interactions rather than sharing information with them.

Twelve parents/carers described an active process of choosing when to interrupt. These may have included a consideration of urgency or an assessment of their child's clinical condition. They were able to describe situations where they felt that even though they could see the nurse was involved in medication administration they would interrupt:

> *'only if there was an emergency with ****, she stopped breathing, if it, I mean we're quite knowledgeable with the machines now, so we know what's dangerous if there's an emergency, if buzzers went off, but heart rate was still fine and oxygen was still fine we wouldn't need to interrupt'* (Mother (participant 4), lines 212-217).

Parents/carers described the impact of their knowledge on their actions when questioning and challenging practice. They highlighted that they felt more inclined to challenge the administration process if it related to a medication or piece of equipment, they felt they were an expert with:

> *'I mean I don't mind so much if it's something that on the drugs that I know about like so I have challenged obviously when it's been the nozinan I've just reminded them you've still got some you know look at the syringe it's still full of the tablet, it doesn't dissolve properly you know and I've said that or if it's you know something that I know about cause we give it on a daily basis at home'* (Mother (participant 10), lines 163-168).

Parents/carers who had children with long term healthcare needs also described understanding the impact of medications on their child and questioning decision-making about their administration:

> *'I think my questions have always been, if I've questioned medication it's always been for a clinical reason not for I think the prescriptions wrong or I think that you know, it's been either stopping something being given cause I don't think ****'s well enough for it or it's not the right drug for him or making sure that the route's right'* (Mother (participant 9), lines 209-213).

In addition, if parents have experienced errors or mismanagement of dosing of medication this will stimulate a challenge as they strive to protect their child, as previously highlighted. However, challenging practice was not described as being easy, one mother described how uncomfortable it was to challenge a nurse to prevent the incorrect administration of a medication:

> *'ooo it wasn't comfortable because I could see what she was doing before she did it and then I just had to stop because I don't think she'd realised that there was, that it was it was that not thought it through or not read the prescription properly or it was just you know I've got to get this medication in here so here's the feeding tube let's get it in without going through that being absolutely sure which port you're going through'* (Mother (participant 9), lines 127-132).

Three parents/carer commented that their expression of having an interest in their child's medication plan was '*being nosy'* (participants 10, 15 and 18). This created a discomfort and could result in parents/carer refraining from either asking questions or looking at prescription charts:

> *'I haven't looked at her chart em to be honest with you like I did probably on the ward just cause there's been so much going on I haven't been quite as nosy as I would be normally (laughs)'* (Mother (participant 10), lines 62-65).

These reported feelings and actions demonstrated that in some situations, parents felt discomfort when needing to challenge an element of practice. They may tactfully support their question with a clinical reason, but if they perceive their child to be in immediate danger, they will stop the process.

6.4.5 Standardised versus bespoke

As previously noted, all parents/carers described a verbal sharing of information by both medical and nursing staff. None of the 19 parents/carers had received any written information about the medicines their child had received. One mother expressed particular surprise at the lack of written documentation; *'I'm surprised, I'm surprised by*

the lack of written information there is for parents' (Mother (participant 9), line 311). Furthermore, the lack of provision of standardised information was noted by parents/carers. One discussed the difference between their child receiving medication in the community and within PICU:

> *'cause when you have children outside of the hospital any medicine you have you give them you can read a little thing in there and you know the side effects*.' (Mother (participant 15), lines 121-123).

In addition, one mother noted that she had received information about the physical attributes of the unit but no information about therapies happening to her child such as the types of medication, or the process involved:

> *'so I think it is like you give an introduction when you get given like a little tour where the toilet is, where the parent's lounge is but the most important thing is what's going on around your baby so to be given that kind of tour I think it will help about the different things that are happening and what the different things mean and do as well all the machines er that'll be helpful as well'* (Mother (participant 15), lines 327-341).

Five parents suggested that there may be positive benefits if written information was provided, as it would allow parents to digest information and difficult names at their own pace:

> *'yeah probably you could have a look back at it and erm have a read of it in your own time rather than just be told, cause as soon as they walk away you think I've yeah I really forgotten now* (Father (participant 6), lines 147-149*)*.

In contrast, three parents/carers did note that it would be difficult to maintain individualised, up to date information for each child due to the fast-changing pace of medication administration within PICU:

> *'things change quite quickly don't they? And I think keeping on top of giving a written summary would actually be quite unrealistic actually erm* (Mother (participant 9), lines 190-191).

All parents/carers described a thirst for knowledge about the medications their child was receiving, but they were also aware of the complexity and fast changing nature of the information. It was evident from the data that none of the units had found a comprehensive way of managing this issue. Nevertheless, without it, parents/carers acknowledged that interruptions were likely to continue as they carried on the role of protector in ensuring their child was safe.

In conclusion, this overall theme of 'I am part of the team' identified a role for parents/carers within the team. This role was important to them as it helped them to ensure their child remained safe whilst in PICU. In order to enable parents/carers to take on this role communication was paramount in ensuring their knowledge was kept up to date.

6.5 Parental contexts, mechanisms and outcomes

The previous three sections (6.2, 6.3 and 6.4) have presented a thematic analysis of the data gathered from parents/carers whose child was an inpatient in PICU. The inductive thematic analysis allowed the parent/carer voice to be presented without being forced into a framework. However, this inductive process did not explore the parent/carer perceptions and experiences of how and when interventions to reduce interruptions to the medication administration process were effective. Therefore, an explanatory realist lens was applied to assist in achieving this aim. The questions outlined in sections 3.8.9 were used within the realist analysis to explore how parent/carer behaviours and actions were influenced in the intensive care setting, particularly in relation to interruptions. This was achieved by identifying any situations or contexts within the PICU that triggered any hidden reactions or behaviours in the parents/carers. This additional layer of analysis uncovers the key contexts, mechanisms and outcomes (see Table 34) associated with the medication administration process within PICU and the use of interventions to reduce interruptions to it.

Table 34 - Parent/carer context, mechanisms and outcomes

Contexts	Mechanisms	Outcomes
• Child and family history • Understanding the medication and the process of administration • Understanding nursing actions or not	• Protecting my child • Reactions to nursing behaviour • My child is in intensive care!	• Knowing when to interrupt • Parental inclusivity • Receiving support

The information displayed in Table 34 identifies the contexts, mechanisms and outcomes that were illuminated in the realist analysis of the parent/carer data. The following sections will critically explore and discuss the contexts, mechanisms and outcomes identified within the parent/carer data.

6.5.1 Context 1 - Child and family history

The data included within section 6.2.1 outlined the journey experienced by the child and their family into PICU was unique to those individuals. There were two broad groups of admission type: planned events (n=7) and an unexpected deterioration resulting in the need for intensive care (n=12). A result of the unexpected deterioration was the removal of any opportunity for prior preparation or explanation, unless they had prior experience of admission to a PICU. Four parents/carers experienced their child's deterioration at home before admission that resulted in prolonged periods with little or no sleep and increased levels of stress. As a result, these pathways were noted to influence behaviour on admission, a lack of sleep resulted in parents possibly taking time away from the bedside to try to catch up on their sleep. However, it is possible that they would then miss information shared during the admission process.

Furthermore, five parents/carers described a pathway that included stays on other intensive care areas before admission into PICU (section 6.2.3). The result of these prior admissions was identified by two parents/carers as influencing their behaviour in relation to interruptions as they had been exposed to the use of interventions to manage interruptions such as the use of tabards with 'do not interrupt' written on them. This knowledge was then transferred into the new setting and applied to their behaviour.

Severity of illness was also an influencing contextual factor, as increased acuity was often associated with increased numbers of medication. Furthermore, parents/carers of children with higher levels of acuity described increased levels of workload for the nurses looking after their child (section 6.3.2). This workload included large volumes of medication administration, this then reduced parental access to safe times when they could ask questions about their child's care.

The increasing population of children being cared for at home with complex healthcare needs has risen in recent years (O'Brien et al., 2017). This has contributed to increased numbers of parents being admitted to PICU with prior experience of being

cared for in intensive care and or administering medication at home (section 6.2.3). Prior experience of being admitted to PICU allowed parents/carers to build up knowledge about routine medications used for sedation and analgesia. This prior knowledge about commonly used medication was identified as important to parents/carers as they already understood the rationale for their use and how they were administered. Furthermore, this knowledge enabled them to identify any differences in administration processes and stimulated them to question why.

Parents/carers of critically ill children with complex healthcare needs included within the study described their experiences of administering medication at home (section 6.2.4). This prior experience raised parent/carer awareness of several issues: organisation, safety, making mistakes and managing interruptions. In addition, they described strategies that they had developed to ensure their child received their medications safely. This discussion with parents about their experiences illuminated that this group of parents were experts in the administration of these medications. As a result, they felt that they were able to challenge nurses about their actions or aspects of knowledge, therefore making interruptions more likely to occur.

6.5.2 Context 2 - Understanding the medication process

The parents/carers included within this study were able to describe the medication process in detail (section 6.3.1). Their observation of nursing action and behaviour had enabled them to identify the routine of the medication process (section 6.3.4). Their knowledge of the routine enabled them to know when the process was beginning regardless of whether an intervention such as the wearing of a red apron or tabard was in place. Furthermore, they were also able to describe the different elements of the process such as calculation, preparation and administration (section 6.3.1) and the requirement for a two-person check (section 6.2.5).

In addition to their awareness of the physical routine, parents/carers also understood that discussions about medication were an important part of the ward round (section 6.3.3). They were aware that this was when changes to the medication plan were made and that if they missed this process, they often were not aware of the changes that had been made. The result of this lack of knowledge was increased questions to the nursing staff when they realised that doses or medications were different.

All parents/carers, including those with prior experience wanted to understand and develop their knowledge about medicines their child was receiving. In addition, it was important to parents/carers that information about the medicines was shared at a level that was appropriate for them to understand and that this knowledge was kept current and up to date.

It was evident in section (6.2.1) that each parent/carer required information to be shared in a way that they could understand. Some expressed a preference for written information, whilst others were content with verbal. It was evident that this knowledge increased during their stay on PICU either using questions, writing a diary or access to the internet.

6.5.3 Context 3 - Understanding nursing actions or not

The parents/carers included within this study described spending a large amount of time observing their child in PICU and the actions of staff surrounding their child (section 6.2.5). They were aware that nurses needed to be at the bedside so that their child could be continually observed, and their safety maintained (section 6.2.6). In addition, they also described detailed observation of routines within the medication process, such as the two-nurse check of medicines (section 6.3.1). The combination of these two elements; observation and routine were identified by parents on occasion to cause them to interrupt. Medication administration was an integral part of their observations.

Performing medication administration at the beside enabled parents/carers to watch the repetitive routines that were included within the process. The prolonged periods of waiting ensured parents/carers observed the actions of nurses administering medication in detail. If the actions or behaviours of nurses are different within this process parents/carers identified that they were more likely to interrupt to ask why. Furthermore, the detailed observation of the medication process enabled them to identify occasions when the checking process appeared quicker and less rigorous, resulting in them feeling apprehensive.

6.5.4 Mechanism 1 - Protecting my child

An important reaction described by parents/carers was wanting to feel safe within the intensive care environment (section 6.2.4). The continual presence of a nurse at the

bedside helped parents/carers to feel safe (section 6.2.6), although, there were occasions when they still felt a need to challenge or interrupt to protect their child (section 6.2.2). Parents/carers of children with complex healthcare needs had an extensive knowledge of their daily medication regimes and their possible reaction to certain medicines. This knowledge enabled them to feel confident to question and challenge the healthcare professionals if they felt it may not be safe for their child to receive a medication. These feelings and actions were stronger if the child and their family had been involved in a medication error previously (section 6.4.4).

Parents/carers indicated in section 6.2.2 that needing to protect their child was an important reaction. This mechanism was activated if parents felt that their child was at risk, as their primary reaction was to ensure their safety (section 6.2.4). This reaction may have been stimulated by a change in their child's condition such as a sudden deterioration or a change in medication that they have not been previously made aware of. Therefore, keeping parents/carers informed and up to date about changes in treatment plans was important in helping to reduce interruptions. Often the reaction caused by this need to protect resulted in an interruption to the nurse to ensure that their child remained safe. The need to interrupt would be a priority over medication administration even though they were aware of the importance of the medicine for their child. The only time that this interruption could be prevented was if the wider nursing team was available to respond to the parental concern and ensure their child remained safe (section 6.2.6).

6.5.5 Mechanism 2 - Reactions to nursing behaviour

Parents/carers frequently described feeling reassured and safe by certain nursing actions or behaviours. The continual presence of the nurse at the bedside (section 6.2.6) offered support to parents as they felt that the nurses were continually available to answer their questions. Being able to observe the two-nurse check of medications reassured parents that the process was robust and rigorous (section 6.2.5). The result of this was that parents felt that their child was safe, and their own needs of reassurance were met, and they were less likely to need to interrupt.

In contrast, parents/carers also identified contexts where they did not feel safe and reassured. They felt vulnerable if their nurse was absent and the team observing their child were not easily accessible (section 6.2.6). Parents/carers lost trust (section 6.2.2)

in the team if they felt that healthcare professionals were not honest with them. Finally, if nursing actions and behaviours within the medication process indicated that the process was not taken seriously, parents/carers felt worried (section 6.2.5). On these occasions' they were increasingly likely to interrupt nurses to seek assurance and feel safe.

Parents/carers described reacting to the body language they observed in the clinical area. If they thought that a nurse was focused and concentrating, they would empathise by thinking that they would not like to be interrupted (section 6.3.2). Equally if the atmosphere was busy and the nurse appeared to have a large workload, the parent/carer was likely to keep out of the way (section 6.3.2). They also had an awareness of 'human error', that mistakes may happen, but the presence of a robust checking procedure reduced parental worry about mistakes (section 6.2.4).

6.5.6 Mechanism 3 - My child is in intensive care!

Parents/carers acknowledged that there were times, particularly during the admission phase where they felt scared and shocked (section 6.4.1). Parents/carers found it daunting to be admitted to PICU, to be in a situation where lifesaving treatments may be required (section 6.2.1). Often this admission process was preceded by periods of stress and worry as their child was prepared for surgery or had had a prolonged period of illness. Although, parents/carers still described feeling this shock even when they had been prepared for elective surgery due to the increased numbers of staff and equipment required to look after their child. The continual presence of the nurse during this period was especially important to help support them and reduce their fears (section 6.2.6).

These mechanisms of shock and feeling scared were described by parents/carers to have an impact on their ability to comprehend information (section 6.4.1). This inability to comprehend resulted in professionals needing to repeat information. In addition, parents/carers had increased numbers of questions as they found it difficult to remember the information they had been given. It was important to them that information was shared with them at a level they could understand (section 6.4.1). However, the longer the parent/carer stays in PICU the more expert they become about their child's condition and the medications they require

6.5.7 Outcome 1 - Knowing when to interrupt

Parent/carer understanding of routines and processes within PICU were important in enabling them to try to know when the best time to interrupt was. They were empathetic to body language and the atmosphere within their bed space (sections 6.3.1 and 6.3.5). They would try not to interrupt during those times, unless they felt their child's safety was at risk.

In three of the four PICU's included within this study, interventions such as red aprons or tabards and no interruption zones had been implemented, yet no information had been shared within parents/carers about this. Furthermore, no parent/carer recalled being asked not to interrupt the medication process (section 6.3.1). Instead, parent/carer knowledge appeared to be primarily developed from observing the processes and asking questions (section 6.3.4). Parents/carers would then apply their own logic and try to avoid interrupting when they could see nurses were busy. Although, there were urgent situations such as an acute desaturation or seizure activity when they would interrupt regardless of the situation (section 6.4.4).

Additional elements that helped parents interrupt less were the use of aprons with 'Do not interrupt' written on and a supportive teamworking environment. The writing on the apron made its use explicit and required less additional information, compared with a plain red apron with no writing (section 6.3.4). Consideration would be needed to translate information for any parents where English was not their first language. The use of teamwork was important to them to support the use of a no interruption zone. This was used in PICU's C and D, in these units' parents/carers felt well supported by the wider team and would approach them if they needed help at any point (section 6.2.6).

6.5.8 Outcome 2 - Parental inclusivity

The thematic analysis presented in section 6.4 indicated that parents/carers wanted to be included within the team caring for their child. Often, they are experts in administering their child's normal medication and this responsibility can be removed when admitted into PICU. Information about their child's medication was important to parents/carers, being included within the discussions allowed them to be part of the team and not to feel in the way (section 6.4.3). Furthermore, if parents/carers are

included within discussions about medication, their knowledge continues to be current, and they are less likely to interrupt to ask why something has changed.

Communication about medications was identified by parents/carers as being important and delivered by both medical and nursing professionals. Within the communication process it was important to allow parents/carers time to ask questions (sections 6.4.1 and 6.4.3) as it ensures that information is shared with them in the correct level of detail at a time when they feel they can understand and absorb it. This communication was important as parents/carers need to be informed to feel confident enough to question medication plans. In addition, if time for communication and questions is not allocated parents/carers can feel uncomfortable asking questions as they feel like they are being nosey (section 6.4.4).

6.5.9 Outcome 3 - Receiving support

The continual presence of nurses at the bedside (section 6.2.6) ensured that parents/carers felt supported during their stay on intensive care. Parents/carers indicated that this support was vital during their admission to ensure they could locate help if a sudden deterioration occurred, answer questions when they arose and help them to feel protected. In addition, the presence of nurses at the bedside increased their confidence that it was a safe the environment. Staffing levels can also affect the support that parents/carers receive. They found that when they first shared a nurse between two patients they were scared (section 6.2.6). This was a situation where the supportive team around the family was important as they were able to offer additional support when their nurse was busy.

Parents/carers indicated that the provision of information about the medicines their child was receiving was an important support mechanism. It was evident in section 6.4.1 that a variety of methods was required to share information; verbal, written, electronic and the completion of a diary were all noted as useful sources. Parents/carers were aware that it would be difficult to individualise written information for their child due to the fast pace of change within PICU. However, reliable electronic resources would be an additional benefit to both written and verbal communication (section 6.4.5).

6.5 Conclusion

The previous two chapters presented the findings from the Realist Review and the analysis of the healthcare professional data. This chapter has added alternate view of interruptions to the medication process by presenting the empirical findings from the analysis of parental data. Following on from healthcare professional chapter, the process outlined began with an inductive analysis that was initially presented as a thematic review. This thematic analysis revealed the complexity within the process, but three themes were illuminated that explored the acknowledged the factors that parents had described as influencing their actions and behaviours when medications were administered in PICU. As with Realist Review and healthcare professional findings, the concluding part of the chapter progressed to identify and explain the important contexts, mechanisms and outcomes that were associated with the administration of medication to critically ill children. In order to comprehend this phenomenon as a whole, the findings from all three chapters will be synthesised to reveal the overall contexts and mechanisms that influence medication administration in a PICU.

Chapter 7 – Synthesis

7.1 Introduction

The aim of this chapter is to draw together three findings' chapters in a final a detailed critical synthesis chapter to present an overall understanding of the phenomenon. Whilst the chapter will initially present a summary of the context, mechanisms and outcome (CMO) synthesis in tabular form, the focus will be to discuss in detail the relationships between the contexts, mechanisms and outcomes that impact on interventions to reduce interruptions to medication administration in PICU. It is acknowledged by (Wong et al., 2013) that realist methods seek to provide explanations of how, when and for whom complex interventions work. Therefore, synthesising the findings collectively will identify the important factors and their role in influencing the intervention. The final section of the chapter will outline the CMO configurations that influence the success or failure of these interventions in practice.

7.2 Summary of the synthesis

The previous three findings' chapters have individually drawn out the contexts, mechanisms and outcomes from the different datasets. The next step taken in the analysis process was to synthesise the findings together but as the singular elements of context, mechanism and outcome. Before the collective synthesis began an example of context, mechanism and outcome (CMO) from each set of findings was discussed with a group of colleagues to verify the initial CMO analysis. These discussions also highlighted possible reasons why the CMO's could be important (see Appendix 7 for evidence of these discussions). The collective synthesis (see Table 35) explored, unpicked and critically analysed the CMO's to understand their impact and influence when interventions were used to reduce interruptions to the medication administration.

Table 35 - Synthesis of contexts, mechanisms and outcomes

	Findings 1	Findings 2	Findings 3	Overall Synthesis	Supporting chapter
Context	• Leadership and culture • Patients and family centred care • Education and engagement • Understanding interruptions	• Patient factors • Expectations and priorities • PICU environment	• Child and family history • Understanding the medication process • Understanding nursing actions or not	• Identifying the patient voice • Conflict within professional and organisational structure • Increased workload • Changes in efficiency • The vulnerable child • Task v holistic care • Uncovering role conflict • Tensions within the process • Protection of the child • Parental loss of control • Complex care at home • Expert and active parents • Professionalism and Consistency • Safety is paramount • Routine and automation	• 1,2,3 • 1,2 • 1,2,3 • 1,2 • 2,3 • 1,2,3 • 1,2,3 • 1,2,3 • 2,3 • 2,3 • 2,3 • 3 • 2,3 • 2,3

				• Contemporary children's intensive care nursing	• 1,2,3 • 2,3
	Findings 1	**Findings 2**	**Findings 3**	**Overall Synthesis**	**Supporting chapter**
Mechanism	• Isolation of task • Empowerment • Trust in the team	• Feelings • Focus v risk • Team interaction	• Protecting my child • Reactions to nursing behaviour • My child is in intensive care	• Internally generated feelings • Reactionary behaviour • Conflicting priorities • The lioness • Fear of mistakes • Accountability • Professional identity • Impact of normality/away from normality • Team intelligence • Whole body focus • Advocacy for the child • Individual confidence	• 1,2,3 • 1,2,3 • 1,2,3 • 3 • 2,3 • 2,3 • 1,2 • 2,3 • 1,2,3 • 2,3 • 2,3 • 2,3
Outcomes	• Interruption rates • Medication errors • Time and money • Satisfaction	• Rates of change • Timely and efficient care • Value	• Knowing when to interrupt • Parental inclusivity • Receiving support	• Experiential satisfaction • Creating a team • The world outside the bed space • Professional behaviour	• 1,2,3 • 1,2,3 • 2,3 • 1,2,3 • 3

	• Adherence to policy			• Parental drive for knowledge • Shortcuts to care • Active decisions • Active management • Medication identity	• 1,2,3 • 2,3 • 2,3 • 1,2,3

The information included in Table 35 includes the CMO's from each findings chapter, alongside a summary of the synthesis themes. In addition, the final column demonstrates which findings chapter supports the development of the synthesis theme.

7.2.1 Context

The context sections in each chapter collectively highlight the situations identified by participants that stimulate reactions, behaviours or actions that affect the impact of interventions to reduce interruptions to medication administration in PICU. It was important to note within the literature evaluated within the Realist Review (Chapter Four) included low numbers of studies that included the patient voice. The predominant voice within the Realist Review was nursing, resulting in a singular view within the literature of how these interventions worked. Within the survey of practice and the MDT interviews the voice widened to include the MDT, although there was no acknowledgement within the findings of patient or parent/carer engagement when choosing and designing any of the interventions.

The low volume of patient voice within the literature and lack of inclusion in the clinical setting raises a query of how patient focused clinical practice is. If the patient is to be at the center of health care, they need to have a strong voice both within the literature and the clinical setting. Within this field despite many studies their voice is not being included. Furthermore, healthcare professionals appear to be selective when focusing on the patient, resulting in decisions that may result in improved efficiency but not always meet the needs of the patient or parents/carers. Moreover, if the patient focus is not built into both the medication process and the interventions that support it, it is likely that there will always be a conflict between the delivery of the process and patient need.

Healthcare professionals appeared to acknowledge the patient when making decisions about interruptions. They often described a decision-making process based on the needs of patients, but there appeared to be a lack of focus on patient safety when choosing not to use or ignore any of the interventions put in place. Unsurprisingly, parents attributed a lot of their interruptions, questions and actions to the need to ensure their child remained safe and not at risk of a medication error or deterioration in condition. These interruptions were important to identify as they may

be difficult to anticipate in advance. Additionally, parents acknowledged that in these circumstances they would always interrupt regardless of what the nurse was doing at the time.

The safety of the child was paramount to parents and the continual presence of the nurse contributed to this. The findings from the Survey of Practice and MDT interviews identified that nursing and medical teams described patient safety as a key priority, it was the key rationale for the continual presence of the nurse at the bedside. In addition, nurses highlighted the difficulty of prioritising what they perceived as equally important patient safety tasks (for example administering medication, taking handover and checking airway equipment). This required an ability to prioritise and make clinical decisions. In contrast, parents did not describe the conflict in prioritisation between tasks, but they did always acknowledge feeling safer with the nurse being close by.

Nevertheless, the use of these interventions to reduce interruptions attempt to take away the decisions that nurses need to make. Theoretically the intervention should reduce interruptions from other staff so reduce the need for the nurse to decide to deflect, delegate or accept it. Although with interruptions such as the acute deterioration of a patient the interventions are overridden as the safety of the patient is paramount. These decisions may be influenced by experience, knowledge or culture. Nurses may be afraid not to recognise a deterioration as they may fear being blamed for not responding. Alternatively, they may have experienced an acute deterioration worsening or an unplanned extubation that they may feel responsible for. There may be a culture within the unit for the team to support and respond for each other, but if that is not present, the need to respond to interruption increases. Whilst the interventions identified within the finding's chapters may help to protect the child from medication errors, they struggle to maintain patient safety in other areas. The response to an acute deterioration requires an immediate action so are always prioritised over medication administration which can be delayed.

The analysis of data from the healthcare professionals (Chapter 5), illuminated that there was sometimes a conflict between role and the organisational aims. The Realist Review noted that organisations can implement an intervention as a reaction to an issue. Often the issue identified within the literature was an increase in medication errors that were attributed to increased rates of interruptions. This implementation

process would often have limited understanding of the type or cause of interruptions. This lack of comprehension could contribute to conflict between the professional and the organisation as engagement was poor due to negative experiences of using the intervention.

The interviews with the MDT team uncovered deeper examples of organisational and professional conflict. AHP's highlighted that their service was commissioned differently to the team based within PICU resulting in difficult decision-making situations. The impact of this was that current intervention design did not comprehend priority decision-making between different departments. Therefore, it often did not fit within the overall organisational aims for service delivery. This was noted by the physiotherapist and pharmacists who outlined the impact that waiting for medication administration to end within PICU could have on the experience of children they were responsible for in other clinical settings.

The survey and MDT interviews highlighted the comprehensive teamworking within PICU as they provided care to the critically ill child, although, each role acknowledged different remits that may result in competing priorities. Parents did not talk about the AHP's or support roles, suggesting they spent less time at the bedside resulting in a reduced awareness of their actions. In contrast, nurses were seen at the bedside continually ensuring that the child/infant received appropriate care. A result of this presence at the bedside was nurse needing to have continual awareness and providing observation of patient condition, as well as interpreting data such as the delivery of ventilation. Furthermore, they provided holistic care to ensure the child/infant was comfortable, through turning, washing, moving and caring for the child. In addition to this the nurse was responsible for the timely delivery of medication. They were dependent on the medical and pharmacy teams to ensure medicines were accurately prescribed and available, as well has having the correct access to administer medicines through. Other AHP's such as physiotherapists provide treatment that ultimately aids the patient condition but can also cause deterioration in the short term. These differences can result in different aims or priorities for each role which may result in decisions that may override interventions and interrupt the process.

Each role has different priorities, both in delivering intensive care and medication. These different priorities can cause conflict between roles or tensions within the process. AHP's can have commitments outside PICU which affects their reactions to interventions within the intensive care. In addition, pharmacists and medical teams have responsibility for all the patients in PICU, and not just a single patient like the bedside nurse. This collective responsibility for other patients can add pressure to these professionals that may trigger different responses to interventions, such as ignoring the red apron and interrupting the medication process because another patient is deteriorating, and they are needed.

Increased workload was also highlighted within all three findings chapters. The Realist Review primarily focused on the patient turnover and the impact of keeping patients and families informed. The impact of patient turnover was possibly not recognised by PICU staff and parents as it is generally not an area where patients change frequently. However, keeping parents updated about the fast pace of treatment plans in PICU was highlighted. Furthermore, the process of keeping parents informed about interventions and their process was also acknowledged as lacking. Parents described a process of absorbing information by osmosis. Although, this may not be possible for some parents, for example those where English is not their first language. Therefore, there needs to be an active process of communication and information for parents within PICU. This is more difficult when the medication workload is high as the nurses may continually be preparing and administering medicines to that child, reducing time to focus on communication.

The analysis of healthcare data (Chapter 5) and parent interviews (Chapter 6) focused on the impact of a high medication workload within PICU, and the amount of time nurses spent preparing and administering medicines. This may lead to long periods where nurses were involved in medication administration. This could create a potential risk of leaving parents feeling vulnerable or worried which can result in increased levels of interruptions. Furthermore, the MDT chapter highlighted increased workloads from low staffing levels. Reductions in staffing levels were highlighted to lower the likelihood that a float nurse was available to fulfil the role of second checker. The impact of this could result in two bedside nurses being involved in the checking process both of whom would need to maintain continual awareness of their patient. Alternatively, the Nurse in Charge (NIC) could be involved who was responsible for

the co-ordination of the whole unit and patient flow. When this occurred participants in the survey and MDT interviews indicated that when the NIC was involved interruption rates would increase due to their ongoing responsibilities.

In addition, workload was also linked with the concept of nursing efficiency within PICU. The Realist Review (Chapter 4) and MDT findings (Chapter 5) identified the impact of efficiency on the use of interventions. Medication administration was identified in all three chapters as a thread that weaves all through the delivery of nursing care. Parents clearly described the meticulous planning of nursing care with medication as the core. Within the PICU team it was identified that the perception of efficiency was often linked to the delivery of timely care. The reflective diary excerpt in Table 36 examines the concept of efficiency in PICU.

Table 36 - Reflective diary entry

Reflective diary excerpt
I interviewed a nurse today who commented on the link between interruptions and efficiency. She noted that timely medication administration was seen as being efficient. Interruptions were likely to increase, particularly from medical teams if they thought tasks weren't being completed quickly enough, particularly if the child is deteriorating. This led me to think about efficiency, in my experience of working within PICU nurses who were observed not to deliver tasks on time were seen as either to be struggling to cope, or not have the time management skills to work in PICU. Yet when we have competing priority tasks to complete it is difficult to achieve these markers of efficiency. I began to wonder where this perception of efficiency originated from, who set these perceptions as being the correct standard? Where does the power to set these types of standards come from? Are they the correct markers? Recently nurses were and are pushed to deliver certain medications (critical drugs) within an hour of them being prescribed. These are now linked within sepsis bundles and toolkits. This target of an hour is robustly monitored and measured and shared widely if areas fail. Delays of more than an hour should be recorded as a medication error for critical drugs. These types of efficiencies are set nationally and are well resourced (usually as a CQUIN) to ensure targets are met. I also wondered whether there were more local pressures for efficiency, from within the team. Does the critical and unstable nature of the work create more pressure for efficiency. I suspect it does, the critical nature of the work means that subtle signs

of change need to be identified and responded to immediately and often medication may be required, creating a need to prepare and administer them swiftly. Perhaps this can lead to additional pressures of needing to be efficient?

(Reflective diary, December 2018)

Weaving medication administration into a cluster of care, for example administering nasogastric (NG) medicines with the start of an NG feed, allows the nurse to be efficient and ensures minimal disturbance to the critically ill child. Removing the medication task out of this cluster may contribute to a perceived reduction in nursing efficiency. If nursing efficiency is reduced, it is possible that this could contribute to decreased satisfaction levels. Furthermore, nurses may also be viewed to be under performing or not coping with the role. All of which may lead to negative experiences of the intervention and a lack of engagement.

Within the nursing literature efficiency is also promoted by using other interventions such as 'Productive Ward' and 'Caring Around the Clock' (see glossary for definition). In contrast to these other interventions the synthesis of the Realist Review (Chapter 4) and MDT findings (Chapter 5) highlighted the isolation of the medication process in interventions such as wearing a red tabard, these interventions promote the clustering of care. This demonstrates an incongruence between interventions as their underpinning frameworks combine fundamentally opposing principles. Therefore, nurses are not able to perform and adhere to the processes required within both types of intervention. It leads to a battle between task orientated and holistic care, which can create conflict for nurses who are educated to deliver total patient care.

Healthcare professionals (Chapter 5) identified that in PICU there are time critical situations where medications are demanded and provided quickly to save a child's life. Situational awareness may be reduced within these events as everyone's focus narrows down to saving the child's life. This can lead to increased interruptions as awareness of the process decreases and demands for medications increase. In these situations, the data indicated within the Chapter 5, that interventions may be ignored as the quick preparation of the medication is vital. It is possible that the shortcuts taken in these critical situations can creep into everyday practice.

The critical nature of PICU highlights the vulnerability of the infants and children. The vulnerability of this population was not highlighted within the Realist Review (Chapter 4) as no study had taken place within PICU. The Survey of Practice and MDT interviews (Chapter 5) highlighted the instability and urgency of PICU, although, it was the parents who illuminated how vulnerable the children are within PICU. Parents described the process of decision-making around medication administration and the impact that can have on their child. This vulnerability was shown to stimulate the parent to challenge, question or interrupt to help them establish what may be happening to their child. Communication with parents and families appeared to be given only the smallest of references within the design of the interventions within the Realist Review and healthcare professional findings. Yet without this comprehension of parental need within the design of the intervention, parents may struggle to adhere to it because their primary concern is that their child is safe.

Prior to admission to PICU parents are likely to control a significant amount of their child's activities and care. This will vary as it can be dependent on age and health needs. Once they are admitted to PICU this can be diminished or even lost. Critically ill infants and children may only tolerate the holding of hands as a change of nappy or turn of head can cause acute deteriorations. This may result in significant levels of support and assurance being required. The whole team may contribute to this support and reassurance through communication and updates. However, the main support structure acknowledged by parents was the continual presence of the nurse at the bedside. Their availability was welcomed as it allowed parents to process the information they received and then follow it up with questions, clarification or at times challenge. Using interventions at the bedside requires them to comprehend the need for this support and reassurance.

Parents acknowledged that if they did not receive this support and reassurance the feelings of loss of control and bewilderment may lead to poor experiences or trigger anger and confusion. This was more evident in parents who were long term inpatients or provided complex care at home as they were experts in their child's condition. They were often aware of how their child would react to changes in medication plans. This population of expert parents is increasing so nursing practice needs to incorporate this knowledge into its processes.

The need for consistent behaviour by professionals using the intervention was highlighted by the Survey of Practice and the interviews with the MDT and parents. Consistent behaviour is required as inconsistency can stimulate reactions in others such as confusion, asking questions and a fear for safety. The medication process is very policy driven. Therefore, there should be an expectation that the process is completed in a similar way by each professional. Although, both professionals and parents noted that individual behaviour varied within the process. Parents noted that some of the variety could be attributed to changes in the medication plan, but there were also inconsistencies noticed in the checking and preparation phases.

This inconsistency in behaviours may be caused by several different factors. There may be a disconnect between policy and practice which results in the policy not being implemented as intended as it does not work within the real world. This results in a conflict between 'work as intended' and 'work as done' and may require human factors expertise within the policy writing team. Alternatively, professionals may develop short cuts in practice when under pressure that become accepted as normal. Finally, professionals may choose not to follow policy or not be aware of its existence. If professionals choose not to follow the policy, it is important they remember that they remain accountable for their actions. Furthermore, if they are not aware or cannot access the policy then system issues must be addressed. These concepts are the building blocks of a 'Just Culture' (Dekker, 2018), that tries to balance accountability and supportive working conditions. Ultimately, whatever the rationale for the disconnect between policy and practice the result is the same for the wider team members and parents. That is, they experience confusion about the use of the intervention, which can lead parents to worry about the safety of their child.

The presence of a medication routine was described in the findings of all three findings chapters. The medication process is one of the most common tasks carried out within healthcare. The process centers around the 'five rights' (right drug, right dose, right time, right patient and right route) which were highlighted in the MDT findings chapter. The use of such a strong message within the process, which in PICU is performed repetitively on each shift can result in automation. This can lead to situations where the individual follows the process without thinking or making active decisions. This may result in an ingrained process that is very difficult to change. Therefore, any intervention or change to process can be difficult to implement as it can feel alien within

a well-known process. The findings within the Realist Review and the MDT interviews demonstrated that participants thought that the intervention needed to fit within the process and not change it. The use of red aprons would appear to be the correct intervention for this requirement as within PICU participants (both professionals and parents) described the routine wearing of aprons for nursing care, and it was only a change in colour. Nevertheless, nurses and consultants described issues with supplies and lack of storage space that resulted in the incorrect colour being worn. Furthermore, staff and parents acknowledged confusion caused by multiple different coloured aprons, as they change depending on the task (for example, bedside nursing care, infectious patient care, cleaning). In addition, automation can lead to a task being completed without the individual actively thinking about their actions or decisions. The risk of embedding an intervention within an automated process could lead to reduced effectiveness as individuals pay no attention to it. Nevertheless, parents welcomed the routine as it enabled them to understand the care being delivered and they would try to adjust their actions so that they did not interrupt during these periods of medication activity. Whilst following a routine is beneficial to professionals and parents as their decisions and interactions are informed by it, the risk of automaticity can lead to no or low-level thinking and the mind may wander elsewhere.

The issues discussed within this section contribute to the knowledge base about contemporary medication administration in PICU. In addition, the unpicking of these issues has helped to identify the contexts that influence the actions and behaviours of both healthcare professionals and parents during the medication process.

7.2.3 Mechanisms

The mechanism section of each set of findings identified actions, behaviours and reactions that were influenced or triggered by the interventions and the contexts in which they were situated. This synthesis critically explores the mechanisms to identify how they impact in the clinical setting and what impact they have on practice.

Within all three chapters feelings were associated with and generated by the medication process and the interventions used to reduce interruptions. Professionals clearly described feelings such as being self-conscious, uncomfortable or unavailable. These negative feelings were associated with interventions such as the wearing of tabards, lanyards or headphones. It was apparent that these feelings were re-enforced

by reactions from other professionals. The Realist Review and MDT findings outlined that the idea within the intervention was that the additional piece of clothing would make the individual standout. This resulted in the wearer being identifiable and this would then prompt the interrupter to make an active decision not to interrupt. This then places the wearer in the spotlight and amplifies their internal feelings of discomfort, contributing to a negative experience of using the intervention the MDT acknowledged that they would be less likely to engage with it.

The volume of medication administration was recognised by the nursing participants to hide the process within the delivery of nursing care. This was driven in part by the concept of efficiency discussed in section 7.2.2. The impact of the hidden process is that the administration of medication submerges into nursing care, it no longer stands out in the nurses' mind, so their mindset may not change to focus on the task. In essence, medication administration seems to have lost its identity as a task that can be complex, difficult and potentially harmful to the child. Furthermore, the loss of identity has also contributed to a loss of respect from other healthcare professionals. In contrast, parents see the complexity and fear the harm to their child so try to respect the process and not interrupt it.

The frequency and volume of medication administration can lead to a checklist of tasks as findings indicated that medication times were planned out with nursing care fitted in around it. Lists of tasks may result in a lack of awareness and reduced focus about medication as the aim was to reach the end of the list rather than thinking about the importance of tasks. Furthermore, interventions were felt by some healthcare professionals to trigger a different mindset; one of focus. It may be argued that the importance of the task itself should make it stand out, although, it is difficult to make a task 'stand out' when it is delivered repetitively during every shift.

Reactionary behaviour was highlighted by both professionals and parents. A common element that triggered reactions from parents was body language. Parents described reacting to changes in body language, such as a closed position when calculations were being completed. This stimulated a transference of empathy, as they imagined that they would not want to be interrupted in the same situation. Whereas often nurses and consultants recognised that time critical tasks or communication resulted in a need for immediate interruption reducing the level of empathy shown to their colleagues.

Whereas the pharmacists, physiotherapist and support staff described strategies they used to reduce their interruptions displaying a higher level of empathy. This may suggest that this empathetic reaction was stimulated by the worry they had for their child. Parents were in an alien environment, on edge and had increased awareness of subtle changes in body language. Whereas professionals were in their normal environment and powered by a desire to deliver timely care to their patient and have less time to observe for changes in body language.

Pharmacists and support staff noticed when the nurse was not fully focused on the medication process, for example participating in a social conversation. If they were seen to be discussing non-medication related subjects, a reaction from the interrupter would be to assume that it was acceptable to interrupt as they were not focused on the medication process. This demonstrated the need for nurses to maintain a consistent professional role. Nurses need to understand how their behaviour influences the actions and reactions of others.

The Realist Review (Chapter 4) and MDT interviews (Chapter 5) highlighted the impact of removing the medication process into a different area and isolating it. This led to less awareness of communication surrounding the plan of care for the patient. This was particularly important for PICU nurses as they predominantly look after one patient and are the lynch pin for the organisation of care for that child. It is important to remember that the nurse is accountable for the delivery of care to the child. It can be difficult to deliver the care required if the nurse is isolated in the medication process for prolonged periods of time, this may be further compounded by a fear of making mistakes. If a nurse had witnessed or been involved in an event where care had not been delivered or actions and a child had deteriorated, their engagement with the intervention may decrease.

In response to this issue, teamwork was acknowledged by both parents and professionals as being important to override this issue. It was acknowledged in Chapter Two that team intelligence was an important theory within the development of aviation safety. In order to develop an intelligent team multidisciplinary training is required. The training provision was explored within the MDT interviews, and this highlighted that within the education programmes for medication administration in PICU there was no interprofessional training or education. This demonstrated the lack

of opportunity for team intelligence to be developed. The frequent rotation of medical staff makes it challenging to organise MDT training and to create intelligent teams. Simulation is increasing in popularity and focusing on the development of an intelligent team would be appropriate for this method of training.

The development of individual confidence for nurses was noted to be important within the Realist Review and MDT interviews. They need to be confident to deflect, delay and delegate interruptions from all levels of the team within and from outside of PICU and parents. This confidence was acknowledged by the MDT to be associated with experience. Without this confidence they are likely to be accepting of interruptions, which in the long run will lead to a culture where it becomes normal to interrupt. In addition to this need for individual confidence, nurses need to be effective communicators. They need to be able to negotiate care with the multidisciplinary team and pre-empt questions from parents. Taking pro-active measures like this would contribute to a reduction in interruptions being received, particularly from parents.

When parents are initially admitted to PICU they described feelings of shock, an inability to comprehend what was happening to their child and fear. It was an alien environment, and they were uncertain about the survival of their child, but once this faded, they were driven by a need to protect their child. In response, healthcare professionals acknowledged in Chapter 5 that their presence at the bedside allowed them to be available to parents which, in turn led to an increase in questioning and interruptions.

The parental need to protect was especially articulated by mothers, and stimulated them to ask questions, challenge actions and correct practice if they believed it to be wrong. They were less likely to just accept the advice and guidance given by the medical and nursing teams. Parents/carers described how they have twenty-four-hour access to a wide range of information via the internet and that they can access this continually while they are resident with their child. Parents/carers noted that it was possible that availability of this material could increase interruptions and challenges as they clarified the accuracy of the information they were being given. Furthermore, parents described how access to this information may increase their confidence to challenge and question as they advocate for their child.

Historically, nurses were seen to be the advocates for the child, but the findings in this study suggests that there are times when this role appears to be allocated to the parent. This was demonstrated in the parental findings (Chapter 6) when there was acknowledgement of the difference between parental responsibility and caring for a child. In contrast, the role of advocate suggests that nurses should always act in the best interests of the child. However, the nurses within PICU acknowledged that there are many competing priorities in a resource stretched environment for the best interests of the child to be continually considered. This was demonstrated in Chapter 5 when professionals acknowledged that increased pressure could lead to shortcuts in practice. Furthermore, there are organisational and political requirements for performance and efficiency, such as the prevention of four-hour breaches within the emergency department that can override quality and result in a team not always acting in the best interests of an individual child.

This section has explored the mechanisms triggered by interventions to reduce interruptions to the medication process. It has demonstrated the complexity of the interactions and behaviours within the team and the impact this has on parents. Furthermore, this section has also illuminated the conflicts faced within the PICU environment.

7.2.4 Outcomes

In addition to the outcomes identified within the Realist Review of reduced interruption and medication error rates, this synthesis has identified multiple different outcomes of interest, these were summarised in Table 35. Satisfaction with the intervention was an outcome that was rarely measured but cited frequently in studies within the Realist Review as a reason for professionals to disengage with the intervention. This was echoed within the Survey of Practice and MDT interviews as no PICU had evaluated staff satisfaction. This may be due to the lack of strategy surrounding the implementation of the interventions as there were only three units that had measured the impact of the interventions. Similarly, to the Realist Review these measurements had focused on measuring time, interruption and error rates, rather than focusing on understanding why the intervention may or may not have worked. This lack of understanding about why interventions work, may have contributed to the difficulty's professionals discussed about sustainability. The MDT acknowledged that the use of these interventions required relentless monitoring and enforcement to ensure they

were used. This suggests a lack of satisfaction within the team and did not feel that the change in practice created a strong enough outcome to support it becoming embedded within their own practice.

In the data analysis of the parent interviews (Chapter 6), satisfaction with the intervention was not strongly identified as an issue and this was not formally assessed in any unit. There was no data shared in any of the data to indicate that patients or parents had been involved in the design of any intervention. Only one parent expressed negative feedback about the intervention as they were concerned about the tabard restricting the availability of the nurse and creating a barrier. Parents expressed positive feelings about the medication process at the beside as it offered assurance that robust checks were generally in place, and if they were not, they were able to identify this and challenge it if needed. They already expressed a desire to respect and not interrupt the process. If this involved the wearing of a tabard or apron, they appeared to accept it. Nevertheless, there were several important factors needed to support this, information about the intervention, consistent use and access to another nurse in case of an emergency. It is suggested that their acceptance of these interventions was based on the safety of their child. If a process is designed with patient safety factors included, they would support this if they felt their child was safe within it. The promotion of safety with families was also anecdotally highlighted in two adult studies within the Realist Review indicating that families would be supportive of interventions.

Parental feelings of safety were strongly associated with a drive for information and development of their knowledge. Parents described in Chapter 6 how they had access to a world outside of the intensive care unit via mobile phone technology. This thirst for knowledge and access to information alongside the delivery of complex health care at home, as created a population of expert parents. They expect to be informed about their child's care and treatment and have the time to notice when they change. Furthermore, parents acknowledged an additional benefit of the development of this knowledge, feeling part of the team. They entered the PICU as the main care giver and decision-maker for this child however, the diagnosis of a critical illness ripped that away leaving them as an outsider observing their child being looked after by healthcare professionals. The inclusion of them within the team was perceived to be

beneficial to them as they felt able to contribute to the plans and not only feel that they were in the way.

The need for professional behaviour was also highlighted as an important outcome within all three findings chapters. Professional behaviour is directed through national standards, organisational policy and local culture. These influencing factors were identified in both the Survey of Practice and the healthcare professional interviews in Chapter 5. The reflective excerpt (see Table 37) identifies the importance of the local culture in the maintenance of professional behaviour.

Table 37 - Reflective diary entry

Reflective diary excerpt
The NMC has removed the standards for medication administration for nurses and this has now been replaced by some guiding principles from the Royal Pharmaceutical Society and the RCN. These principles outline the requirements for organisations for the safe delivery of medication but do not address individual responsibility. As I was reading the new guidance, I couldn't help but wonder what impact this will have in practice. Within my data analysis I have noted the importance of professional behaviour within the process. I wondered if this removal of specific standards for nursing delivery of medication may lessen the individual accountability by placing it at a system level. There is short section within the Code of Conduct about medication administration, but it is limited to five summary points. This includes a recognition of individual limitations but offers limited guidance regarding responsibilities within the process. I think this adds increased responsibility on the leaders and educators within the clinical setting to ensure healthcare professionals demonstrate professional behaviour within the medication process. However, this analysis has also highlighted how difficult is for this to happen. Reflective Diary (April 2019)

Written guidance (RPS and RCN, 2019) is available that addresses organisational requirements and policies can guide the process, but the delivery in practice sits within the local area and is influenced by the culture. This local culture may support or hinder the implementation of any intervention. Evidence from Chapter 5 suggests that the unit culture needs to have a patient safety focus at its heart so that practice can be developed to be as safe as possible. Furthermore, the professionals acknowledged

that a high standard needed to be role modelled and poor practice challenged. In Chapter 6 parents also expressed an expectation that poor practice was challenged by team leaders. If the professional practice is not present to begin with it is possible that interventions that expect it to follow policy will fail as they do not comprehend the real world.

The findings from the Realist Review and MDT chapters acknowledged that the routine process within medication administration can affect the identity of the process and active thinking. It is possible that with the routine and automatic elements of medication administration active thinking can be lost and the medication process may hide within the delivery of other aspects of care. This may also be further compounded as the workload within the unit can drive the delivery of care so that everyone is striving to achieve their own priority tasks without actively thinking about others. The introduction of these types of interventions where the medication process is made to stand out is trying to stimulate an active decision-making process. Nevertheless, this has been demonstrated to be easily overridden by conflicts in priorities and increased workloads.

This section has explored the novel outcomes associated with the implementation of interventions to reduce interruptions to the medication process within PICU. These have not previously been identified within the literature and the impact of not comprehending these outcomes highlights the potential success and failure of these interventions. Furthermore, it has highlighted the impact of any disconnect between expectations of practice and the real world.

7.3 CMO Configurations

7.3.1 Introduction

The previous sections in this chapter have synthesised the evidence provided within the three findings chapters. However, this synthesis has kept the individual element of context, mechanisms and outcomes as separate entities but it is extremely important to understand how these elements interact and influence each other. The following section will provide a culmination of this work by critically exploring how these concepts interact by probing the relationships between the contexts, mechanisms and outcomes for both healthcare professionals and parents/carers. These relationships will be presented graphically as CMO configurations (CMOCs) (Pawson and Tilley,

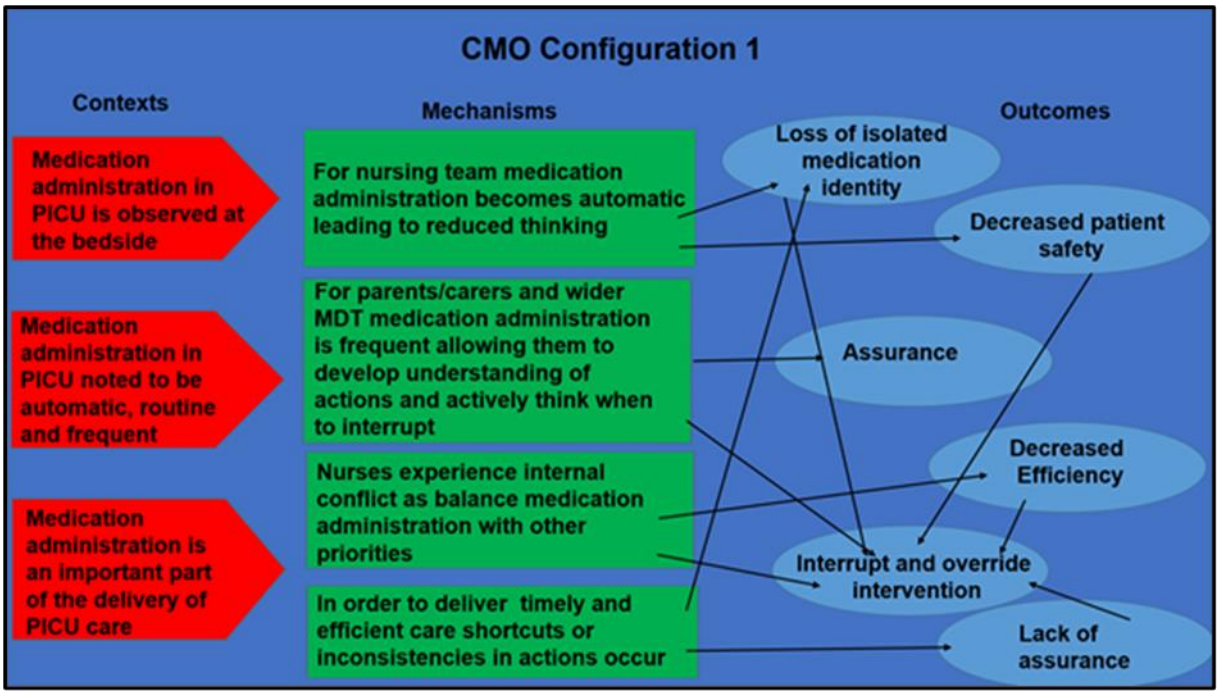
1997). The verification process outlined in Chapter Three identified five areas of interest: (i) process driven actions (ii) parental feelings of safety, (iii) challenging interruptions, (iv) creating a team and finally (v) the art of safety. Reflecting on these areas has highlighted significant elements that underpin the important elements within the four CMOCs. These configurations are presented in the following sections alongside a narrative that will articulate how these elements interact and influence behaviour, before a section that summarises the overall picture.

7.3.2 CMOC 1 – Comprehending the routine

Within the first CMOC the contexts illustrated medication administration processes that triggered hidden mechanisms within healthcare professionals and parents that influenced the outcome of interventions to reduce interruptions. The CMOC presented in Figure 14 illuminates the CMO from both healthcare professional and parent viewpoint. The arrows within each figure illuminate the complexities and how the underpinning mechanisms interact and influence the outcomes.

Within the Realist Review the descriptions of the medication process were limited and confusing with different routines used to design studies (medication rounds and individual administration episodes). In contrast, all healthcare professionals and parents/carers included within the empirical study were able to narrate a comprehensive picture of medication process in PICU (see sections 5.2.1 and 6.3.1). Moreover, healthcare professionals and parents/carers were all aware of actions, and equipment that were associated with the process at the bedside. However, the wider MDT and parents/carers highlighted their observation and interpretation of body language which helped to inform their decision making, this awareness was not described by the nursing team. The visibility of the actions, body language and equipment allowed healthcare professionals and parents/carers to be aware of the beginning and end of the process. Both sets of data identified the routine that was embedded in the process, with both professionals and some frequent or longer stay parents/carer having an awareness of the five rights of medication administration. However, whilst the contexts were similar for both groups the mechanisms, outcomes differed.

Figure 14 - CMOC 1: Comprehending the routine



Healthcare professionals acknowledged a medication process that was visible, routine, frequent and automatic. Similarly, parents/carers described a visible and frequent routine that was easily identified even by those who were knew to PICU. Over extended periods of time this knowledge developed to an extent where longer-term and frequent visitors were able to identify when actions or behaviours were inconsistent. These contexts of routine triggered underpinning mechanisms that impacted on thinking and decision-making for both healthcare professionals and parents/carers although these differed between and within the two groups.

Registered Nurses acknowledged an underpinning mechanism associated with a potential increase in automatic actions, due to the frequency of medication administration, that could result in a reduction in thinking. This mechanism was associated with two outcomes: a loss of the isolated medication administration identity due to it being embedded with the delivery of nursing care and a potential decrease in patient safety due to reduced thinking about their actions. The loss of the isolated medication administration process was an important outcome to acknowledge, as this was a key element of the programme theory associated with interventions to reduce interruptions, presented in Chapter 2. Without an isolated medication administration process there is likely to be increased interruptions and interventions are less effective as it is difficult isolate the task from other elements of nursing care.

Conversely, the wider MDT (Consultants, Pharmacists, Physiotherapists and support staff) and parents/carers described an alternative mechanism linked to the frequent medication administration process. The frequency of the process and presence of the visual cues ensured the process had a clear and distinct identity. This mechanism enabled them to interpret and react to the actions being taken by the Nurse administering medications and to choose when they interrupted, which was suggestive of a more active thinking process. Parents/carers described an active process of thinking as they carefully chose when to interrupt which was developed early in their PICU stay, even if the environment was new to them. Interestingly, parents/carers described an awareness of body language associated with the process that was not acknowledged by the professionals in the MDT. This may be due to the length of time they spent observing the process and having the time to understand how body language related to the different sections of the process enabling them to recognise the identity of the medication process. However, interruptions only decreased if they were reassured by the actions they were observing, if shortcuts or inconsistent behaviour were noted interruptions would increase due to confusion or questions about the safety of their child.

Within the study Nurses acknowledged a mechanism of internal conflict as they balanced frequent administration with other elements of PICU care. This was identified in both the Realist Review and the empirical data, with both chapters identifying an internal conflict raised by this concept. Parents/carers acknowledged that the medication process is woven throughout the delivery of nursing care within PICU. They recognised that care was organised around the medication plan for the day. This was suggested within the MDT findings to be linked to efficiency and that the isolation of the task could decrease their ability to be efficient in the delivery of care. Within the Realist Review it was highlighted that nurses found it difficult to remove themselves from the clinical area due to the risk of care not being delivered or missing important communication. This was amplified within PICU as Nurses found it difficult to not respond to clinical deterioration of critically ill children. When a supportive team was present within the PICU and working towards the goal of allowing the medication process to be isolated, the Nurse could purely focus on the task. When this occurred, the nurse felt safe to focus on the administration task as they were aware that their team was continuing to deliver the continuous observation and care required.

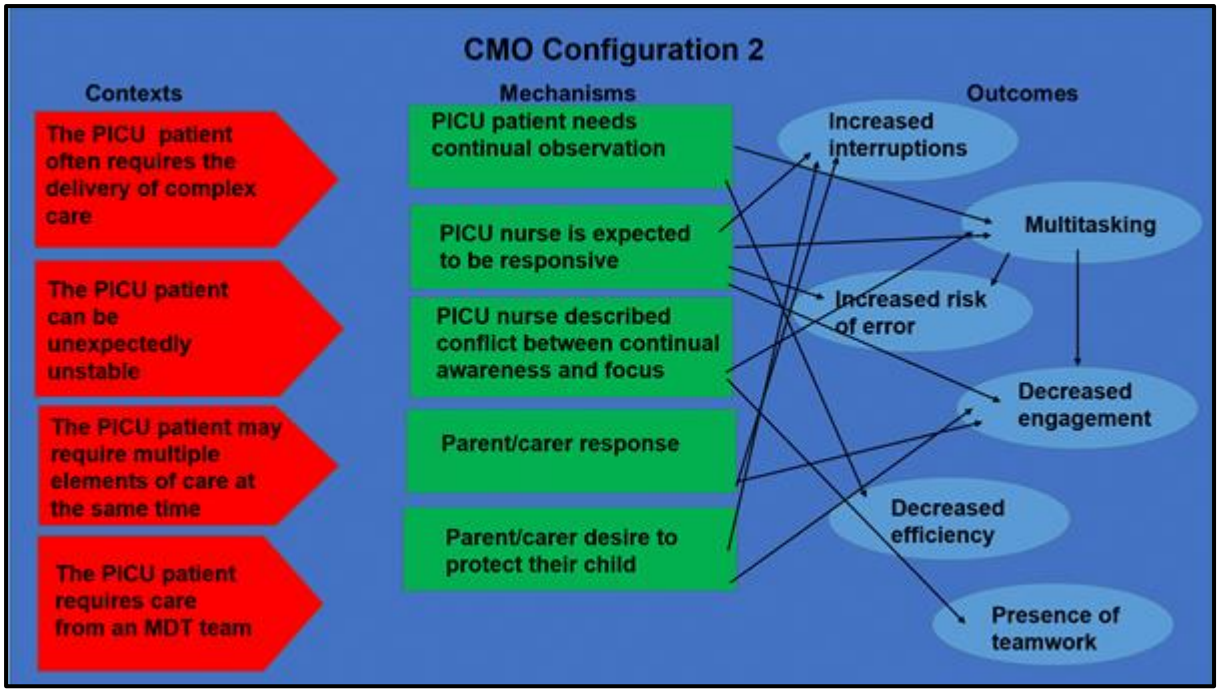
Efficiency was also noted to be a context that could stimulate a hidden mechanism of taking shortcuts. The impact of efficiency was acknowledged in section 7.2.1 as the delivery of timely care was noted to be important within the PICU environment. This may result in the nurse feeling a pressure from themselves and the wider MDT to deliver care within the timeframes required. In order to achieve this a shortcut in processes are looked for to save time. In relation to the interventions used within this study they are likely to be overridden if it was thought that valuable time could be saved. The culmination of this CMOC is the impact on the patient as their safety can be compromised from the reduced thinking, decreased efficiency and pressure to take shortcuts.

This first CMOC has explored the hidden mechanisms triggered by the routine and frequent medication administration process within PICU. The differing impact of these mechanisms have been critically discussed and their importance in understanding the effectiveness of interventions to reduce interruptions to the medication administration process in PICU. Understanding these mechanisms and the behavioural theory that supports them will be important in future interventional work when trying to reduce interruptions to medication administration.

7.3.3 CMOC 2 – The critically ill child and their environment

The CMOC in Figure 15 shows the impact of the critically ill child and their environment on the behaviours and actions of both healthcare professionals and parents/carers. The contexts contained within CMOC 2 focus on the delivery of complex care and the management of instability. Both parents/carers and healthcare professionals acknowledged within their interviews the unpredictable nature of instability within PICU, with the bedside nurse having to respond to alarms, movement by the child and clinical deterioration.

Figure 15 - CMOC 2: The Critically ill child and their environment



These contexts presented in CMOC2 (see Figure 15) generate specific mechanisms for the Nurse caring for the child. The Nurses described a mechanism of maintaining situational awareness, such as having a continual knowledge of vital signs. This resulted in an outcome of multi-tasking, as whichever task they were undertaking they continued to also monitor the patient's condition. Nurses also described a mechanism of responsiveness as they were expected to acknowledge or action alarms or changes in condition. This is linked with another underlying mechanism of conflict as the Nurse tries to balance their focus on a critical task like medication administration and maintaining awareness of patient condition. This inability to be able to offer full focus on one task contradicts the design of current interventions that require that isolation of process. Each of these mechanisms generate an outcome of multi-tasking, which can also be associated with a risk of error as attention is split between different elements of care and increased rates of interruptions as Nurses respond to patient need. One strategy that decreases the need for continual awareness is the presence of teamwork. If another member of the team can provide oversight and respond to the child, the Nurse can move away and purely focus on the medication administration process.

The context of the critically ill child and their environment generate underpinning mechanisms of responsiveness for parents/carers. They will observe the Nurse to see if they respond to the alarm or change in condition. Seeing a response from the Nurse may reassure the parent/carer if they feel that their child is safe. If a parent/carer is not

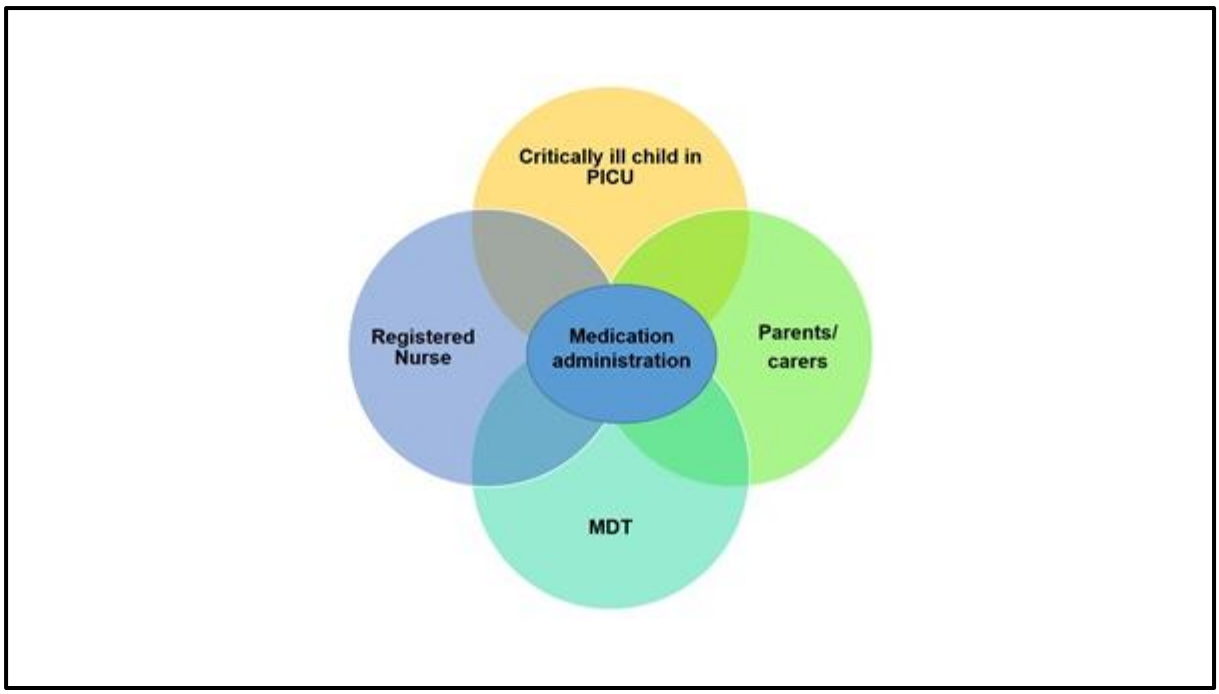
reassured or feels their child's safety is compromised this will stimulate an underpinning mechanism of protection. This can be affected by parent/carer prior experience and knowledge, new parents/carers in PICU described the uncertainty and worry they felt on admission and the anxiety that this could trigger. They tried to try to alleviate this worry by searching for knowledge from the team within PICU which could lead to interruptions. Whereas parents/carers who had more experience in PICU or had a child with complex health needs often described a significant level of knowledge about their child's condition and medication administration. They could describe an active decision-making process choosing when to interrupt but would challenge practice if they thought safety could be compromised.

In conclusion, these two individual CMOC's have summarised the key elements within the medication process and the delivery of care to critically ill children that affect the effectiveness of interventions to reduce interruptions. It is important to identify the key mechanisms as both healthcare professionals and parents/carers have explained the impact that they have on their behaviour and actions. However, these two CMOC's do not operate in isolation so the following section will explore how they interact with each other.

7.3.4 Understanding the overall picture

The CMOC's explored in sections 7.3.2 and 7.3.3 illuminate the complexities associated with interventions to reduce interruptions to medication administration in PICU. Following on from these two CMOC's the diagrams in Figure 16 - 19 explore the interactions within interventions to reduce interruptions medication administration in PICU.

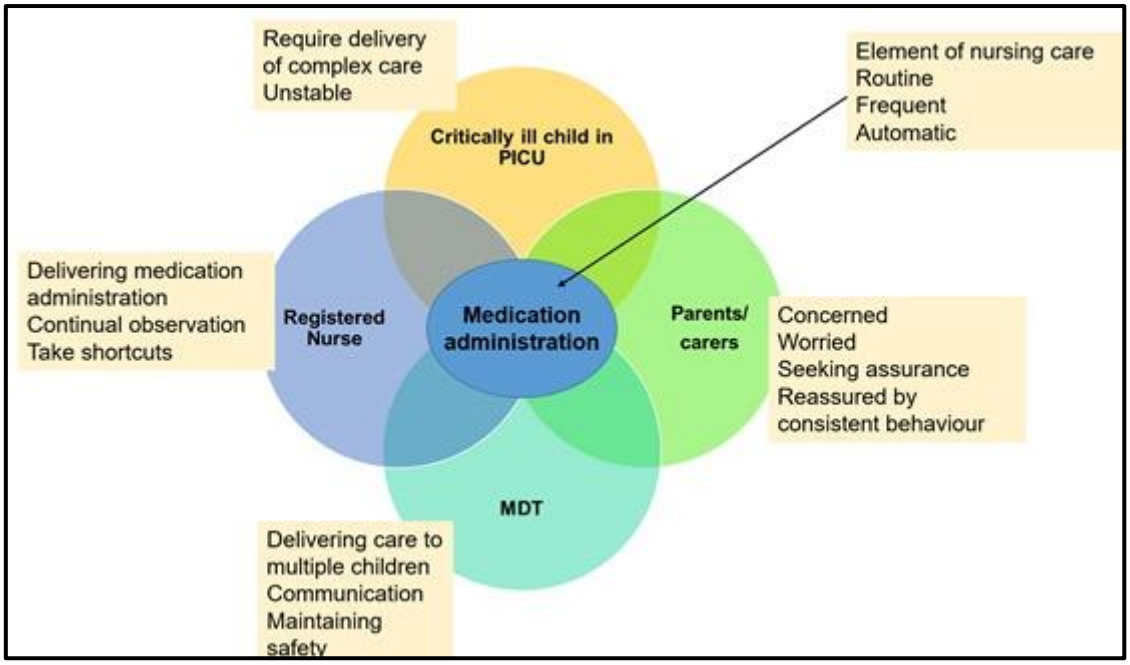
Figure 16 - Interactions within the medication process



The picture in Figure 16 shows the underpinning agents involved in interventions to reduce interruptions to medication administration in PICU. There are three circular shapes within the picture outlining the key agents involved. At the center is medication administration highlighting the interactions that are in place between the agents and the process. This study has suggested that the frequency, complexity and integration of medication administration in PICU has a significant impact on the actions of healthcare professionals and parents/carers but is an important element in the plan of care for the critically ill child and is an important factor in the development of future interventions to reduce interruptions.

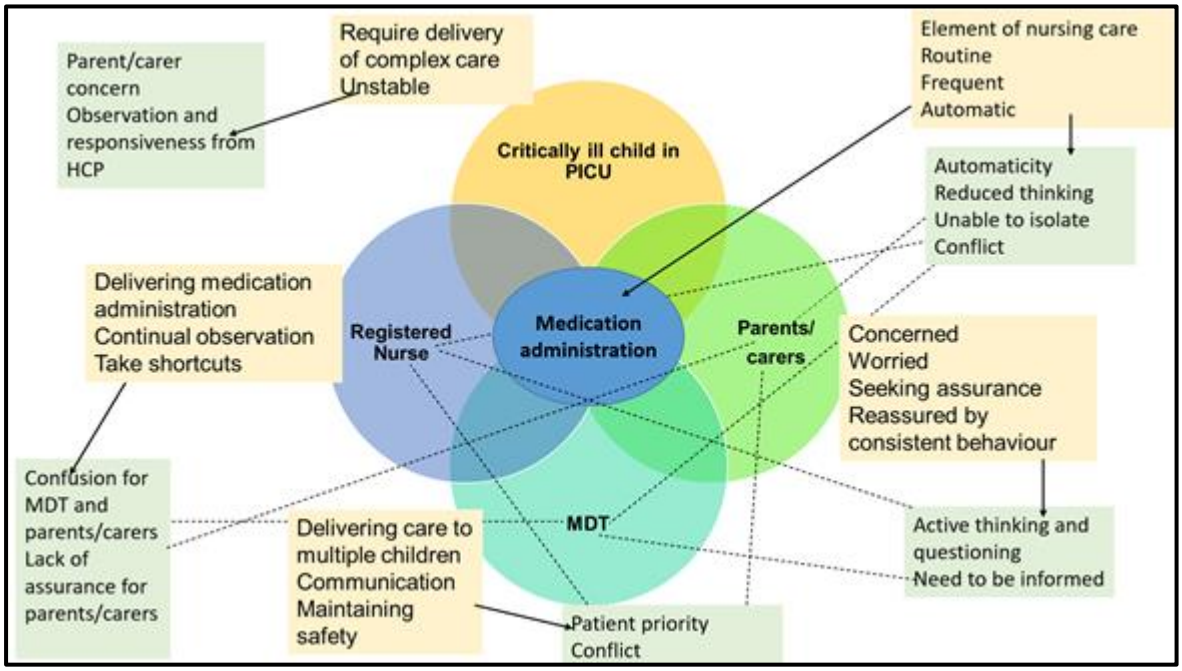
Following on from the first diagram in Figure 16 it is important to understand the contexts that trigger the mechanisms when interventions to reduce interruptions to medication administration in PICU. In Figure 17 these contexts have been illuminated.

Figure 17 - Understanding the contexts



The contexts are identified within the pale-yellow boxes within the diagram. Each element within the first picture has associated contexts that trigger mechanisms that influence the behaviour and actions of others. It is important that future intervention development acknowledge these contexts due to the mechanisms they trigger.

Figure 18 – Understanding the mechanisms



The diagram in Figure 18 completes the picture as the mechanisms that are trigged by the contexts are added in the pale green boxes. The solid arrows demonstrate the connection between the contexts and triggered mechanisms. The addition of the

dotted lines shows the influence that they can also have on other agents demonstrating the complexity of introducing interventions to reduce interruptions to medication administration in PICU. In future intervention development it will be important for researchers to comprehend the impact of maintaining patient safety in PICU, understand the medication workload and the impact of routine as well as the difficulties in isolating the medication process. Finally, any future intervention will need to consider the impact it has on enabling the Nurse to deliver a consistent process as both parents/carers and the MDT interpret their actions within the process to try to reduce or manage the interruption impact.

7.4 Conclusion

This chapter has synthesised the findings from each of the elements used in this thesis those being the Realist Review and empirical data (Findings 1, 2 and 3). These were initially critically discussed as individual contexts, mechanisms and outcomes but then moved to a synthesis approach that critically explored how the data from the different sources (Realist Review and empirical studies) connected, influenced and impacted on each other. Furthermore, it uncovered fundamental influences that were process driven and patient related interactions that are important for the design of future interventions to reduce interruptions to medication administration in PICU, none of which had been highlighted in the literature previously. These were summarised in the final diagram in Section 7.3.4 and will be the foundation stones for the discussion that follows in Chapter 8.

Chapter 8 - Discussion

8.1 Introduction

The final chapter of this thesis will discuss the findings from Chapters 4, 5 and 6 which defined, explored, and critically discussed the phenomena with the aim of understanding why and when interventions to reduce interruptions to medication administration were effective by exploring how they worked, for whom and under what circumstances. In order to answer these questions a Realist Review of the literature was undertaken, followed by a survey of PICU practices in England, and semi-structured interviews with healthcare professionals and parents.

Preceding chapters (Chapter 4, 5 and 6) outlined the critical analysis from each thematic review of the data. Following each thematic review, a realist lens was applied to identify significant contexts, mechanisms and outcomes that influence behaviours and actions when interventions were used to reduce interruptions to medication administration. The culmination of this analysis was the four themes highlighted within the synthesis *(Safety of the child, Isolation of the process, Routine and Automaticity and Professional Behaviour*), which will in this chapter be critically expanded and explored in depth. In doing this, the relationships within the synthesis will be situated in relation to wider research and draw on pertinent theories from psychology, nursing and education in relation to the three levels within Critical Realism (see Chapter 3). In addition, the quality and limitations of this study will be explored. It is thus anticipated that by expanding these themes within the wider literature this chapter will demonstrate the novel contribution that this thesis makes to the body of knowledge. Prior to the exploration of these themes, sections 8.2 and 8.3 will clarify how the aim identified in Chapter 1 was achieved and offer the researchers personal reflections on the study.

8.2 Meeting the aim

The aim of this study was to answer the research question to understand how, when and in which circumstances interventions to reduce interruptions to medication administration in PICU were effective. To address this aim, the study design was informed by the gaps identified in current literature (Chapter 2) and included:

i. A Realist Review of current literature to illuminate contexts and mechanisms that affect the outcome of interventions to reduce interruptions to the medication administration process (Chapter 4).

ii. A survey of practice across PICU's in England to identify interventions in use and their effectiveness. Followed by an exploration of perceptions and experiences of using interventions to reduce interruptions to medication administration in PICU from members of the MDT and the identification of key contexts, mechanisms and outcomes within the data (Chapter 5).

iii. An exploration of parent/carer perceptions and experiences of the medication administration process and the identification of key contexts, mechanisms and outcomes within the data (Chapter 6).

iv. A synthesis of the key contexts, mechanisms and outcomes identified in Chapters 4, 5 and 6 with the production of CMOC's that outline how certain contexts and mechanisms influence the effectiveness of these interventions.

The narrative review in Chapter 2 highlighted a wealth of studies where interventions had been implemented with differing levels of effectiveness. These differences in the literature directed the researcher to understand how, when and for whom these interventions through a Realist Review. Whilst there had been a systematic review (Raban and Westbrook, 2014) which assessed the effectiveness of interventions, there was no literature appraisal that sought to explain how they worked, thus the Realist Review was novel in its approach. Furthermore, due to the lack of literature concerning these interventions within PICU, the Realist Review identified contexts and mechanisms that needed to be empirically explored. It was evident within the narrative and Realist Review that the literature did not adequately illuminate which interventions to reduce interruptions to medication administration, if any, were implemented within PICU. Following on, the Realist Review (Chapter 4) clearly illustrated that that the MDT team was able to influence the effectiveness of the interventions to reduce interruptions to the medication administration process. However, crucial to the essence of this was that healthcare professionals outside of nursing had no apparent voice. In addition to this finding, the Realist Review suggested that visitors/carers may also be able to influence the effectiveness of interventions through their knowledge and understanding of the rationale for use. This was felt to be especially pertinent to

PICU, as at the time of data collection parents/carers were routinely present at the bedside. The presence and need for parents/carers to be at the bedside in PICU is clearly documented within the literature (Ames et al., 2011, Colville et al., 2009, Dampier et al., 2002, Geoghegan et al., 2016, Hill et al., 2019). In line with existing literature the findings from this study supported the importance of parents/carers being present at the bedside but further developed this body of evidence further, by exploring with parents/carers their perceptions and experiences of medication administration in this environment.

The narrative and Realist Review (Stage 1) that were completed at the beginning of this study, identified a gap in the literature concerning interventions to reduce interruptions to medication administration in PICU. Therefore, it was important not to assume that they had been implemented in practice. As a result of the identification of this gap Stage 2a (see Table 5) of this study was designed. The Survey of Practice in England, sought to identify what interventions had been used in PICU, as well as exploring their effectiveness. The findings from the survey revealed that similar interventions (red aprons, tabards and NIZ's) had been implemented in PICU, with the addition of new types such as wearing black gloves or a red clothes peg. Furthermore, the survey illuminated variability in medication administration processes, differences in roles and behaviours, as well as highlighting the impact of unit culture. However, there was no data informed assessment of their effectiveness but anecdotal data concerning attitudes and engagement was described.

In addition to the Survey of Practice (Stage 2a), semi-structured interviews were conducted with participants from MDT (Stage 2b) who work within PICU. Unlike many other studies the MDT participants included Consultants, Pharmacists, Physiotherapists and support staff in addition to nurses, enabling novel contexts such as the environment, expectation, priorities and patient factors to be identified. As well as mechanisms such as feelings, risk, focus and team interactions that influenced their actions and behaviours in response to these interventions. Furthermore, the analysis of this data exposed the simultaneous requirement of nurses to provide continual observation, awareness and responsiveness alongside the administration of medication and the impact that the wider team could have on this. The findings from the MDT also illuminated how integrated the medication administration process is

within the delivery of PICU treatment and care, indicating how difficult it is to separate it into a singular, isolated task that would allow the interventions to be effective.

Both the narrative (Chapter 2) and the Realist Review (Chapter 4) identified the paucity of data from parents/carers resulting in them not being involved in studies or being able to share their perspective. The inclusion of parents/carers within this study (Stage 3) illuminated a set of findings that has never previously been explored, therefore contributing a novel understanding of the phenomenon. However, since this data was collected the despite low numbers of children being hospitalised for COVID-19 (Siva et al., 2021) the impact of the pandemic has had significant impact on the delivery of care. The impact of COVID-19 has impacted in many ways to the PICU environment including the following issues:

- Restricted visiting in PICU to the presence of a single parent and no extended family (Virani et al., 2020, Andrist et al., 2020).
- The impact of wearing Personal Protective Equipment (PPE) on communication with families (Kanthimathinathan et al., 2021, Siva et al., 2021)
- Communication to PICU families being delivered by healthcare professionals not normally involved in this process (Kanthimathinathan et al., 2021, Tedesco et al., 2021)
- The delivery of care to adults within the PICU environment (Siva et al., 2021)
- Long-term impact on the mental health of the PICU team and parents/carers admitted during this time (Tedesco et al., 2021)

During the data collection period it was common for parents/carers to have 24-hour access to the bedside. The inclusion of parents/carers within this study has illuminated findings that demonstrate a wealth of observational data and knowledge about that they hold about the medication administration process. Their actions and decisions were informed by their prior knowledge/experience as well as the assimilation of their observations. Parents/carers identified that nursing behaviours and actions influenced

and prompted their actions. In contrast to current literature where parents are often viewed as helpless or powerless (Alzawad et al., 2020, Hill et al., 2018), this study has illuminated the active decision-making process that parents/carers may experience when deciding whether to interrupt the medication administration process.

The application of a Critical Realism lens has not been applied previously in the evaluation of interventions to reduce interruptions to medication administration in a PICU setting and has thus illuminated new and novel comprehension of how they work and when. The application of Critical Realism has identified key contexts and mechanisms that influence the behaviours and actions of both healthcare professionals and parents/carers that affect their interaction with interventions that seek to reduce interruptions to medication administration. As a result of this analysis, the final sections of the synthesis (Chapter 7) illustrate using CMOC's, the four key themes that impact on the effectiveness of these interventions in the complex real world of PICU: *(1) Safety of the Child; (2) Isolation of the Process; (3) Routine and Automaticity; and (4) Professional Behaviour*.

Prior to the critical discussion of the four key themes identified within the synthesis the researcher will outline the overall reflections of the study using a first-person approach. The inclusion of an overall reflection section was thought to be important for two reasons:

i. The thesis began with a reflective preface and the inclusion of this overall reflection section closes this circle and demonstrates the researcher's journey and learning.

ii. It allows the researcher to offer her personal reflections on the method used offering insight into the benefits and challenges of using Critical Realism.

Following on from the overall reflection the discussion will critically discuss current literature and theory in relation to the four main themes identified within Chapter 7. To conclude the chapter there will be an assessment of quality before the strengths and weaknesses of the study are discussed.

8.3 Overall Reflections

The quote at the beginning of the thesis *'if we want more evidenced-based practice, we need more practice-based evidence'* (Green, 2008;i24) summarises my inspiration for the design and completion of this thesis. Whilst in the main this thesis was written in the objective voice it was felt at this point in the discussion chapter that some personal reflections would be helpful.

From the beginning of my career in nursing research I have been driven to try to understand the issue of interruptions within the clinical setting and wanted to see how everyday life in healthcare impacts on the individual's ability to use current interventions to reduce interruptions to medication administration in practice. I believe that the application of a realist lens has contributed to the development of novel insights into this phenomenon as it was able to offer explanations about how and when interventions work. The use of Critical Realism has supported the analysis to explore and examine the contexts and hidden mechanisms that influence the individual's ability to use the interventions. On initial examination of the phenomena, it could be easy to think that individuals simply chose not to use the interventions that have been designed to help them. The initial use of an inductive thematic analysis (see Chapters 5 and 6) contributed to the strong participant voice within this study as the key themes were identified and evidenced with rich, detailed data (Braun and Clarke, 2006). The additional use of Critical Realism and the formation of CMOC's allowed the identification and narration of the behaviours and actions that were stimulated or influenced by certain contexts and without the use of this method these would remain hidden. Unlike other approaches such as symbolic interactionism, Critical Realism uses of the concept of context to enable the researcher to develop causal explanations that can illuminate the dynamic features that influence mechanisms and ultimately affect how the intervention works (Greenhalgh and Manzano, 2021). The identification of contexts and mechanisms was challenging at times, requiring repeated analysis and multiple discussions with the supervisory team. I repeatedly returned to the thematic analysis to search for the explanatory data to support the formation of the CMOC. This issue has been echoed by other realist researchers (Dalkin, 2014, Jagosh et al., 2014) who illuminated the need to review, re-think and re-write the formation of CMOC's.

Within this reflective section I have contemplated the impact of using Critical Realism within this field and noted the additional benefits of its use. Overall, I feel that this study has illuminated novel insights into the medication administration process in PICU such as:

i. parent/carer awareness and understanding

ii. unobservable feelings and thoughts that influence actions

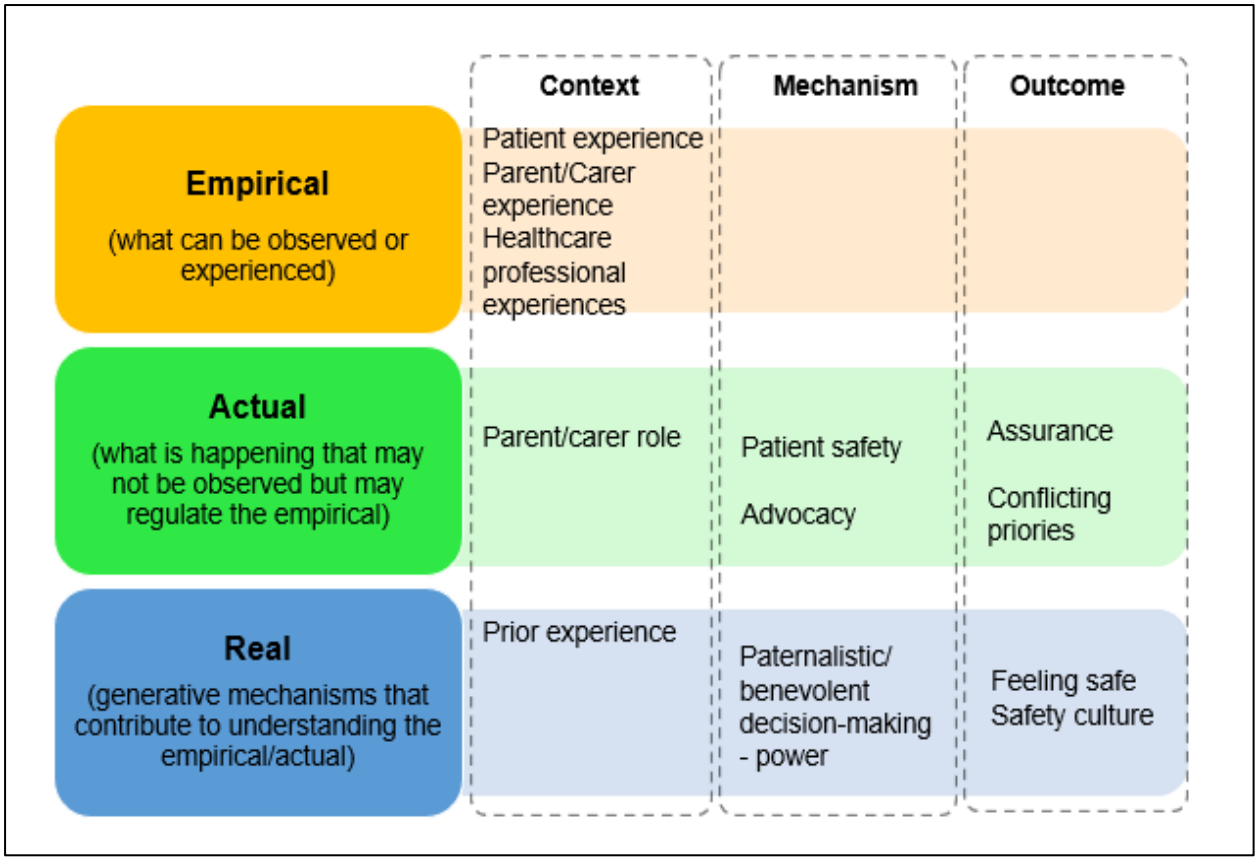
iii. the barriers and facilitators that affect the wider MDT in their use of interventions to reduce interruption to medication administration in PICU.

Thus, providing evidence as to how, for whom and in what circumstances interventions to reduce interruptions work. These personal insights will now be situated in the context of discussion in relation to wider literature and theory within the four main themes identified in Chapter 7.

8.4 Safety of the Child

'Safety of the Child' was a theme that comprehended the actions and behaviours that influence and interact between parents/carers and healthcare professionals when involved in medication administration. This theme has been separated into the three levels described within Critical Realism: empirical, actual and real (Figure 19).

Figure 19 - Critical Realism, medication administration and safety



The graphic included within in Figure 19 illuminates that within each of the three Critical Realism levels there are conceptual elements that were identified within the analysis of this study. The empirical level concepts illuminate the contexts of experiences and perceptions of parents/carers and healthcare professionals in relation to the safety of the child. Whilst the actual level acknowledges contexts, mechanisms and outcomes that influence the empirical level. Whilst the concepts within the real level are those contexts, mechanisms and outcomes that are hidden but trigger actions or behaviours relating to patient safety. The influence of these elements will now be explored using literature and theory to comprehend their impact in the real world of PICU.

8.4.1 Empirical Level – Patient, Parent/Carer and Team

A strong argument presented by healthcare professionals (nurses, consultants and pharmacists) for medication administration being completed at the bedside of the critically ill child was the requirement for continual observation to maintain patient safety. This was also echoed by all parents/carers who also acknowledged the close monitoring provided by the nurses whilst administering medication. Within the empirical level, the medication administration process can be easily observed. In addition to this, both healthcare professionals and parents/carers described their

experiences of the process (see Chapters 5 and 6). The requirement for medication administration to be completed at the bedside demonstrates that interventions to reduce interruptions needs to comprehend this context of a bedside location and the requirement for nurses to maintain a continual awareness of their patient's condition. Current interventions appear not to incorporate this additional complexity, therefore reducing their effectiveness. It is important to reflect on the environment within PICU as it was noted by healthcare professionals to be constructed to protect the child with the use of technology and large MDTs, but this also contributes to increases in interruptions, therefore impacting on the maintenance of a culture of patient safety.

This study did not include the voices of any children and young people who had been inpatients on PICU as participants, however, drawing on other sources of literature it is suggested that they do remember some of their experiences. Manning et al. (2017) reported from their longitudinal, qualitative study of PICU survivors that children recalled elements of care such as, pain and anxiety. Knowing that children may recall their time in PICU may encourage parent/carers and healthcare professionals to talk to the child and explain what care or treatment they are about to deliver. Rennick et al. (2011) identified that mothers in PICU found a 'talk and touch' intervention beneficial to help them comfort their child. They found that this intervention enabled parents/carers to provide comfort and maintain involvement in their care. Interestingly, within this study ten parents/carers described talking to their child as it helped to pass the time. However, offering explanations of care to the child was not discussed by parents/carers or healthcare professionals in this study and it is possible that this could be viewed as an interruption if it stopped medication administration. The lack of recognition of this may suggest that it was not perceived to be an interruption or possibly the explanation was not given. Current interventions are designed to discourage non-medication conversations however, this discussion would focus on the medicine being administered so may be viewed as beneficial, although they could be completed prior to the administration process.

Whilst this study did not explore if care was explained to the children, it did illuminate that parents/carers were informed about medications by both medical and nursing professionals within PICU (see Chapter 6). It also revealed the importance of keeping this knowledge current, otherwise interruptions were more likely to occur as parents/carers sought to understand why medications had changed. This was echoed

in the literature (Jee et al., 2012, Greenway et al., 2019b, Hill et al., 2019) that suggests that honest, open, timely and understandable information was required by parents/carers to help relieve stress in the PICU. The information from 17 parents/carers within this study highlighted that ensuring parents/carers have timely access to information about their child can reduce interruptions and may contribute to making interventions more effective.

Following on from being informed about medication administration, this study demonstrated that parents/carers routinely observed the medication process and were able to offer clear descriptions of the actions and behaviours involved. At the time of data collection, prior to COVID-19, parents/carers were able to spend unlimited time with their child in PICU. They described experiencing heightened levels of anxiety and worry, in response to concern about the safety of their child, which was also reflected by previous research. Colville et al. (2009), Shudy et al. (2006) and Abela et al. (2020) suggested that the main stressors for parents/carers were the sights and sounds of PICU, the acuity and uncertainty about their child and changes within their role. However, this study demonstrated that fear and anxiety did not stop parents/carers from interrupting the medication administration process as three experienced parents/carers described their experiences of challenging and interrupting when they felt that their child's safety was at risk. Whilst parents/carers new to PICU did not describe actual situations where they had challenged a nurse administering an incorrect medication, they did highlight episodes where they had questioned nurses about why part of the process had been completed differently. Within this cohort of parents/carers the context of prior experiences may influence their knowledge and actions. In addition, this study suggests that those who have not been admitted to PICU previously also quickly recognise changes in practice and are confident to ask questions. In the wider literature that examines the parent/carer role in PICU, October et al. (2014) and Ames et al. (2011) suggested that parents/carers identified that they wished to advocate for their child's needs and require trust between themselves and the team. However, it is evident that current interventions to reduce interruptions to medication administration do not comprehend this mechanism within the parent/carer role. The interventions expect parent/carers to be quiet during the medication process, but this study has demonstrated that parent/carers can promote patient safety and prevent errors.

Within the context of delivery of care and treatment in PICU, the medication administration process contributes significantly to the workload (Dickinson et al., 2012). The findings from the MDT in PICU (Chapter 5) which included Consultants, Nurses, Physiotherapists, Pharmacists and support staff, suggested that nursing professionals experienced an administration process that was often interrupted. In contrast, the remaining members of the MDT acknowledged that they were observers of the process, although medical and pharmacy staff had a role in the prescribing of medications. Similarly, to all parents/carers, the MDT within PICU were able to comprehensively describe the medication administration process, suggesting they experienced occasions where they had been able to observe the actions and behaviours. However, despite their awareness that of the process and that it should not be interrupted to reduce the risk of errors, there were still occasions where other priorities took precedence such as competing priorities and the delivery of time critical treatments, thus reducing the effectiveness of the intervention.

In summary, the exploration of the empirical level illuminated both observable and experiential contexts. Medication administration as a context was noted to be a distinctive and clearly defined process. It has identified how interruptions are stimulated by location of the medication administration process, as nurses aim to support parent/carer stress/anxiety and provide continual observation of the child. Furthermore, this level has highlighted the novel context of parent/carer observation. Their ability to describe the process and their recognition of changes practice are impressive, suggesting that they have an important role in the delivery of patient safety within PICU. These complex issues have been explored and their impact on the effectiveness of current interventions discussed. Current interventions focus on the reduction of all interruptions, but this study has suggested that on occasion they are essential to maintain the safety of the child.

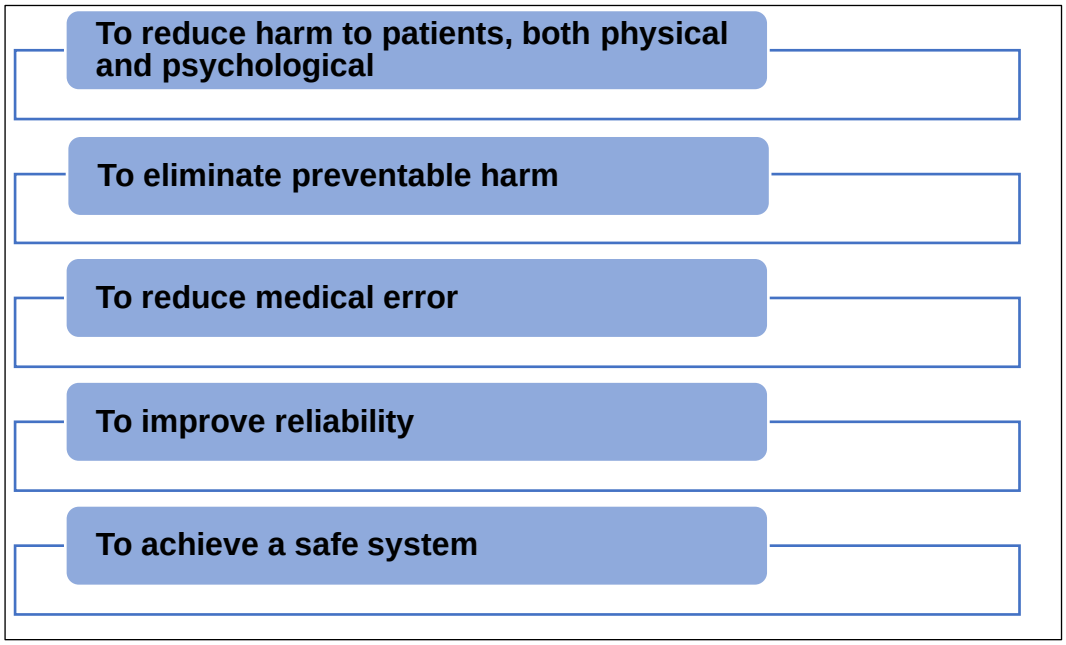
8.4.2 Actual Level – Protecting the Child

At an actual level, it is important to understand what is happening that may not be observed but that may regulate the empirical level (Walsh and Evans, 2014). Within the actual level, this study (see Chapters 5 and 6) identified that mechanisms such as patient safety and advocacy (see Figure 20), influence how and when interventions to reduce interruptions to medication administration work. Understanding the impact of these influences are important as patient safety and advocacy are important drivers

within the delivery of PICU care (Huynh et al., 2017, Butler et al., 2018). Moreover, these constructs can generate conflicting priorities for the individuals that can affect outcomes when using these interventions. A conflict in prioritisation between the delivery of medication and direct patient care has been acknowledged by Alteren et al. (2018) but this study has illuminated how this continues when interventions are in place. In addition, conflicts were highlighted by the nursing team (see Chapter 5) as they attempted to balance different patient safety strategies that they were required to deliver such as taking accountability handover at a time when medications have been prescribed.

The mechanism of patient safety is widely discussed within healthcare literature, with organisations such as the World Health Organisation (2020), the Institute of Medicine (Donaldson et al., 2000) and the NHS (Oikonomou et al., 2019), all of whom offer a similar definition of reducing preventable harm (World Health Organisation, 2020). Examining this definition more closely identified that the term patient safety was multifaceted, as described by Vincent and Amalberti (2016:4) who acknowledged five different elements (see Figure 20);

Figure 20 – Five elements of patient safety



The narrative literature review in Chapter 2 highlights an association between interruptions and medication errors, that may result in harm. Within this study the five elements of patient safety (see Figure 21) were acknowledged; nursing professionals

within the MDT described the impact of interruptions on medication administration whilst episodes of preventable harm from errors were described by three parents, suggesting more work is required to improve reliability and safe systems. It is acknowledged by World Health Organisation (2020) that all areas of healthcare are associated with a degree of risk and that patient safety interventions and strategies should aim to minimise preventable harm.

Within the field of patient safety, Vincent and Amalberti (2016) identify that there are many areas where strategies are implemented to reduce harm such as medication safety, surgical checklists, infection prevention and handover communication. This study demonstrated that multiple strategies (see Chapter 5) had been implemented within PICUs in England to reduce interruptions to medication administration. Interestingly, Vincent and Amalberti (2016) also acknowledge that there are very few successful and widely used patient safety interventions, thus indicating the difficulty of implementing robust processes within complex healthcare environments. Perhaps the updated review of the MRC Framework for Complex Interventions (Skivington et al., 2021) will help to make safety interventions more effective. This echoes findings from this study which demonstrated the difficulties faced by PICU teams to implement interventions to reduce interruptions to medication administration. As with all medical and nursing practice, Mitchell (2008) notes that there needs to be a proven evidence base to support the implementation of interventions to improve patient safety. In addition to this, healthcare professionals need to be constantly aware of new approaches and best practice (Woodward, 2016). This need for a robust evidence base requires input at an agency level, as professionals need to ensure their knowledge is current. Bindon (2017) highlighted that continued development of individual knowledge is the responsibility of the nurse, however, she also indicated that this can be hampered by organisational issues such as a lack of time. Therefore, the structures within the clinical environment need to support the continued education of nurses, particularly in the allocation of protected educational time.

In addition to the support of continual education, nurses need to build systems that encourage the use of an evidence base in practice. Renolen et al. (2019) found in their grounded theory study that the implementation of evidence-based practice required systems were required at both an individual and organisational level. Furthermore, the easier step was the formulation of evidenced-based guidelines, but it was more difficult

to see them in use in the clinical situation. Within this study, the findings in Chapter 5 suggested that interventions to reduce interruptions to medication administration were more effective in a PICU with a strong patient safety and quality improvement ethos. The patient safety and quality focus as outlined appeared to encourage the development of an evidence base that supported the use of the intervention such as the recognition in two units that interruptions occurred during prescribing and administration resulting in a collaborative approach within the implementation process. Additionally, without this underpinning analysis, interventions were not sustained as their impact was not evaluated and the results not shared.

Finally, at an organisational level they need to invest in the research and development of patient safety interventions. In addition to the awareness of what is required from agents, structures and organisations, Herepath et al. (2015) acknowledge in their realist analysis the importance of context when implementing patient safety interventions. This study also illuminated the importance of context which was an important finding as it demonstrates that interventions to reduce interruptions to medication administration need to comprehend everyday contemporary practice within PICU. In another study, Herepath et al. (2015) identified that interventions were adapted and influenced by values and beliefs within clinical areas. This was reflected within the findings of this study as the impact of interventions to reduce interruptions to medication administration was often affected by the values and beliefs of the individual's using them, particularly if the organisational culture of the PICU did not drive their use, therefore reducing the effectiveness of these interventions.

Exploring patient safety in PICU reveals that it is often measured by key performance indicators such as mortality rates, unplanned extubation numbers, medication errors, pressure area and infection levels (Shaikh, 2020). Many of these situations can be directly observed or indicated by the instability of the child. For example, in this study one mother, who had previously been admitted to PICU, described the cardiovascular instability caused by the administration of a medication, resulting in a cardiac arrest. In turn, these then generate alarms that are observed by healthcare professionals and parents/carers. The change in condition may stimulate a physical action from a member of staff or raise anxiety or stress levels within parents. Studies within the literature (Colville et al., 2009, Abela et al., 2020) about parent/carer experiences in PICU it was highlighted that parent/carer main anxiety on admission was a fear for

their child's safety. Similar findings were illuminated within this study concerning parent/carer fears of safety. In this study, parents/carers who were experiencing their first admission to PICU expressed feelings of fear and shock at the start of the admission. In addition, all healthcare professionals described the importance of the safe delivery of care to the critically ill child. There were, however, differences in perceptions of safety between healthcare professionals and parents/carers. For example, in this study, as a cohort healthcare professionals (nurses, consultants and pharmacists) equally cited patient safety as a rationale for decision-making. Whereas parents/carers expressed a need to feel that they and their child were safe in the intensive care environment.

One factor that limits the patient safety evidence and may have contributed to the difficulty of implementing patient safety interventions was noted by Vincent and Davis (2012), which was the lack of involvement of patients and families in the field. Daniels et al. (2012) identified in their study that of the 153 safety related events described by parents/carers, only 2.5% had been reported by healthcare professionals. Both these studies highlighted that parents or carers may have different perceptions of what constitutes a safety event. In this study, three sets of parents described safety events, but all indicated that they had been reported and investigated by the individual Trust incident reporting processes. Two of these parents/carers (who were long term admissions) described challenging practice and medication administration when they observed potential errors. This suggests that long term parents/carers could have a role in observing medication administration processes to help maintain the safety of their child. However, to deliver this challenge to ensure safety, it is possible parents/carers may need to override the intervention that aims to restrict interruptions. Within the cohort of parents/carers in this study it was those that had children with complex health needs or who were long term admissions in PICU that described overriding the intervention to reduce interruptions. To improve the effectiveness of these interventions they need to comprehend and encourage the development of parent/carer role in maintaining patient safety, not to override it. Micalizzi et al. (2015) have seen a two thirds reduction in patient safety events in PICU after the introduction of a parent/carer and healthcare professional partnership. This thesis has suggested that there may be a change in the balance of power as parents/carers seek to challenge and question healthcare professionals, helping to maintain patient safety. However, this change in power for parents is currently based in the real level within

critical realism as it is stimulated by a mechanism, currently this is often the experience of a medication error. A more equal balance would need to be seen within the empirical level, where healthcare professionals actively seek to demonstrate engagement with parents around safety. The introduction of this type of partnership would require a culture where safety is embedded.

Arguably, an essential part of being a children's nurse is to be an advocate for their patients (Spence, 2011). It is also noted by Spence (2011) that an important part of advocacy is having the knowledge, experience and power to act in the best interests of the patient, all of which applies to the maintenance of safety in the PICU. However, this study has raised the issue that there may be conflicting priorities between the best interests and safety of these patients when examining interruptions to the medication administration process. This was discussed by nurses, consultants and parents in this study who recognised there were occasions where the medication process was interrupted or stopped to allow the nurse to respond to an alarm, change in vital signs or patient movement. These actions may lead to confusion and conflict for nurses within their decision-making about maintaining the safety of their patient and this was acknowledged by both junior and senior nurses within this study. It is possible that parents/carers could have a role within this situation to help reduce conflicts. Within the literature studies have explored the role of parents and escalation when a child deteriorates (Gill et al., 2019, Gawronski et al., 2018, Colville et al., 2009), highlighting benefits of their involvement. Gawronski et al. (2018) identified within their qualitative study that parents were able to identify factors for escalations of care, making them trustworthy partners. Gill et al. (2019) examined escalation phone calls during a six-month period and found that in 12% of cases, parents had identified and expressed concern about deterioration. They identified that many of the parents who were escalating concerns were those who had children with complex conditions, indicating an understanding of their child's condition. However, it was also noted that positive impact could be limited by hierarchies, poor listening and lack of awareness, indicating the need for a robust implementation process and engagement from the organisation.

This study has demonstrated that interruptions to the medication process occur at times for important and valid reasons, but that current interventions to not comprehend the need for them to occur. However, the role of parents/carers within these situations has not been explored and may be beneficial to the safety of critically ill children which

is a novel finding to add to the evidence base. If harnessed constructively, this knowledge may enhance the safety of children within the PICU environment. This was particularly evident in this study as two parents/carers of children who were longer term patients or had complex needs, expressed a view about carrying on providing parental responsibility whilst in PICU. Carter et al. (2012) suggest that parents/carers of children with complex needs are used to being empowered to make decisions about safety at home. Furthermore, Greenway et al. (2019b) illuminated in their study that parent/carer knowledge was undervalued by the medical team. Interestingly, this finding was highlighted by parents/carers but not recognised by healthcare professionals. Within this study, parents/carers of long-term admissions or children with complex needs described sharing their knowledge as well as challenging practice and this may have contributed to patient safety as some challenged the 'paternalistic' delivery of PICU care and identifying a role as protector and advocate. Current interventions to reduce interruptions to the medication process in PICU do not acknowledge this developing role for parents, the expectation is that they see the red apron or sign saying, 'do not disturb' and parents/carers follow the instruction to sit quietly and wait. Whilst parents/carers in this study understood the rationale for not interrupting medication administration, they also recognised when interruptions were important. This study as well as Richards et al. (2017) illuminated that over time and with experience parents/carers may become much more active within their decision-making and behaviour and this contradicts the expectations of current interventions.

In conclusion, this section has synthesised the contexts, mechanisms and outcomes from the actual level in relation to the safety of the child. It has explored the concept of patient safety and the key structures that influence actions in practice but raised questions about the role of the parent/carer in the provision of patient safety. Currently, parent/carers roles in patient safety are not embedded and there is evidence both within this study and the literature to suggest that this needs to be explored further.

8.4.3 Real Level – Building the partnership within a safety culture

The real level within Critical Realism seeks to identify mechanisms that help to comprehend understanding of the actual and empirical levels. This study illuminated those parents/carers of long-term patients or children with complex healthcare needs demonstrate more in-depth knowledge. Furthermore, they would question/interrupt a nurse if they were concerned that their child's safety was at risk. This finding

contrasted with Richards et al. (2017) who identified in their integrative review, a power imbalance that can make it difficult for parents/carers to speak out. Within this study, the findings illuminated that parents/carers of children with complex healthcare needs or who had been inpatients on PICU for a longer period were able to describe situations where they had directly challenged healthcare professional's decision-making. With two parents explaining that their challenges were driven by an experience of a medication error that led to harm, that had been reported and investigated using the NHS Hospital Trusts incident reporting system (Howell et al., 2015). Importantly these actions of challenge sit within the real level of Critical Realism as they are unlikely to be observed until stimulated by prior experiences or feelings. This may suggest parents/carers that have no prior experience of PICU risk experiencing inequality in their due to their lack of knowledge about helping to keep their child safe. Whereas the experiences of parents/carers of children with long term and complex healthcare needs may already understand this concept.

However, at times the structure and organisations restrict this protection, as legal and ethical frameworks support the medical and nursing professions to act in the best interests of the child. Frameworks such as the United Nations Convention on the Rights of a Child (United Nations General Assembley, 1989), The Children Act (England and Wales) (Department of Health, 1992) could, however, challenge this control if parents were seen not to be acting within the best interests of their child. Auckland and Goold (2019) highlight those recent high-profile cases in the UK have included young children with complex disabilities where medical teams have thought that further treatment is futile. They acknowledge that parents/carers cannot have unrestricted control over decisions for children as they are vulnerable and unable to make decisions. The decision-making role is allocated to the courts in The Children Act but this does not appear to overtly consider whether best interest decisions are the safest. Moreover, Auckland and Goold (2019) also note that the families of recent children in the UK where courts have been involved in deciding care, are now fighting for the law to change so that it can only occur when parent/carer decisions are causing significant harm. The imbalance of power within this legal system supports a paternalistic delivery of healthcare that may restrict the development of effective collaboration with parents as the medical team is able to challenge and overrule parent/carer decisions. Additionally the principles of the Mental Capacity Act (Department for Constitutional Affairs, 2007) would be applied to young people over

the age of 16 years includes a family view of what is appropriate for the individual and their wishes. The parents/carers within this study identified that when their child was admitted to PICU their care and treatment was selected by the healthcare team. It is important to note that the administration of critical care is not without risk, as medications for instance may have dangerous side effects. This was also reflected by Scanlon (2014) who highlighted that preventable harm may occur for different reasons such as infections, medication errors and procedural complications. This illuminates that providing care that is in the best interests of the child may not always be safe. Thus, indicating that there is a power imbalance, with healthcare professionals having a significant number of legal structures to facilitate this.

The actions of healthcare professionals when directing treatment were often suggestive of a paternalistic approach, described by Fernández-Ballesteros et al. (2019) as a situation where the person or team with the superior knowledge make benevolent decisions on behalf of the patient. Paternalism is noted by Aycan (2006) to suggest a system where decisions are made within a hierarchical structure with an imbalance of power, as the superior person provides care and makes protective decisions. This study illuminated that at an organisational level some healthcare professionals need to make decisions that may be in the best interests of a cohort of patients but may compromise the safety of an individual child. An example of this was provided by one pharmacist who described needing to interrupt medication administration in order to meet the needs of patients in other areas. This impacted on parents/carers as their stay lengthened in PICU in terms of developing their knowledge and confidence to take part in discussions about the care their child received. Birchley (2014) also identified that plans of care are often discussed and negotiated with parents/carer as the child may be too young or incapacitated to be involved in any decision-making. This is particularly relevant within PICU where children are often sedated and intubated so are unable to contribute. However, he expressed a concern, that agreement between healthcare professionals and parents did not automatically result in a decision that was always within the best interests of the child, as decision-making in PICU often focuses on biological need when social or psychological need are also important. What this study found was that the situation of interrupting medication administration within PICU is complicated process. The lens of the nurse may conflict with the parent/carer.

As previously discussed in Chapter 6, parent/carer knowledge can be suggested to sit within a continuum. Those who were new to PICU also developed their knowledge and understanding during their child's stay, whilst parents with children with complex medical needs have significant levels of knowledge about their care and medications. Embracing this knowledge within a therapeutic relationship offers reassurance to parents/carers and enables them to continue to contribute to maintaining their child's safety as they would do prior to admission. This thesis illuminates' parents/carers as agents who may strive to protect, seek in-depth knowledge to support this and pick up subtle signs such as body language to inform their decision making. This aligns with recent research from palliative care and long-term families (Carter et al., 2012, Henderson et al., 2017, Mitchell et al., 2019a, Shapiro et al., 2017) that is demonstrating how parents/carers want to take more control for their child's care. A difficulty in achieving this was highlighted by Micalizzi et al. (2015) who outlined the difficulties healthcare professionals in PICU have in balancing the delivery of safe and efficient care alongside positive patient experience. From the synthesis of findings of this study parents/carers appeared to want to have a role in protecting their child. They sought assurance that their child was safe in the PICU where they were being cared for. This study and Colville et al. (2009) found that parents/carers were reassured by intense observation and monitoring. This demonstrated that the structure and organisation of PICU was important in helping parents/carers feel safe alongside the actions of individual agents working in the area.

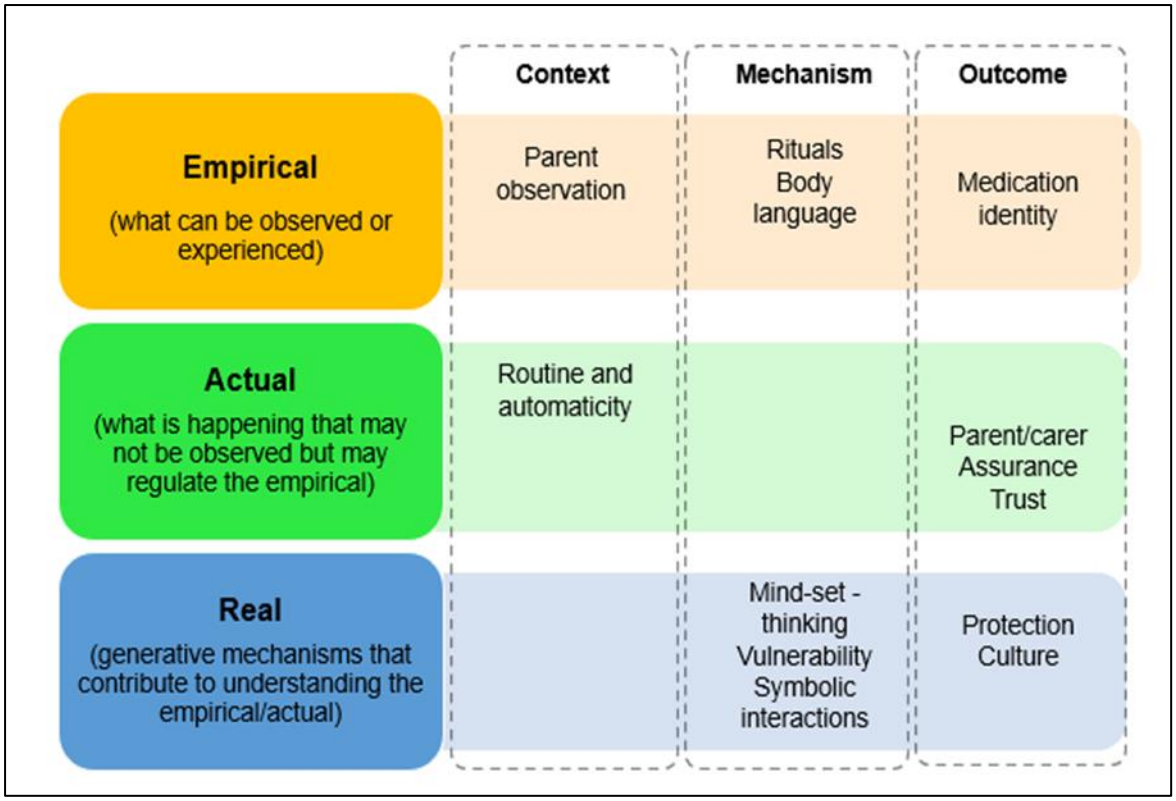
The aim of this study was to understand when and how interventions to reduce interruptions to medication administration work. Section 8.4 highlighted that the important circumstance that influenced the effectiveness of interventions to reduce interruptions to medication administration was the constructs of patient safety and advocacy within PICU. Furthermore, this study has highlighted that not all influencing factors are observable, and that research needs to highlight the complex hidden behaviours and actions that affect safety and medication administration in PICU. It is essential that nursing research seeks to understand how the behaviour and actions of parents/carers and healthcare professionals are influenced by unobservable mechanisms. Furthermore, if the unobservable mechanisms are not comprehended by interventions implemented within PICU then they will be less likely to be effective.

In conclusion, this theme has explored the context of safety in PICU using a Critical Realism lens. It has identified key mechanisms that relate to safety but that influence behaviour and actions that can stimulate interruptions to the medication administration process. Additionally, the section has identified how these unobserved mechanisms can decrease the effectiveness of interventions to reduce interruptions to the medication administration process. In the visible, empirical level the instability of the patient may be clearly observed. Currently patient safety within the PICU is weighted in the favour of the healthcare professionals which is supported by the legal frameworks that govern the country. However, this thesis has demonstrated the need for the development of a partnership between parents/carers and professionals as they have illuminated their role in the maintenance of the safety of their child. Currently interventions to reduce interruptions to medication administration do not allow this parent/carer role to be embraced and this should be considered for future work in this area.

8.5 Routines and Automaticity

The synthesis in Chapter 7 concluded with the presentation of four CMOC's, one of which related to the influence of routine and automaticity on the medication process as well as within interventions to reduce interruptions. The concept of routine and automaticity when examined by a Critical Realism lens illuminates elements within each layer that need to be explored and discussed and these are represented graphically in Figure 21

Figure 21 - The routine medication process



The Critical Realism layers in Figure 21 suggest that there are observable elements that agents can display such as the presence of a medication identity, use of ritual behaviour and different types of body language. This study demonstrated that both parents/carers and members of the MDT (Consultants, pharmacists and the physio) described a medication administration process that consisted of a set of actions that often occurred in the same order (see Chapters 5 and 6). Furthermore, two parents/carers noticed that the body language of nurses changed throughout the process depending on the action being undertaken. The structure in the actual level such as routines, automation, trust and parental assurance may generate or influence the behaviour of agents. Within the real layer the structures from the actual resulted in unobserved focused mindsets or feelings of vulnerability and anxiety. Within this study nurses recognised that the use of interventions to reduce interruptions could influence them to focus on the medication administration process. Alternatively, it could result in feelings of anxiety as the process was altered by the introduction of new actions. Exploration of the real level highlighted that these observable elements may also be influenced by unobserved mechanisms that sit within the real level such as symbolic interactions and culture.

8.5.1 Empirical Level - A distinctive routine

Within this study, the context of medication administration that was associated with a frequent and repetitive process in PICU and was acknowledged by all healthcare professionals to be distinctive. The process described by Consultants, Nurses and Pharmacists was more detailed about the structures that influence it such as medication administration policy. However, the Physiotherapist and support staff were able to describe their responses to key features such as the wearing of aprons and use of equipment. These key features were also acknowledged by all parents/carers from their observations. Furthermore, parents/carers who were in their first admission to PICU were able to identify this process from the key features. This data suggests that the outcome of this distinctive routine is that medication administration has a unique identity that is easily recognised within the MDT and by parents/carers. Suggesting that interventions that aim to reduce interruptions need to deliver more than making the medication administration process stand out, as both the MDT and parents/carers have demonstrated within this study that it already has its own identity.

This outcome of medication identity was informed within this study by the process being routine, frequent and repetitive, leading to a context where automatic behaviour and actions were used. Nurses, Consultants and Pharmacists described how it influenced their engagement with interventions that aimed to manage interruptions. They identified that if the routine was altered their ability to continue with their automatic actions and behaviour was affected and was likely to affect their engagement with the intervention. Although actions of routine and automaticity may be observed the influence of it sits within the real level of Critical Realism as it generates a mechanism that affects the individual's ability to engage with an intervention. Conversely, the presence of routine and automation was described by parents/carers to offer an assurance of safety and allowed them to identify the process of medication administration, which in turn helped to inform their actions and behaviour. The findings from this study suggest that the presence of a routine for parents/carers was important but for healthcare professionals involved in medication administration, changing the routine by adding in an intervention could decrease its effectiveness.

The context of routine within the medication process created challenges in the embedding interventions of interventions which was associated with both positive and

negative consequences. A positive consequence of disturbing the routine of medication administration, by adding an intervention, was a suggested a change in the mindset of the nurse that allowed an increase in focus on the process. Although within the NHS implementing change is can be challenging and not always sustained (Lachman et al., 2015). Conversely, a negative impact of disturbing the medication routine could was associated feelings of frustration and discomfort that would result in decreased engagement with the intervention making it less effective.

Ritualistic behaviour has been critically explored in many disciplines since the 1920's (Wolf, 2013) contributing to a comprehensive debate. It was noted by Greenway et al. (2019a) that rituals often display routinised behaviour that is not supported by knowledge or understanding. Whereas Laurent (2019) presents opposing perceptions of rituals where they are associated with a lack of thinking, alternatively offering a feeling of security and comfort due to their routine nature. Additionally, Bell (2009) suggests, rather than assume them to be a thoughtless action, think of them as a strategy for culturally acting within the world. Within nursing literature, Philpin (2002) acknowledged that the examination of rituals can offer a rich insight into actions and behaviours. An area of practice within this study that may be perceived as ritualistic is the use of the 'Five Rights of Medication' (Martyn et al., 2019) as nurses, consultants and pharmacists described its regular and routine use in the administration process. Manges and Groves (2019), who note that rituals are repeated episodes of symbolic actions and often include taken for granted behaviours. Furthermore, they may contribute to the maintenance of social structures, demonstrate values and identity, as well as connect the individuals to the larger organisation. Interestingly, Hobson et al. (2018) note that rituals must have a purpose or meaning, and this is what distinguishes it from a habit.

The medication administration process has been identified by Wolf (2013) as a therapeutic nursing ritual that is highly visible. Critical realism situates this process within the empirical level as an observable experience. Within this study the nursing and pharmacy professionals alongside parents/carers, described the visible routine that included set actions and equipment to highlight its beginning. Parents/carers particularly commented on the two-check process that was involved in medication administration. This recognition of a widespread policy driven practice indicates how the context of medication administration ritual is organisationally and structurally

driven, rather than at an agency level. This was acknowledged by participants who identified the impact of culture and leadership within the PICU environment. The pharmacists and consultants within the study described the importance of nursing leadership when embedding and engaging with interventions. Whereas parents observed and acknowledged the impact of both the senior nursing (nurse in charge, matron or ward manager) and medical team (consultants) in the planning and delivery of medication and the management of errors.

The impact of rituals has been linked within the literature to positive and negative unintended consequences. This was acknowledged by Wolf (2013) and Bourgault and Upvall (2019) who explored the impact of rituals within nursing. Wolf (2013) indicated that positive views of ritualistic behaviour suggest that they may allow the sharing of traditional knowledge and contribute to the formation of a group identity as well as relieving anxiety. Whereas, Rubio-Navarro et al. (2019) suggest that rituals may develop in pursuit of efficiency. However, if the theory of symbolic interactionism was added to the concept of rituals it would illuminate the importance of all stakeholders understanding or interpreting the meaning behind it. If the meaning has been misunderstood, then behaviours that react to the ritual may be incorrectly influenced. Conversely, negative views suggest that rituals may be viewed as inflexible preventing the future development of nursing practice. This was identified by Zeitz and McCutcheon (2005) in their discussion of evidence-based care, as they acknowledged that routines and rituals were driving the delivery of care rather than professionals using their clinical judgement. This may suggest that as agents' nurses were following a routine organisationally developed process rather than using their clinical knowledge to assess and make a plan of care. However, within this study it was evident that all nurses were aiming to follow organisational structures such as accountability handover, 'Five Rights' of medication administration and positive patient identification, however, when interruptions occurred, they were unplanned, and the individual agent was required to make a clinical decision on how to respond.

The perceived effectiveness of these interventions also required engagement from the whole team, including families and visitors to enable it to work. Yet in this study, overall parents/carers described minimal information being shared about the medication process or interventions to reduce interruptions. This restricted their ability at an agency level to adhere to the expected process as they were not able to apply any

meaning to the behaviours they were observing. Although at an empirical level they were able to collate information from the visible elements of the process. Twelve parents/carers in this study were able to describe anticipating some of the more hidden mechanisms such as creating a focused mindset as they observed subtle changes in body language and made assumptions that these professionals would not want to be interrupted. The positive identification of body language used by staff is in contrast to Colville et al. (2009) who found that some parents/carers highlighted a use of inappropriate body language. It is possible that an intervention that includes the routine focused mindset would be respected by parents/carers if they are able to recognise it and understand the rationale for using it.

The discussion in this section has situated the observable actions and perceived experiences identified within the medication administration process relating to routine and rituals within the current literature. The presence of routine was noted to have both positive and negative consequences. Routines helped parents/carers to interpret actions and behaviours and to understand the care that was being delivered to their child. However, for nurses making changes to the routine was difficult to implement and sustain. The impact of ritualistic practice was also discussed noting that structures within other Critical Realism levels and impact on observable behaviours and actions.

8.5.2 Actual Level - An automatic process

The following section will critically discuss the contexts and outcomes that were identified as important within the actual level whilst examining their impact on the behaviours and actions of healthcare professionals and parents/carers. The Survey of Practice (see Chapter 5) indicated that at an agency level, nursing and medical professionals viewed the medication process as an important part of patient safety. This was also acknowledged by Wolf (2013), Magalhães et al. (2019) and Bucknall et al. (2019) who concluded that this was a high priority process, contributing to the development of trust between patients and nurses. Within this study parents/carers highlighted how trust within the relationship decreased if medication errors were made, particularly if there was a lack of transparency. Trust was not illuminated within the healthcare professional findings; their focus was often affected by structural events such as the delivery of timely and efficient care. The findings within this study illuminated that engagement was significantly affected when the intervention was seen or perceived to interfere with workflow. Furthermore, isolating medication

administration as an individual process was counterintuitive to the principles of Family Centered Care (Uniacke et al., 2018) and the delivery of holistic nursing care that are important elements within nursing.

The repetitive nature of medication administration, that was described in this study in Chapters 5 and 6, can lead to repetition that can then create automatic actions within the process. Toner et al. (2015) described automaticity as being associated with actions that are fast and stimulus driven and are characterised by a lack of attention, intention and awareness. In contrast, they note that controlled behaviour is believed to be slow, conscious and effortful. In this study nurses described a process where the actions taken were repetitive, however, when an intervention was added to the process it slowed this down as they needed to think about the next steps, this conscious decision making is often perceived to be disruptive to an efficient performance (Wheatley and Wegner, 2001, Toner et al., 2015). The use of automatic behaviour increases as the individual becomes more experienced with the skill or process, Toner et al. (2015) highlight that ultimately it requires less and less attention until it becomes automatic. This study illuminated that this was relevant to PICU as the routine use of medications such as sedation and analgesia, alongside the high volume allows nurses to become skilled and expert in the process. Therefore, they are more likely to develop the use of automatic skills and they may become so familiar they are no longer aware of it. However, within the study twelve parents/carers noticed an undulating automaticity within the process as they observed the body language of nurses who demonstrated a focused stature when checking calculations as opposed to a more open observational stance when preparing medications. Their observation of this undulating automatic process contributed to their decision-making process when choosing when to interrupt. Close observation of individual behaviour may allow automatic behaviours to be observed within the empirical level. However, the automatic process may resemble a routine being followed. The observable difference when automaticity is seen is the ability to complete physical tasks without thinking and focusing on another person/behaviour/action (Wheatley and Wegner, 2001). This phenomenon was highlighted by both healthcare professionals and parents/carers within this study.

The influence of automaticity is seen at an agency level as repeated actions stimulate intuition to be used where the individual becomes so familiar with the process that they

understand something instinctively without the need for reasoning. This is seen in sports professionals as an expert performance as they can instinctively predict future moves or actions (Wheatley and Wegner, 2001). However, this may lead to 'inattentional blindness' where cues are missed and mistakes may be made (Toner et al., 2015). The lack of adherence to policy was acknowledged by healthcare professionals within this study. It is possible that the automatic elements within the medication process reduce the individual's awareness to the rules and they may not be aware of their lack adherence. Within this study the positive effect that interventions can have to enable the individual to focus was highlighted by studies in the Realist Review and nurses in the MDT interviews. Feldon (2007) highlighted that mindfulness is thought to improve attention and focus whilst suppressing interfering information and de-customising automatic responses. If individuals can inhibit automatic actions, they may be able to retain flexibility to react to different circumstances therefore, finding a balance between thought and automation. It was suggested within this study that the use of an intervention such as a red apron or tabard offered that moment of thought to focus on the medication process and the actions required within it.

Within nursing the seminal Intuitive-Humanistic Decision-Making Model suggested by Benner (1982) outlines the impact of experience and knowledge on clinical decision-making. The model suggests that the delivery of safe care requires technical expertise, critical thinking, experience and clinical judgement. To achieve this, nurses require access to continual learning and need to have professional accountability, independent and interdependent decision making and creative problem solving. Within this model there is a lack of information about the impact of automatic behaviours on clinical decision-making. Furthermore, it was difficult to examine the impact of experience within the findings of this study as the recruitment methods resulted in a sample that did not include junior nurses.

The synthesis within this study acknowledged that within the context of medication administration at times nurses accepted interruptions and did not always follow policy or use interventions. Whilst it is acknowledged in the literature that medication administration is a ritual (Wolf, 2013) in this study the interventions to reduce interruptions had not embedded so were easier to challenge or ignore. The findings of this study suggested that they perhaps had a wider awareness of the situation and realisation that there were occasions where interruptions occur to maintain the safety

of the patient(s). This was described by nurses who were team leaders or in charge of a whole PICU who spoke about the need to manage flow or support junior staff manage their patient. In addition, the synthesis in Chapter 7 also suggested that decision-making may be overwhelmed by contextual factors such as patient instability, busyness and expectations to deliver timely and efficient care. This may contribute to the use of automatic actions as the healthcare professional tries to manage multiple different urgent decisions at the same time.

The novel inclusion of parents/carers within this study highlighted that often parents/carers in the study made decisions about interrupting, especially if they had prior experience. There was one father who did not describe an active decision-making process, he was experiencing his first admission to PICU and accepted that healthcare professionals were behaving appropriately. These findings and the current literature (Mayan et al., 2020, Edwards et al., 2018, Da Silva et al., 2017) have recognised a novice to expert process for parents. Less experienced parents/carers described a rationale based on an observation that identified actions were different to last time. Whereas more experienced parents/carers within the study were able to narrate a more complex decision-making process where experience and knowledge informed it leading to them challenging practice rather than purely interrupting. However, within the healthcare professionals' findings there appeared to be no recognition of this parent/carer decision making process. Recognition of the knowledge and rationale of parent/carer decision-making is important as it contributes to understanding interruptions from their viewpoint.

The outcome of trust and assurance for parents/carers was identified as important within this section, as it was negatively affected by medication errors. Thus, demonstrating the importance of improving medication administration safety. Nurses were noted to be medication administration experts in PICU due to the frequency and volume of the workload. Understanding the impact of this frequency on the use of automatic behaviour is important. This was recognised by nurses in their descriptions of the process whereas, parents/carers observed an undulating automaticity dependent on the action being undertaken within the process. Understanding these novel contexts and outcomes are important in the development of future interventions to reduce interruptions to medication administration.

8.5.3 Real Level – Actively thinking

The real layer within Critical Realism seeks to identify unobservable mechanisms that influence or explain the actual and empirical layers. Within this study, reactions were generated by the medication administration process and the interventions used to reduce interruptions. On occasion the interventions were perceived positively by nurses, as they acknowledged that they could create the mechanism of a focused mindset. An individual's mindset was acknowledged by Buchanan and Kern (2017) to relate to their underlying assumptions that allow them to perceive and understand the world. They also describe how the influence of a mindset cannot be ignored but that it can be changed. In contrast to a positive mindset, other nurses, pharmacists and consultants revealed negative feelings like discomfort and embarrassment. These feelings were hidden and stimulated by certain structures such as the implementation of interventions such as wearing a red tabard or headphones. When interventions were implemented to try to improve medication safety, medical and nursing professionals were more responsive to the negative feelings, such as discomfort or embarrassment, that were stimulated. Although triggered by structures within the actual, these reactions sit within the real domain of critical realism as they are stimulated by events within the real world but are not observable. Ultimately nurses acknowledged that if they viewed the intervention to have a positive impact by creating focus, they were more likely to engage, however, if negative feelings of were generated there was a decrease in engagement.

The association of rituals and vulnerability has also been highlighted by Hobson et al. (2018) who propose that ritualistic behaviour is associated with emotional deficits. They suggest that rituals are more likely to be used when individual agents experience an undesired emotional reaction. The use of a ritual helps to cope with any anxiety produced by this reaction, as their attention is directed away from emotions (Brooks et al., 2016). Nurses within this study alluded to the impact that making a medication error had on professionals, as these individuals were reported to be more likely to adhere to a routine. It is perhaps this emotional response to the possibility of making an error that has resulted in the 'Five Rights' becoming embedded within nursing practice (Wolf, 2013). It has a purpose of protecting the patient and implies that it helps to relieve the anxiety that errors making may raise. However, Martyn et al. (2019) acknowledge that there is limited evidence to prove that the 'Five Rights' process has reduced medication error. It is interesting to apply this theory of protection and lower

levels of anxiety to the interventions to reduce interruptions and the difficulty that many PICU's had in implementing them.

Zeitz and McCutcheon (2005) also highlighted that in an ever-increasing medico-legal world the use of rituals can offer security to professionals. Wolf (2013) identified that the use of nursing rituals within medication administration, offered nurses a sense of protection. This ritual has dominated the medication process for nearly two decades, however, Martyn et al. (2019) notes that its effectiveness remains unknown. This debate was reflected in this study, the number of reported medication errors remains high in PICU (Alghamdi et al., 2019), but all nursing and pharmacy professionals within the interviews in the study highlighted the 'Five Rights', which was discussed in Chapter 2 (Section 2.2), as a dominant method that guides the medication process. The use of this ritual as a protective measure may contribute to the difficulties clinical areas face when trying to implement changes, as the removal of the routine may expose a vulnerability. This may demonstrate an imbalance of power within an organisation as the implementation of processes that do not comprehend the routines already in place may expose an unexpected vulnerability within the workforce. Lazar (2018) acknowledged this relationship within organisations, emphasising the importance of leaders being aware of vulnerabilities experienced by their colleagues. These feelings may be deeply hidden and only activated when generated by a change in routine.

Within this study the findings suggested that when interventions were sustained, the whole MDT within PICU were involved and able to support its use. To enable nurses to use the intervention effectively, it was identified that the wider nursing and medical team needed to support the ongoing delivery of care. The delivery of ongoing care was commonly allocated to other nurses, however one nurse described how medical colleagues would observe the child whilst they prepared and administered medication. Although other members of the PICU team, such as the pharmacists and physiotherapist were not always able to support the intervention due to them having competing priorities such as the delivery of patient care in other areas in other clinical areas. These competing priorities would influence them to override the existing PICU interventions resulting in an increase in interruptions and reduced engagement.

The novel inclusion of parents/carers within this study highlighted the detailed awareness of their child's issues but showed that they were not always included in the development of interventions relating to reducing interruptions to medication administration. Furthermore, parents/carers reported that they were rarely informed about the use or change of interventions. Overwhelmingly, this study showed that parents/carers were able to clearly narrate the medication routine and were able to articulate subtle changes in behaviours. They outlined in the interviews that this was their child and the intensive nature of the PICU meant they were in a prime position to observe behaviours but reported that they tried to avoid interrupting the process. However, seven parent/carers reported that they would interrupt if they felt the safety of their child was at risk of compromise. However, many claimed that if they had to, they would if they felt the safety of their child was at risk of compromise. Sundal (2019) concluded within her phenomenological study that nurses must be aware of the competence and parent/carer contribution in the delivery of care to hospitalised children to ensure a collaborative partnership that is more equal.

When considering parent understanding of actions taken by healthcare professionals, Symbolic Interactionism may offer additional understanding. Symbolic Interactionism is a sociological theory that aims to understand how individuals interact to understand and create a world (Carter and Fuller, 2015). Furthermore, it aims to understand how society is created and preserved with the interpretation of interaction creating meaning. Individual actions, interactions and behaviours are influenced by these shared meanings. Symbolic interactionists believe that reality exists due to the individual definitions of social interactions and people react to this understanding of reality (Carter and Fuller, 2015). In his work, Blumer (1962) bases the theory of symbolic interactionism on three assumptions; firstly, that individuals construct meaning via a communication process. Secondly, that self-concept is a motivation for behaviour and finally there is a unique relationship between the individual and society. In his summary of symbolic interaction, Denzin (2016) suggests that it offers a theory of action, meaning, motives, emotion, gender, race agency and structure. It also highlights the individual understanding agents have of their reality and that these personal meanings influence reactions and behaviours. Application of this theory to the medication process in PICU enhances the importance of prior experience. This study showed that if parents are new to the environment, they will need to place meaning to new objects, interactions and concepts within PICU, whilst dealing with the

shock of their child being critically ill. This study also showed that whilst some parts of the medication process are symbolic and visible on an empirical level, parents/carers need to assign a meaning of focus and concentration to the process to be able to understand the need to minimise interruptions. Structures identified in this study that could influence the meaning assigned to this process such as the sharing of information about medication and the need for minimal interruptions. However, this study demonstrated that this rarely occurred.

The synthesis of findings drawn from this study highlighted that teamwork is a fundamental element within healthcare. The role of the MDT within the implementation phase of this complex intervention was perceived as critical. The synthesis identified that for the nursing staff involved in medication administration, interventions to reduce interruptions could be viewed positively, as they could create a calm environment, which enabled them to focus and concentrate. However, for this to occur the study identified that the rest of the team needed to protect this time and provide the nursing care and communication required by the patients and other professionals. Ultimately, the study recognised that this requires a relationship within the team based on trust, (Costa et al., 2018) which if not present negatively impacts on the effect of the intervention. The findings generated within this study contributes significant knowledge of observable and hidden mechanisms that influence the engagement of staff within interventions to reduce interruptions to medication administration. However, it is more focused at an agency level and this study has identified the significant impact of structural and organisational influences and actions. This study has demonstrated the need to understand the culture, contexts and structures that interventions are influenced by, and these should be comprehended prior to implementation.

In this study the empirical data showed that the designs of the intervention were occasionally informed by theory or a review of pertinent literature and its application to the individual context of the unit. Within this study it was frequently recognised though, that professionals described the transfer of an observed intervention elsewhere into their unit without any consideration of the contexts or hidden mechanisms that may affect its implementation. Only three units with an embedded safety team acknowledged the need to understand the interruptions prior to implementing interventions. This demonstrates the novel contribution that this study

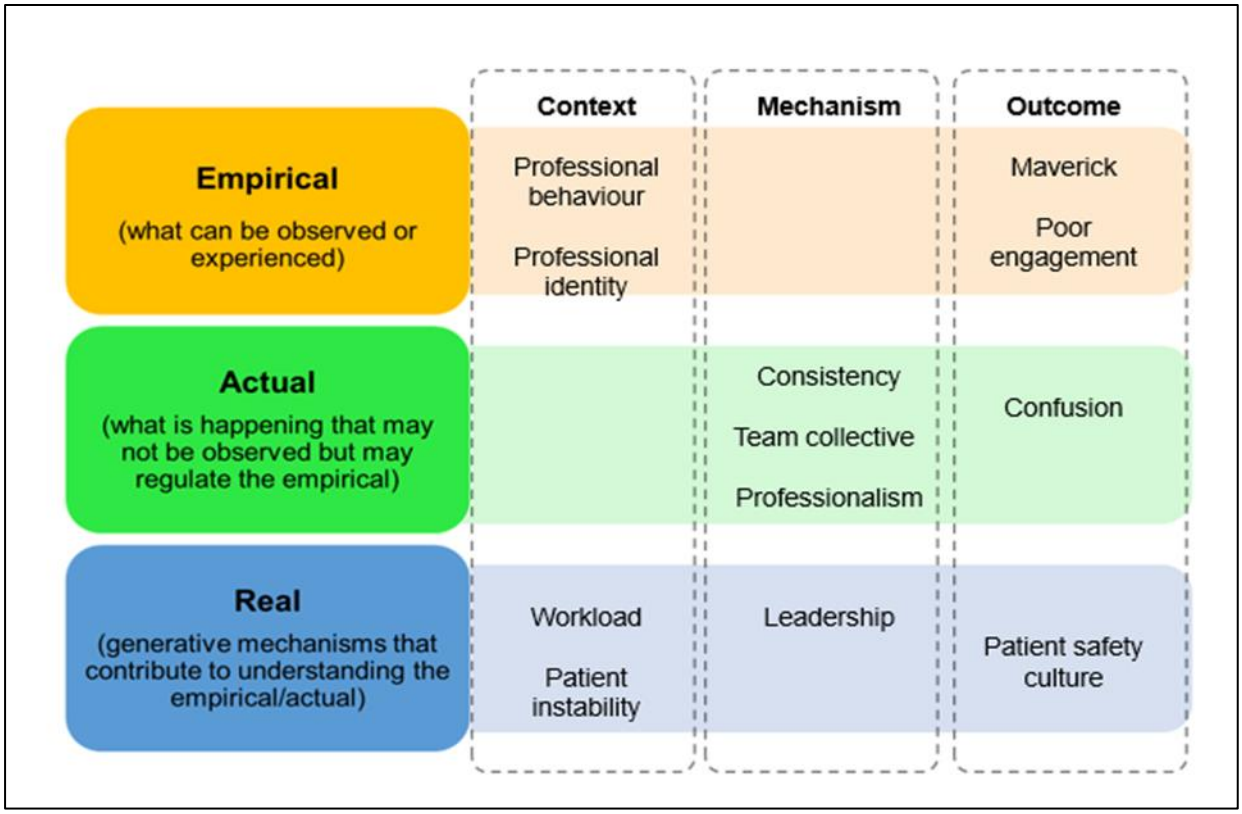
has made to the evidence base by highlighting the hidden mechanisms within the actual and real levels of critical realism that can influence behaviour when these interventions are introduced. However, despite this, there was a common purpose which was to reduce interruption rates to medication administration and by an assumed association reduce medication errors. It is frequently debated within the literature whether interruptions directly cause increased rates of medication errors. Johnson et al. (2017) and Westbrook et al. (2010) have used non-participant observation to demonstrate an association between interruptions and procedural failures. In contrast, reviews Thomas et al. (2017) and (Raban and Westbrook, 2014) find it difficult to prove a direct link between interruptions and errors. In this study the purpose of these interventions was frequently linked to structural and organisational goals to improve patient safety and rates of medication errors. As outlined in the introduction to this thesis (Chapter 1), there are strong drivers from both national and international organisations (Donaldson et al., 2017, Elliott et al., 2018) to reduce medication errors within healthcare. This thesis suggests that although standardisation in process can be effective, in complex areas such as PICU the understanding the context is important as it may significantly influence the effectiveness of an intervention.

In summary, section 8.5.3 has critically explored the impact of routine and automaticity on medication administration. The use of a Critical Realism lens has illuminated the hidden structures that can influence behaviour such as culture and symbolic interactions. The novel inclusion of parents/carers illuminated the importance of routine as it enabled them to interpret the actions and behaviours of healthcare professionals. This study illuminated an active parent/carer decision-making process informing their actions when deciding to interrupt. This is not comprehended in the design of current interventions to reduce interruptions but is important for future development. Finally, the analysis identified several unobservable feelings that may be stimulated by routine and automaticity such as vulnerability and anxiety and the protection that the use of rituals may offer. By illuminating these unobserved feelings, the impact of implementing interventions to reduce interruptions helps to understand their impact and why they may not be effective in practice.

8.6 Professional behaviour

The theme of professional behaviour was identified and explored within both the finding's chapters (4,5 and 6) and the synthesis (section 7.2.1). Drawing from the findings of this study, this section will discuss the impact of professional behaviour within the medication process, its influence on interruptions and their management. This Critical Realism analysis of professional behaviour has been graphically represented in Figure 22.

Figure 22 - Critical realism and professional behaviour



The Critical Realism analysis has illuminated contexts such as professional identity and behaviour, workload and patient instability. As well as mechanisms of consistency, professionalism and leadership. Both of which impacted on the outcomes of not adhering to policy or being a maverick, poor engagement, confusion and creating a patient safety culture.

8.6.1 Empirical Level – Observing inconsistency

Within this study the behaviour of healthcare professionals was clearly observed by parents/carers, who acknowledged a lack of consistency in actions. When this mechanism of inconsistency was noted by parents it stimulated them to interrupt to clarify why actions were different to previous episodes. Parents/carers quite clearly described observations of inconsistency suggesting that this behaviour was easily identified. This was surprising due to the repetitive acknowledgement of the 'Five rights of medication practice' described by both pharmacists and nurses within the study. This suggests that either the five rights processes do not fit with contemporary nursing practice or the culture within PICU allows inconsistent and autonomous actions to be taken.

Whereas other professionals described a lack of adherence to policy or behaviours that may not have been considered as professional. An example of this was the pharmacist who had observed conversations about personal plans. At an agency level Willetts and Clarke (2014), Hoeve et al. (2014) and (Andrew, 2012) acknowledge that professional identity is defined by the values beliefs that guide thinking and actions. The Realist Review identified that one of the core values for nurses was being available to patients and the implementation of interventions to reduce interruptions to medication administration prevented this as they could not respond to their needs. Furthermore, within PICU the nurses in this study emphasised the need for them to be able to be responsive to any instability in the patient which was also observed by parents/carers. Two units had negated this by using a central medication station and emphasised the need for teams to work together to provide care whilst nurses were away from the bedside preparing medication.

Within the findings of this study a lack of consistent behaviour within the process of medication administration was highlighted by both MDT and parent/carer findings. However, professional behaviour is also affected by structures such as culture and leadership suggesting that if a lack of adherence to policy is accepted as normal within the clinical setting this may influence the actions of individuals. This is associated with culture and leadership being vital in every PICU, as this study suggested that units with clear leadership were shown to challenge, monitor and re-visit practice that was thought to improve medication administration. A theory that acknowledges the impact of the influence of the group is social identity theory, as it suggests that an individual's

sense of worth is influenced more by social groups than it is by personal identity (Mavor et al., 2017). Furthermore, Tajfel and Turner (1979) suggested that belonging to group can provide a sense of self-esteem and pride and a sense of belonging to the wider social world. Once a member of this group the individual may be influenced by or adopt the identity of the group to which they feel they belong as it can structure their thoughts and behaviours, affect how they may feel and what they say and do (Haslam et al., 2019). Willetts and Clarke (2014) suggest the use of social identity theory as a lens through which to understand professional identity in nursing. They found that nurses felt a sense of belongingness and identity when joining the group. Within this study the findings suggest that professional behaviour is an important part of the social identity, otherwise inconsistent behaviour stimulates confusion and increased interruptions. Is important that the social identity of the PICU team, has professional behaviour at its heart.

In summary, this discussion of factors identified within the empirical level has illuminated the impact of the mechanism of inconsistent practice. This has not been discussed previously in the literature concerning interventions that reduce interruptions to the medication administration process. Parents/carers and the MDT have identified the significant impact that inconsistent practice has on their behaviour as they seek to understand why different actions may be taken and whether it is a risk for their child. The literature suggests that creating a culture with an emphasis on professional behaviour with strong leadership may be beneficial within the development of future interventions.

8.6.2 Actual Level - Influencing the mavericks

Within this study Consultants, Pharmacists and parents/carers acknowledged that there were inconsistencies in some nurses' actions within medication administration, which resulted in the outcome of confusion. This was suggestive of a lack of adherence to medication process as there should be limited inconsistencies if it was followed. Furthermore, this study illuminated the influence that leadership and culture had on professional behaviour, as these were noted to contribute to what was accepted practice within the PICU. It was suggested within Chapter 5 that some professionals may be mavericks, choosing not to follow policy as it did not fit with their individual goal setting.

Hofmann and Jones (2005) highlighted that the team behaviours can lead to the production of structural norms within a team creating a collective personality and that as these are shared with new members of a team this should result in consistent behaviour. However, as noted previously, this study has highlighted there was a lack of consistent behaviour within PICU. It was also noted by Hofmann and Jones (2005) that collective behaviours more likely to be influenced by external factors such as leadership, particularly in newer teams. In all acute inpatient settings including PICU the participants within the team delivering care change daily, resulting in the frequent establishment of new teams. This highlights the important influence that organisational leadership has within PICU as well as shift leadership roles. It is essential that all levels of leadership share the same collective identity that will help generate consistent behaviour that will help to reduce interruptions.

The collective identity of a PICU team may also be influenced by the concept of professionalism. A simple definition of professionalism is 'the competence or skill expected of a professional' (Soanes and Hawker, 2005, Hoeve et al., 2014, Kaya and Boz, 2019). However, the complexities of this concept have been highlighted by Burford et al. (2014), Yoder (2017) and Kaya and Boz (2019) who suggest that are three elements of professionalism; individual, interpersonal and organisational. At an individual level the concept of professionalism is influenced by personal beliefs and identity, including high standards of competence and knowledge. Interpersonal concepts related to consistency in behaviour, communication and showing humanism. Whereas the organisational factors were influenced by the norms and values of the workplace. This was further discussed by Ravani Pour et al. (2014) who suggested four views of professionalism (see Table 38).

Table 38 - Viewpoints of professionalism (Ravani Pour et al., 2014)

Following on from this study, Ravani Pour et al. (2014) suggested that contextual variables influenced individual perceptions of professionalism. Within this study parents/carers were influenced by actions and behaviours they could observe; consistency, body language, and leadership that challenged standards. Whereas the nurses, consultants and pharmacists were predominantly influenced by standards and organisational beliefs, with personal values not being explicitly discussed. However, it was suggested by senior two senior nurses and a pharmacist that individuals chose not to adhere to policies and standards or follow processes within interventions to reduce interruptions. These findings suggest that the importance of consistency within professional standards is either not recognised or embedded and that personal choices override interventions.

In conclusion, this section has critically discussed the context, mechanisms and outcomes identified within the actual level of this theme about professional behaviour and their impact on when interventions to reduce interruptions to medication administration work. The section has highlighted individual, team and organisational structures that can increase and decrease the effectiveness of these interventions. Current interventions do not always address these structures from these different viewpoints, therefore do not address key mechanisms such as professionalism and team behaviours that are important in ensuring these interventions are effective.

8.6.3 – Real Level – Influencing professionalism

It has been identified in Section 8.6.1 some nurses have choice in managing their own actions, for maintaining their professional identity. However, there are elements within the structure of the unit that may sit within the real level in Critical Realism, that stimulate responses that may result in unprofessional behaviour, for example, culture, time pressure, unpredictable events and workload. However, it was also acknowledged by nursing and pharmacy participants that these structural stimuli can become excuses over time for shortcuts/unsafe behaviours to become the norm.

Within the actual level individual decisions and choices are hidden but may be describable. These may be influenced by mechanisms within the real level such as role-modelling or leadership. Alternatively, hidden mechanisms such as culture, time pressures, conformity, peer pressure may stimulate certain behaviour.

Structures within the real level that could influence professionalism were culture, leadership, team behaviour and motivation. This indicates the influences that are present at agent, structural and organisational levels. These influencing structures could contribute to positive personal or team identities, or if they are not in place lead to confusion for those trying to interpret behaviour.

It is suggested within literature that there are personality traits associated with rule following and decision-making. In the wider psychology literature researchers (de Boer and Zandberg, 2013, Fiddick et al., 2016, Funke et al., 2019) have found that participants who score highly for in the personality traits of neuroticism and conscientiousness were more likely to follow rules and procedures. Within nursing Drach-Zahavy and Srulovici (2019) found that four personality traits: conscientiousness, agreeableness, openness and neuroticism were significantly associated with accountability and were less likely to miss elements of care. These studies are suggestive of the need for different approaches to the management of personality traits in clinical areas. Within this study it was highlighted that there was no work within any intervention to address different personality types, each one was a 'one size fits all' approach.

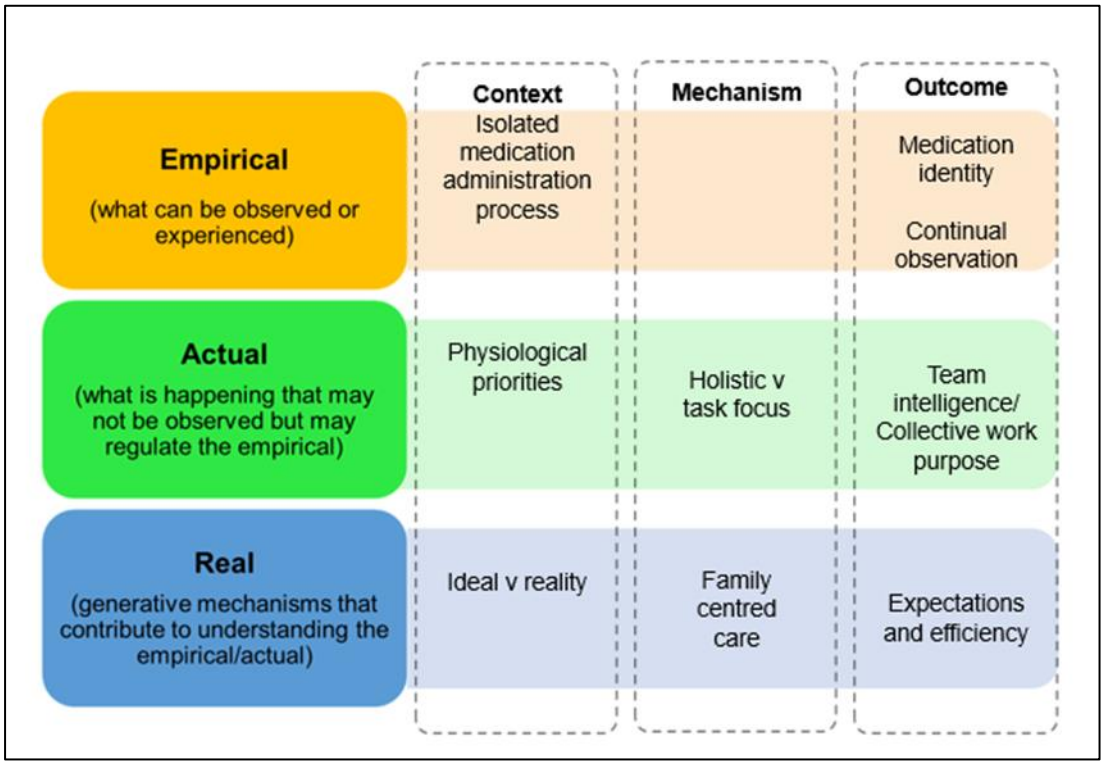
In summary, this section has used Critical Realism to critically examine the impact of inconsistent and unprofessional behaviour on the medication administration process in PICU. It has identified structures that may improve and deliver positive professional and team identities. As well as outline the impact of inconsistent behaviour.

8.7 Isolating the Medication Process

This study illuminated a theme focusing on the isolation of the medication administration process (see Figure 23) and the ability of healthcare professionals being able to deliver this. In contrast to the empirical studies within the Realist Review (Chapter 4) where medication rounds were often undertaken, the findings in Chapters 5 and 6 clarified that within PICU's in England the medication process was completed

for individual patients at the bedside in all units except for two, where a central medication station was used.

Figure 23 - Critical Realism, medication administration and isolation of role



The diagram in Figure 23 outlines the Critical Realism analysis of this theme and embeds the CMO's identified in the synthesis at the end of Chapter 7. The contexts focus on reality of medication administration in PICU and its position in relation to other variables such as physiological instability. The identified mechanisms are associated with the structures that influence the delivery of medication administration in PICU. The final column identifies the outcomes that were generated from the contexts and mechanisms within this theme.

8.7.1 Empirical Level – The challenge of isolation

Organisational guidance within the national standards (Paediatric Intensive Care Society, 2015) indicate that intubated and ventilated children require one-to-one care

(see glossary for definition) to ensure constant monitoring and observation are delivered. This requirement has resulted in a context where nursing teams in most units in this study completing medication administration at the bedside. As a result, the findings from this study indicate that nurses were seen (by the MDT and parents/carers) to respond to alarms from ventilators and monitors and to attend to children who may be awake and moving whilst preparing medication. Furthermore, nurses were unable to completely detach from their responsibility of providing continual observation of the child reducing their ability to focus completely on one process. Yet the design of interventions to reduce interruptions to medication administration have been developed using the Sterile Cockpit theory (see Chapter 2) which requires the individuals' attention on one task. This conflict between practice and intervention design reduces its effectiveness as nurses find it challenging to work in this manner.

It was evident both within the Realist Review and the empirical study that interventions to reduce interruptions prioritise the medication process and attempt to isolate it from other aspects of nursing care. The term nursing care, is itself a complex phenomenon, a concept analysis by DalPezzo (2009) identified the following definition which illuminates the multiple elements it includes:

'Nursing care is a skilled, safe, high quality, holistic, ethical, collaborative, individualized, interpersonal caring process that is planned and designed based on the best evidence available, and results in positive patient outcomes, optimization of health, palliation of symptoms, or a peaceful death.' (DalPezzo, 2009:261)

This concept of isolation was acknowledged by the MDT within the study as they described wearing an item of visible clothing (apron, tabard or gloves) that for the duration of the task. The wearing of these items denoted the beginning and end of the process, therefore isolating it from other elements of nursing care or treatment. However, the medication administration process appears to already have an identity, as described in Section 8.5 that is clear and obvious to both staff and parents/carers. The complexity that was highlighted in the findings of Chapter 5 was that the medication process was difficult to segregate from the delivery of care to critically ill children. Both nurses and consultants described the combination of delivering medication administration whilst resuscitating a child and the physiotherapist

described how they could interrupt the process to request help with suction or airway management. This is additionally supported in the literature by Jennings et al. (2011) who found in their ethnographic study that medication administration is woven into the delivery of nursing care. Thus, negatively affecting the effectiveness of these interventions as the process is difficult to isolate due to the requirements of delivering care and treatment in the PICU.

This section has explored the elements observed within the empirical level associated with the concept of isolating the medication process from other elements of nursing care. This section has illuminated the complexities of isolating the process when the national PICU standards require the continual provision of one-to-one care and observation of critically ill children. This section has revealed a disconnect between practice the development of interventions to reduce interruptions to medication administration that can result in their decreased effectiveness.

8.7.2 – Actual Level – Delivering holistic care

Attempting to isolate the medication process, can lead to it being viewed as a singular task, which contradicts current nursing practice where holistic care is advocated (Zamanzadeh et al., 2015). Despite the presence of holistic nursing in the literature there is also evidence to suggest that nursing care is advancing back to a more task orientated approach (Odland et al., 2014). Task orientated care was used in nursing during the early 21st century. As nursing theory developed (McCrae, 2012) and the professional status of the nurse developed (Bradshaw, 2012) practice moved towards the use of holistic care. Despite this, more recent developments have moved towards more task focused interventions such as checklists and ‘intentional rounding’ (Bradshaw, 2012, Sims et al., 2018). It was suggested within the findings in Chapter Five and the synthesis in Chapter 7 that the association with patient safety and the need to be efficient are driving forward task focused lists within PICU (Mckelvie et al., 2016, Tarrago et al., 2014, Li et al., 2016). The purpose of checklists is dual fold, with Reijers et al. (2017) highlighting in their systematic review that they describe the routine and guide decisions and tasks within it. This purpose may lead to a significant benefit noted by Ullman et al. (2013) that was the prevention of problems associated with the task, alongside begin able to demonstrate that it had been completed. However, Reijers et al. (2017) identified that checklists were problematic if they did not integrate with existing processes, are not sensitive to context and can cause a loss of

autonomy. By trying to implement an isolated medication administration task its effectiveness may be decreased as the context of providing continual awareness conflicts with the intervention.

It seems possible that the drive towards task focused care mixed with a nursing education that aims to deliver holistic care could create a conflict within contemporary paediatric intensive care nursing. Sharp et al. (2018) in their critical ethnographic study found that nurses organise their work in response to urgency of task and nursing routines. A finding that was echoed within this study as the structure of PICU requires the individual to have a constant awareness of their patients' condition. This was noted by both parents/carers and nurses who described how they needed to respond and manage patient care. Whilst an individual could ignore this requirement to have continual awareness it was highlighted within this study that there is an expectation from the team and the organisation that is a mechanism that contributes to an outcome of patient safety. Furthermore, within this study the structure of teamwork may help if colleagues are available and ready to step up to deliver high quality care. However, this expectation of constant vigilance for one patient may not support the structure of working as a team.

This study identified the importance of colleague support and team intelligence for the MDT within PICU, as allowing the nurse to focus completely on medication administration relies on the availability of the team to provide quality care in their absence. The third generation activity theory developed by Engestrom (1987) and (Engeström, 1999) explores development and learning within teams. He describes a collective work purpose that is shared by the team, completed by individuals who have a joint vision, which is mediated by tools, such as knowledge, skills and regulations and achieves a common goal or outcome and is affected by factors such as rules, workload, production. However, it was shown within the findings of this study that at times individual agents were driven to prioritise their patient over a collective work purpose. The nurse (as the agent here) is thus accountable for the delivery of timely care for their patient and it is possible that the pressure to deliver this may overrule the structural rules within a PICU. Furthermore, this study illuminated the complex teams that operate within the PICU. Nurses are dependent on other professions within the team (medical staff and pharmacists) to deliver safe medication administration, however these agents are influenced by alternate hidden mechanisms that nurses

may not be aware of. For example, in this study the Pharmacists had responsibility for patients outside of PICU and the safe administration of their medication may require the resources and knowledge provided by them. These differences in priorities, funding and expectations can affect collective work purposes and shared visions, as the pressure to be delivering care a cohort of patients or in multiple different clinical settings will affect the individual actions. In this study this difference within collective purpose was seen in multiple different ways, nurses at the bedside described a focus on their patient, whilst the nurse in charge acknowledged a responsibility for all children in the PICU and managing the flow of patients into and out of the area, as did the consultants. Whereas the Pharmacists and the Physiotherapist contributed to the care of children in other areas such as other children's wards or outpatients. These differences in service provision contributed to sets of differing priorities and resulted in tensions between differing priorities. These differing priorities then also influenced actions and behaviours towards interventions that reduced interruptions to the medication administration process and could reduce its effectiveness. The effectiveness decreased if the care of another child became a priority, but information needed to be shared about the child receiving medication.

In summary, this section has critically discussed the mechanisms of delivering holistic nursing care and its influence on the use of interventions to reduce interruptions to medication administration. This study has illuminated the disconnect between the intervention design and the delivery of nursing care within PICU. The novel inclusion of the wider MDT within this study has illuminated the impact of service design and influence of maintaining patient safety in other areas on the effectiveness of interventions to reduce interruptions.

8.7.3 – Real Level - Family centred medication process

Recent changes towards the implementation of task orientated processes have been attributed by some researchers to low staffing levels and the rationing of care (Mandal et al., 2020). Within this study the findings from experienced nurses suggested that there was a conflict between the delivery of ideal care and the context of what occurred. As a result of this they expressed concerns about competing priorities and the time critical nature of the work. Within the literature Orchard et al. (2017) acknowledged that nurses may have limited time to apply any theories of nursing into practice and that there is too much focus on the delivery of medical interventions to

engage with holistic care. This was recognised by two experienced nurses who commented on the pressure from medical teams to work efficiently to deliver time critical medications quickly. One consultant also acknowledged exerting this pressure on nursing colleagues but recognised that she had lost situational awareness at times and had not observed that they were already busy.

In addition to a lack of time, there may be a knowledge gap between theory and practice or lack of awareness of how to implement nursing theory in practice (Lynch et al., 2018). This was evidenced in intensive care by Kurniawati et al. (2017) who found in their phenomenological study that psychosocial and spiritual needs were overruled by the need to respond to time critical physiological needs. These findings combined with the literature suggest that within current PICU practice it is difficult to isolate the one process of medication administration which is required by these interventions to reduce interruptions therefore decreasing their effectiveness.

A structure commonly used within PICU to offer a holistic approach is that of family centred care (Coats et al., 2018, Hill et al., 2019, Richards et al., 2017). Benefits of family centred care have been shown to be increased parent/carer and healthcare professional satisfaction and shared decision making (Hill et al., 2019, Richards et al., 2017). However, limitations have also been noted; lack of recognition of parent/carer role and knowledge (Richards et al., 2017), unequal participation in decision-making as it increases with time in PICU (Hill et al., 2019) and lack of parent/carer voice (Richards et al., 2017). These limitations were illuminated within this study with regard to medication administration, parents/carers of children with complex healthcare needs reported a lack of recognition of their knowledge and not always being involved in decision-making as highlighted in Chapter 6 (Section 6.4.3) when being part of the team was discussed. Furthermore, the continuum of beginner to expert parent was also identified within this study. The literature also suggests that there can be conflict within the delivery of family centred care as there are competing priorities between the delivery of safe and efficient care balanced with ensuring high levels of parent/carer satisfaction (Richards et al., 2017). However, within this study the parent/carer findings suggested that their satisfaction was largely informed by feeling that they and their child were safe. To achieve this, they wanted to be informed, have their knowledge and voice heard and observe robust and consistent practice. Both Uniacke et al. (2018) and Benzies et al. (2019) highlight that family centred care needs to be

developed further to recognise parent/carer capacity and encourage their active engagement in treatment. Current interventions to reduce interruptions do not recognise this parent/carer role nor do they encourage their active engagement. Parents/carers are expected to sit quietly at the bedside and not interrupt, but this study has illuminated that they are increasingly able to contribute to the safety agenda concerning medication administration.

In conclusion, section 8.7 has critically examined the key theme of isolating the medication process and has identified influencing structures that affect interventions to reduce interruptions. The novel inclusion of the wider MDT and parents/carers has contributed to the illumination of these hidden complexities that need to inform future developments within the field. Parents/carers were able to identify that nurses were continually aware of changes in their child's condition as they responded to alarms or movements that demonstrated they may be waking up. The continual and time critical response to these physiological parameters restricts nurses in their ability to isolate the medication process, leading to a hidden conflict between what is ideal and the reality.

8.8 Critical Review of Research Methods

The previous four sections have situated the findings from this study within the current literature and theory. Following on from this will be a critical appraisal of the methods used to generate the findings discussed. The assessment of quality within any study is essential, as it demonstrates the trustworthiness of the findings (Korstjens and Moser, 2018:121) and is contributes to the achievement of best practice (Santiago-Delafosse et al, 2016). As identified in Chapter 3, qualitative research is assessed using the criteria outlined by Lincoln and Guba (1985) using four factors; credibility, transferability, dependability/confirmability and reflexivity., reliability and objectivity (Korstjens and Moser, 2018:121, Jenner et al., 2004).

The method used (see Chapter 3) within the study was inspired by realist philosophy that aimed to explain how and why interventions work or do not work in different environments. A realist lens had not been used prior to this study to examine the use of interventions to reduce interruptions to medication administration. The use of this realist lens enabled the findings to identify contexts and mechanisms that influence their impact within PICU. In addition, the rich contextual data included within the

finding's chapters may allow the CMOC's to be considered in other areas. Having discussed the main findings of this study in relation to the literature and theory, the quality of them will now be expounded.

8.8.1 Credibility, trustworthiness and triangulation

The concept of creditability is important in qualitative work to assess whether the researcher has presented a true reflection and interpretation of the original data (Korstjens and Moser, 2018:121, Miles et al., 1994, Denzin and Lincoln, 2005, Lincoln, 1985). The strong participant voice in chapters 5, 6 and 7 contributes to the credibility of this study as the reader can identify the data presented by participants. The survey and interviews were conducted during the winter season which is a busy period for PICU's within the England (Paediatric Intensive Care Audit Network, 2020). The surveys and interviews were always booked at the participants convenience; however, the researcher was aware that time constraints due to clinical responsibilities may affect the time that the professionals could donate to the study. To address this issue the PIS identified that interviews and survey telephone calls could be abandoned and re-booked at any point. This was also re-iterated at the start of the telephone calls which contributed to an improved relationship as the participant was aware that the interviewer was cognisant of their clinical responsibilities.

Prior to the parent/carer interviews being conducted, the researcher contacted them via text messages on a study phone. This allowed the parents/carers to arrange the interviews at their convenience, enabling the needs of them and their child to be paramount in the process. However, there was also a risk that their time could be restricted due to the critical nature of their child's illness, therefore the researcher ensured prolonged periods of time were allocated for each interview to allow for a flexible approach to timings (Menzies et al., 2016). In addition, the bedside nurse always knew how to contact the parent/carers and researcher should they be required by their child. These measures contributed to increased engagement (Menzies, 2018) with parents/carers as they were reassured that the interview would only be conducted if they were comfortable to leave the bedside and would be informed of any changes to their condition.

Triangulation is also an important element within the assessment of credibility, as it refers to the examination of the research issue from at least two different points

(Steinke :178). Investigator triangulation relates to the use to multiple researchers (Korstjens and Moser, 2018). Whilst the data collection, transcription, coding and analysis was completed by a single researcher regular review by the supervisory team enabled research issues to be debated from multiple angles. The supervisory team reviewed fifty percent of coded transcripts and differences in opinion were discussed and agreed at supervisory sessions. In addition to the supervisory review, a CMOC from each of the finding's chapters (5, 6 and 7) were reviewed by colleagues to establish whether the interpretation of the data was credible. Collectively these different review methods ensured that an authentic representation of the data was presented within this thesis.

Trustworthiness within realist methodology can be improved by the researcher being acutely aware of the underlying data that supports their argument and not base in on one source alone (Wong, 2018:138). In this study clarity about sources is presented in Chapters 5 and 6 alongside evidence from transcripts. It is also important to be able to easily identify the analysis and interpretation within the findings of the study. Within this study there is a clear evidence trail that demonstrates the process from transcript to theme to the building of CMOC's as the thematic analysis is presented prior to the identification of CMO's. There is further interpretation within the synthesis (Chapter 7) which triangulates the CMOC's from each section of the study. This synthesis unpicks the relationships and differences between CMOC's therefore contributing to increased trustworthiness within the study. The aim within realist studies is to produce an explanatory theory which is underpinned and based on trustworthy data. However, it has been identified that the trustworthiness of some data may be questionable but can still contribute to the development of an argument which informs the suggested theory (Wong, 2018). The highest quality theory is plausible because it is coherent and is supported by trustworthy data. Coherence relates to how logical and consistent an argument is. Haig and Evers (2016) note that the end theory is more likely to be coherent if it offers a good explanation. To achieve coherence the theory must explain as much as possible about the phenomena. It should be simple and not have ad hoc assumptions within it. Finally, the theory should fit with current knowledge.

8.8.2 Transferability, dependability and confirmability

Inclusion of detailed description within the presentation of findings allows for them to be transferred to other contexts or settings (Santiago-Delefosse et al., 2016, Korstjens

and Moser, 2018, Miles et al., 1994). The nature of the realist analysis methods ensures contextual data is clearly presented, examined and central to the findings of the study. This contextual data was obtained from multiple PICU's within England which would increase transferability within the paediatric intensive care environment within the UK. The clearly presented contextual data would also allow other nationalities to see if the findings were transferable to their system of healthcare. Furthermore, the focus for the study was PICU, however, adult intensive care and neonatal units may also find that some of the findings are transferable for their area of practice.

The criteria of dependability and confirmability relate to the transparency of the research process used within the study (Korstjens and Moser, 2018). The methodology section (Chapter 3) presented each step of the research study, outlining the philosophical or methodological reasoning for their choice. In addition to this chapter, examples of research protocols and data analysis methods are included in the Appendices (see Appendix 2 and 5). Confirmability refers to the neutrality of the interpretation included within the analysis (Korstjens and Moser, 2018). This should not be restricted by the researchers' own views but embedded in the participant data. Within this study regular supervision sessions challenged the researcher to ensure the data represented the participant voice and not her own nursing-based views. The researcher has maintained an audit trail through her reflective diary, supervisory notes and notes on decision-making.

8.8.3 Reflexivity

Reflexivity is an essential requirement of the researcher within qualitative studies as it enables them to examine their own assumptions, pre-conceptions and values (Korstjens and Moser, 2018, Santiago-Delefosse et al., 2016). Furthermore, the researcher must understand how these elements refer to their decision-making throughout the study, ensuring they are self-aware (Ortlipp, 2008). A detailed reflexive diary was maintained which reflected on each section of the research process. This was especially important due to the researcher having a nursing background in the clinical area as it enabled her to reflect on her own clinical experiences and ensure these were not overwhelming her analysis. The researcher made the decision to leave that area so that she reduced the influence of clinical practice on her viewpoints. This enabled the researcher to stand back and question the data more effectively as she

was no longer immersed in what was thought to be normal practice. From this viewpoint it was easier to ask and respond to the 'so what' questions raised by the findings and synthesis. The reflective sections and excerpts included within this study highlight the issues noted by the researcher within this diary.

8.8.4 Strengths and Limitations

Reflection on the strengths and weaknesses within a study are essential in establishing its contribution to the research topic. The aim of realist methods is to understand complex situations and offer explanations as to why actions or behaviours occur. In this study this was done through the identification of the contextual influences that stimulated the production of mechanisms which in turn affected behaviours, choices, feelings and actions associated with interventions to reduce interruptions to medication administration. Within the field of complex interventions, the contexts and mechanisms may improve or decrease the effectiveness of an intervention (Pawson, 2006). One of the strengths within this method is the uncovering of the hidden mechanisms and the contexts which influence and it this study it enabled the researcher to examine the observable, uncover perceptions and suggest hidden mechanisms. This offered novel insights which help to explain when, for whom and why interventions to reduce interruptions to medication administration are effective. However, it must be recognised that realist methods can only offer explanations based on what is known at the moment (Wong, 2018:140), it is unlikely to provide a concrete, final answer to complex situations. As research in this area progresses and new knowledge is revealed, explanations and theories will also develop. Within healthcare delivery this is less of a limitation due to the nature of the dynamic, evolving clinical setting.

One of the strengths of the design in this study was the inclusion of both literature and empirical elements. Whilst this is not uncommon (Creswell, 2011), these distinct sections allowed current literature to be reviewed through a realist lens before empirical data was collected from multiple sources. However, it is important to acknowledge that the Realist Review predominantly included studies from adult clinical settings. Whilst this may be viewed as a limitation it did allow potential CMO's to be identified for exploration within the empirical data The collection of empirical data from multiple sources added another strength as it included a range of different professionals and parents/carers from multiple different PICU's within England. This

data was then synthesised in Chapter 7 offering the reader the opportunity to comprehend the combined views of the phenomena. The synthesis embedded literature, healthcare professional and parent/carer data within the suggested theory. As noted in the quality assessment triangulation is an important (Korstjens and Moser, 2018) and the inclusion of the synthesis chapter offered this as data from different sources were synthesized.

The concept of being an insider researcher was both a strength and a limitation (Unluer, 2012, Greene, 2014, Costley et al., 2010). As a PICU nurse researcher it was important to ensure the two elements were balanced and the knowledge from working in the area did not overpower the researcher drive for new knowledge. The clinical knowledge allowed the researcher to understand the clinical language used within the interviews and to be able to identify comments which required further discussion. The limitation, however, was the temptation to insert the researchers' own assumptions, both with professionals and parents/carers. To combat this open questions such as 'can you describe….?' or I'm not sure I understand that, can you explain it in more detail….?'. These types of questions encouraged the participant to share richer data with the researcher. However, there was also a risk that the participant's voice would not be heard within the finding's chapters, it was essential that there was a balance between professional expertise and the intricacies that were illuminated within the research. The strong challenge from the supervisory team allowed time for reflections and opportunities for the authenticity and rigor of the findings to be challenged.

The inclusion of multiple informants in both parts of Stage 2 is also a strength (Saunders and Townsend, 2016) as it allowed the phenomena to be examined from multiple viewpoints which uncovered novel insights from medical, allied healthcare professional and support workers experiences. These insights provided key data to explore their impact on the effectiveness of interventions to reduce interruptions to medication administration on PICU. It should be acknowledged though that there were some limitations to the sampling process within healthcare professionals. The main sampling strategy involved the use of the PICS membership list. This restricted the sampling as not every member of the PICU team was a member. However, participants from each of the identified professional groups were obtained.

The inclusion of parents/carers within the study allowed their views and experiences of medication administration in PICU to be illuminated and allowed them to have a voice in an area where it had been omitted. The sample of parents/carers included both genders and four participants from an ethnic minority adding a variety of perceptions to the data that allowed novel insights to be revealed. The analysis of their data revealed novel information about the impact medication administration had on their feelings of safety within intensive care. Furthermore, it uncovered novel data regarding their understanding of the process and the decision-making process they follow when deciding whether to interrupt or not. Although the study was advertised widely within the PICU's included in the parent/carer study but not everyone chose to participate. Recruitment was more successful when parents/carers were approached in person, which was an important lesson for future research. The parents/carers that were not included were those whose child was approaching end of life and where there were safeguarding complications. These voices were therefore not heard within this study.

8.9 Conclusion

This chapter has developed the findings from this study further by situating them within the current literature and theory. This discussion has added depth to the findings as it has identified current literature and theory that are in support of them. In addition to this the discussion has illuminated areas where the findings challenge the current conclusions in the literature. More interestingly it has also illuminated novel contributions to the field of reducing interruptions to the medication process particularly in PICU. The chapter has also provided a critical review of the research methods which evidence the strengths within the methods used and identified their limitations. This critical review provides transparency to the reader and allows them to be confident that the findings of this study are of good quality. The novel contributions identified within this study have illuminated the complexities and challenges within the medication process and the interventions to reduce interruptions. This new knowledge has implications for the development of future research and current nursing practice. The recommendations and implications for practice will be presented in the concluding chapter that follows.

Chapter 9 – Conclusion

9.1 Introduction

This chapter will provide a summary of the implications for practice, future research and education illuminated within this study. Alongside these implications recommendations for practice will be highlighted.

9.2 Implications and recommendations

The implications and recommendations are summarised within the following table (Table 39). These are presented in three key areas: future research, education and clinical nursing practice.

Table 39 - Implications and Recommendations

	Implication	Recommendation	Suggested actions
Clinical practice **a) Critically ill child**	Medication administration in PICU is complex and frequent activity	Future research need to explore the impact of routine and automatic behaviour when developing future interventions	Using the COM-B (Capabilities, Opportunities, Motivation and Behaviour) behaviour change theory understand the professional's capability to engage with the intervention – does the intervention fit with current routines or is an education programme required to change the routine? Implementation and evaluation of a pharmacy technician in the role of second checker.
	Nurses are constantly cognisant of patient condition	Staffing levels within PICU should include additional staff to allow all professions to focus on medication administration	

Clinical Practice **b) Parents/carers**	Parent/carers would like to be involved as part of the team during the medication administration process	Parents/carers should be supported to be included in in the team around the child	Co-design of a medication information app to allow parents/carers to share information about long term medications and enable professionals to keep parent/carer knowledge current.
	Including parent/carer knowledge	Parents/carers should be invited to share their knowledge and administer medication to their child whenever possible	Parent/carer led ward rounds. Co-design of parent/carer passports detailing their knowledge and skill in administering their child's medication to facilitate continued participation.
	Parents are reassured by the presence of nurses at the bedside	Medication administration should not be removed from the bedside unless there are alternate provisions for care from another professional	Further work when implementing the pharmacy technician as a second checker should include the development of an intelligent team to deliver ongoing care and support to families whilst medications are being administered.

Clinical Practice **c) Nurses**	Nurses continually present at bedside	Future interventions need to understand staffing models and the impact on the medication administration process and safety outcomes	Strategies to help professionals recover from interruptions should be developed.
	Understanding impact of inconsistency in actions and behaviours	Medication administration training should include expectations of behaviour and their impact on others	
	Nurses need to own the medication administration process	Nurses need to be empowered to challenge interruptions through building safe and open cultures	Interventions should support nurses to be resilient to interruptions whenever possible; there should be a culture of deflect, defer and challenge in response to unnecessary interruptions.

Clinical Practice **d) Medical team**	The medical team play an important part in keeping parents/carers up to date with information about medications their child is receiving	Ensure parents/carers are updated daily within the ward round about medication	Engage with parent/carer led ward rounds Participate in the co-design of an electronic medication information app
Clinical Practice **e) Allied Health Professionals**	Prioritising patient care outside of PICU can influence AHP's to interrupt medication administration	Pharmacists, Physiotherapists and other AHP's should be an integral part of PICU team an any responsibilities in other areas should not interrupt their time on PICU	Development of PICS standards and a service specification that funds AHP's as full-time members of the PICU team.
Future research into interventional design	Changing behaviour is difficult with medication administration due to the 'routine' built into the process	Future interventions need to include an understanding of behaviour change theory	Use a behaviour change theory such as the COM-B to develop an intervention that understands the key elements needed to help the MDT to engage with it.

	The effectiveness of interventions is often affected by the availability of supplies within the NHS	The implementation of future interventions should include a review of supply availability	Intervention designs teams should include a representative from the NHS procurement process.
	Difficulty in isolating medication administration	Medication administration can only be isolated when there are additional staff present either to provide care for child or complete process	Further work when implementing the pharmacy technician as a second checker should include the development of an intelligent team to deliver ongoing care and support to families whilst medications are being administered.
	Challenges in sustaining effective interventions to mitigate or minimise interruptions	Future research needs to employ implementation science methodology to ensure effective interventions are embedded and sustained in clinical practice	Using the COM-B framework intervention development should comprehend whether the professional has the opportunity in their current workload/role to use the design proposed.
Education	Interventions to reduce interruptions to medication	MDT education programmes aimed to improve team intelligence	Medication simulation programmes for the MDT.

	administration on PICU impact on all members of the MDT.		

9.2 Final conclusions

In conclusion, this thesis has illuminated how, when, why and for whom interventions to reduce interruptions are effective in terms of medication administration. It has achieved this by exploring interruptions and medication administration within the contemporary world of PICU using a realist approach. Existing research had focused on the implementation of interventions to reduce interruptions to the medication administration process. However, this thesis has demonstrated that within this literature there was an absence of understanding about how, when and in which circumstances these interventions were effective. Furthermore, the literature also failed to understand the perspectives of the MDT or parents/carers who had to interact and engage with the interventions to reduce interruptions.

This study aimed to address these gaps by using a Critical Realism informed method which explored the contexts that affected the use of interventions to reduce interruptions to medication administration. Moreover, these contexts were then examined to understand the mechanisms that they triggered and the impact this had on both healthcare professionals and parents/carers. The inclusion of the wider MDT and parents/carers in the study has illuminated the complexities within the medication administration process in PICU that challenge the underpinning theory of current interventions. This approach enabled the aims and objectives to be met and is believed to be unique in the context of PICU. It thus brings a new fresh lens to the context of PICU and medication adherence.

This study identified the complexity within the delivery of medication administration in PICU, the impact and influence the process and interventions had on healthcare professionals and parents/carers. Furthermore, it also illuminated the conflict and challenges that may be generated when interventions to reduce interruptions to medication administration are introduced. Collectively, this thesis offers unique and novel contribution by enhancing understanding of the phenomena of interruptions as part of the medication process for critically ill children and young people. It builds contemporary understanding of the complexity and interrelation intricacies at play which have implications for international PICU and medication safety practice, policy and future research

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Appendix 1 – Realist Review Protocol

Background

Medication administration is a complex activity which requires prolonged periods of focus and concentration (Thomas et al, 2014). In the Paediatric Critical Care (PCC) environment, medication episodes are particularly challenging due to the volume, variable weight range and accuracy of dosing required (Dickinson et al, 2012). Interruptions to medication administration are often documented as having a detrimental impact on patient safety (Cooper et al, 2016). Interruptions have a negative impact on prospective memory which often leads to omissions in tasks (Grundgieger and Sanderson, 2009). Interventions have been identified and tested within the literature since the beginning of the 21st century, which aim to reduce the frequency and impact of interruptions on medication administration. These interventions embrace concepts such as wearing visible clothing, no interruption zones, education, protocols or a combination of some or all the elements.

Several systematic reviews have analysed and synthesised the results of the interventional studies using strategies such as systematic review and meta-analysis. They fail to conclude which intervention, if any, demonstrate statistically significant beneficial results (Raban and Westbrook, 2013, Berdot et al, 2015 and Harken et al, 2016). Several systematic reviews have investigated the effectiveness of interventions to either reduce interruptions (Raban and Westbrook, 2013) or promote safer medication practices (Berdot et al, 2015 and Harken et al, 2016). There is limited evidence to support the use of specific interventions which improve medication safety or reduce interruptions. Within the reviews the primary reason attributed for the lack of a definitive recommendation is poor research design. It is noted that observers are not blinded to the intervention being tested which may lead to a risk of bias and there is a lack of multisite trials which reduces the generalisability of the results.

Rivera and Karsh (2010) identified within their narrative review those interventions such as checklists, colourful vests and visible signage reduced interruptions. The conclusions and recommendations within this review are limited as it was not systematically designed and did not include any meta-analysis or assessment of quality. However, Raban and Westbrook (2013) developed this concept by evaluating interventions to reduce interruptions and errors. Their inclusion criteria ensured that studies reported quantitative data based on observation of interruptions or errors using pre/post or control groups for comparison. Ten studies were included in the review, only three demonstrated a statistically significant reduction in interruptions. Error rates were measured in three studies but only two demonstrated a statistically significant reduction. As with previous reviews no individual intervention was identified to demonstrate statistically significant reductions in interruptions or error rates and the researchers concluded that the evidence base was weak.

They recommended that future studies should be experimental in design (controlled before and after or cluster randomised trials). Within these studies it will be important to consider the complexity of the interruptions, be aware of the necessary/unnecessary classification and develop the relationship between interruptions and medication error (Raban and Westbrook, 2013). The lack of robust RCT's available within this field restricts the analysis within the systematic review process, therefore a realist review methodology will be used.

Methodology

Realist review and synthesis have an explanatory focus (Pawson et al, 2005) and seek to understand the mechanisms by which an intervention works or not (Rycroft-Malone et al, 2012). This interpretive theory-driven exploration of the literature attempts to illuminate the how, why and when associated with the effective delivery of complex interventions (Wiese et al, 2017). On this occasion, it has been selected because decision making during medication administration is complex (Colligan and Bass, 2012 and Dougherty, Sque and Crouch, 2011) and interventions created to reduce this need to engage with this complexity. Furthermore, the outcomes associated with these complex interventions are dependent on the interaction between the participant and their context (Wiese et al, 2017). Pawson et al (2005:22) note that the evaluative question underlining the review is 'what is it about this programme that works for whom in what circumstances?'

The research questions for this review are:

- What are the important contexts in which interventions to reduce interruptions during medication administration result in their intended outcome?
- What are the mechanisms generated by interventions to reduce interruptions during medication administration?
- What outcomes are measured when interventions to reduce interruptions to medication administration are implemented?
- In which circumstances are interventions to reduce interruptions to medication administration most effective?

Procedures

The process within this realist review will follow the steps defined within the RAMESES publication Standards for Realist Synthesis (2013).

Defining the scope of the review

Exploration of the literature within previous studies has highlighted a substantial body of evidence. The aim of the review is 'to explore and understand how, why and when interventions to reduce interruptions to medication administration are effective.' This focused aim will drive the review initially, however, the iterative process within the review where theories are developed and tested will be data driven.

Search strategy

The following databases, British Nursing Index (BNI), Cumulative Index of Nursing and Allied Health Literature (CINHAL), EMBASE, Medline, and PsycINFO will be searched. These databases were selected to allow relevant literature from the fields of nursing, medicine, pharmacy and psychology to be identified supporting a well-developed strategy. Extensive reading of the literature for other studies allowed the researcher to be familiar with the interventions and identify the relevant search terms.

The initial search strategy will be as outlined in table 1, however, realist review searches are concluded when the author(s) feels that theoretical saturation is complete. This will involve a four-stage approach; background search, a theoretical search, testing the theory search and a final search once synthesis is complete (Pawson et al, 2005) The literature searching will be completed by RB, however, theoretical saturation will be discussed at supervision and agreed by the team (JM and JC). The iterative search process will be summarised within a flow diagram as completed.

Table 1 Background search strategy

Search terms	
Population/patient receiving medication	Medicines OR medication OR drugs OR medication administration
Interventions	AND Tabard OR vest OR lanyards OR sash No interruption zone OR no distraction zone OR Sterile cockpit OR quiet time Checklist OR protocol education OR simulation OR intervention
Comparator	AND Interruptions OR distractions OR disruptions
Outcome	AND Reduction OR error OR Safety

Study selection criteria

Realist reviews do not use a hierarchical approach to evidence because it is felt that multiple methods help researchers comprehend a more detailed set of data (Pawson et al, 2005). The selection of data within a realist review is driven by both relevance (does it address the theory under testing?) and rigour (does it make a credible contribution to the theory being tested?) (Pawson et al, 2005).

Relevance will initially be driven by topic as theory is developed and further searches will aim to locate literature to test the theories generated from the background search. The databases in the background search will be from inception to current date to enable the development of the interventions to be explored. All empirical studies and quality improvement projects will be selected for inclusion, titles and abstracts will be imported into EndNote. Only studies which are published in English will be included due to a lack of access to translation. Studies will be excluded if the interventions to reduce interruptions are related to other healthcare activities for example the delivery of general nursing care. The rationale for this decision is that medication administration is a unique, complex task that requires specifically designed interventions (Campbell, 2013).

Although the selection of studies in a realist review is not based purely on critical appraisal, it is important to have an awareness of methodological limitations during the synthesis phase (Weise et al, 2017). Therefore, CASP (Critical Appraisal Skills Programme, 2017) or JBI (Joanna Briggs Institute, 2014) checklists will be used to facilitate this critical appraisal.

Data Extraction

Initially data will be entered on to a Microsoft Word document (see Appendix 1) noting authors, year, department and geographical area, intervention, outcome measured, methods, associated theory and limitations (Pawson et al, 2005).

The results and discussion sections of the selected papers will be coded manually to identify context, mechanism and outcomes (Weise et al, 2017). These will be reviewed by a member of the supervision team.

Data analysis and synthesis

The aim of the synthesis is to examine in detail how the intervention works, for whom, in what circumstances, in what respects and why? (Pawson et al, 2005).

A matrix will be generated which will document the development and testing of theories, which will be reviewed by a member of the supervision team. This theory development and testing will be supported by coded data and extracts from literature. Furthermore, literature will be searched to identify contrasting arguments to challenge the theories as they are developed as this will help refine theory development (Weise et al, 2017).

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Appendix 1 – Data extraction form

Title

Authors

Study design

Contextual data (extracted from introduction, methods or findings section)

Participants (gender, age, experience, discipline, role, etc) and number of

Characteristics of intervention (s) (theory, implementation method, length)

Identification and/or analysis of moderators or mediators of the interventions effect if applicable

Authors speculations on effects characteristics of the intervention, participants, interveners or setting had on implementation

Did implementation involve the use of any of the following?

- Management
- Champions
- Education sessions
- Feedback and audit
- Environment redesign
- Rewards
- Coercion
- Performance data

Participant perceptions (views on effectiveness, usability, barriers, facilitators, influences)

Appendix 2 – Stage 2 protocol

A mixed methods exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

RESEARCH PROTOCOL

Coventry University

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Rationale

In the United Kingdom (UK) the economic burden of preventable harm from medicines is estimated to be in excess of £1 billion per annum (Frontier Economics, 2014). In addition to fiscal cost, high profile reports indicate that medication errors have a demonstrable negative impact on quality of care, patient experience, outcomes and safety (The Francis Report, 2013, Patients First and Foremost, 2013, and The NHS Outcomes Framework, 2016/17).

In 2014, there were 19 760 children admitted to Paediatric Intensive Care Units (PICU) in the UK (PICANET, 2016). These children require medication as part of their treatment plan, with 33% requiring vasoactive medicines (PICANET, 2016). This demonstrates the high volume of complex medication administration which is required within PICU. In addition to these requirements, children are at increased risk of being involved in medication errors; McDowell, Ferner and Ferner (2009) identified that medication errors are higher in paediatric departments and intensive care units. Furthermore, the National Patient Safety Agency (2007) estimated that children are three times more likely to be involved in a medication error.

Medication administration for children is especially challenging due to the complexity of dosing due to large variations in weight range, the adaption of adult based medication for children and age-appropriate dosing (Dickinson et al, 2012). Medication administration within PICU also requires precise, difficult calculations (Dickenson et al, 2012) which may be required at any point during the 24-hour timeframe. Adding to the complexity is the critical nature of the illness which requires constant nursing observation and promotes the preparation of medication at the bedside.

Medication administration is also a complex activity which requires prolonged periods of focus and concentration (Thomas et al, 2014). Interruptions to medication administration are often documented as having a detrimental impact on patient safety (Cooper et al, 2016) and have a negative impact on prospective memory which often leads to omissions in tasks (Grundgeiger and Sanderson, 2009). Interventions have been identified and tested within the literature since the beginning of the 21st century, which aim to reduce the frequency and impact of interruptions on medication administration. These interventions embrace concepts such as wearing visible clothing, no interruption zones, education, protocols or a combination of some or all the elements. A recent randomised controlled cluster trial (Westbrook et al, 2017) indicated that whilst the rate non-medication interruptions can be reduced from 50/100 administrations to 34/100 only 48% of nurses would the support the continued use of the intervention bundle. These results indicate the need for medical professionals to be involved in the design of these interventions to ensure they are appropriate for the environment in which they are designed for.

A local pilot observational study conducted in 2014 highlighted that within the paediatric critical care environment interruptions to medication administration are frequent (Bower, 2015). A follow up exploratory qualitative study (Bower et al, 2017) illuminated factors which are important in PICU nurse decision making when interrupted during medication administration. These factors have not been considered during the development of current interventions. The study indicated that there appears to be a culture of acceptance and that there are normal levels of interruptions. It also identified that PICU nurse decision-making when interrupted is influenced by the need to maintain interpersonal relationships with both the wider team and parents and that it is essential they are not seen to be rude. The complexity or familiarity of the medication can dictate which body language is demonstrated, which may invite or block interruptions. Providing clinical education in medication administration can generate

interruptions or it can enforce adherence to protocols. Finally, communication within a PICU is complex in nature and interventions need to facilitate essential conversations.

However, despite multiple studies implementing interventions to reduce interruptions to medication administration (Pape, 2003, Anthony et al, 2010, Westbrook et al, 2017) there remains limited robust evidence which demonstrates sustainable impact on the reduction of medication errors (Raban and Westbrook, 2013). In addition, many studies highlight a lack of engagement from health professionals in adhering to the protocols and processes associated with the interventions (Verweij et al, 2015, Nelms and Treiber, 2011 and Westbrook et al, 2017). A review of the literature (Bower et al, 2015) has demonstrated that there is only one study which includes implementation of an intervention on a paediatric ward (Colligan et al, 2012) and no studies within PICU. Nevertheless, to ensure the safety of critically ill children receiving medications within PICU, medicines need to be administered accurately, within an environment which protects the nurse from unnecessary interruptions and allows maximum concentration. However, within PICU, there is an additional need for interventions to comprehend the essential communication, continual observation and parental support that are required to ensure that critically ill children and their families receive safe and compassionate care. Therefore, future research needs understand how interruptions to medication administration are currently managed and do these interventions meet the needs of this unique, complex population?

STUDY TITLE: A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Introduction

It has been identified within the in the rationale that there is a lack of evidence available which examines the phenomena within the PICU environment. Therefore, it is essential that current practice is identified within the England as this is, at present, unknown. This knowledge will contribute to the evidence base of the development of an intervention by identifying current practice and understanding their impact on key outcomes such as reductions in interruption rates and medication errors.

Furthermore, engaging PICU healthcare professionals within the development phase is vital. Interventions are not powerful in isolation; their power lies with the professionals who are required to use them (Clark, 2008) and it is vital that any intervention is acceptable to the professionals who are expected to use it. Their knowledge and experience both in practice and of using current interventions will allow in-depth exploration of the context in which interventions work and produce maximum impact. Ultimately this new knowledge will contribute to the development of an intervention to reduce interruptions to medication administration in PICU which is acceptable to the teams required to use it and understands the complexity of paediatric critical care.

Aim and Objectives

The overarching aim for the study is:

To understand how and when interventions to reduce interruptions to medication administration in PICU are effective.

Figure 1- structure of research aim

Population – Health care professionals
Exposure – Interventions to reduce interruptions to medication administration
Outcome – impact on interruptions and practice

This aim will be supported by the following objectives

- To conduct a telephone survey of PICU's in England to explore current medication practice and identify which interventions to reduce interruptions are currently in use and how their effectiveness is measured.
- To explore the barriers and facilitators to existing interventions to reduce unnecessary interruptions with the MDT within PICU using semi-structured interviews

The research question is:

How do interventions to reduce interruptions to medication administration work, for whom and under which circumstances within the paediatric intensive care environment?

Research Paradigm

The paradigm which will be used within this study is that of Critical Realism. In contrast to positivism, where a single concrete reality is thought to exist and to interpretivism where multiple realities are believed in, Critical Realism believes that there are multiple perceptions of one mind-independent reality (Healy and Perry, 2000). Critical Realism assumes a reality exists, because individuals behave as though this is true, however, this cannot be proven (Easton, 2010). Furthermore, within Critical Realism it is noted that there are differences between reality and the individuals' perception of it (Kraus, 2005). These beliefs indicate a contradiction within Critical Realism; that an unknown, independent reality exists and that reality is socially constructed (Easton, 2010). However, it is through the examination of social constructs (behaviours and perceptions) that reality can be described and explained. Therefore, Critical Realism is particularly useful in the examination of events which aim to explain why things are as they as they are.

This philosophy aligns particularly well with this study as is aims to understand why existing interventions to reduce interruptions do always produce robust, sustainable changes on outcomes. The predominantly qualitative methodology seeks to understand individual perceptions and experiences (Bryman, 2012) of using existing interventions. These perceptions and experiences will be obtained from a variety of professionals who deliver care to critically ill children and will be analysed to explain the context and mechanisms (Maxwell, 2012) which influence the impact of such interventions.

Study Framework

This design of this study will be supported by the Medical Research Council Framework for the development of complex interventions (Craig et al, 2008). As shown in figure 2, the

framework has a comprehensive four staged approach. This framework supports extensive preparatory work which seeks to understand which interventions work and in which context. This preparation is thought or be vital in the design of successful interventions (Craig et al, 2008). Furthermore, interventions should be tested in feasibility of pilot studies which incorporate rigorous evaluation before being implemented in practice. The framework also supports ongoing evaluation to ensure that the intervention is effective and does not negatively impact in other areas of practice. Clarke (2008) states that the power lies with the participants using the intervention rather than the tool itself and the understanding of mechanisms which influence their actions. Applying this framework to the development of an intervention attempts to ensure that the design understands the complexity of these underlying influences.

This study will focus on the first stage of this process, ensuring that the intervention design is underpinned by robust exploratory studies. Completing an in-depth exploratory phase is essential in the design of a robust intervention (Craig et al, 2008).

Figure 2 MRC Framework for the development of complex interventions (Craig et al, 2008)

Outline of study

The following flow chart (figure 3) outlines a study design which has been formulated to identify and critically evaluate the evidence required in development phase of the MRC Framework for the design of Complex Interventions. This stage requires the current evidence base to be identified and evaluated so that areas that have not been explored within the literature are highlighted. This also allows for the evidence to be review using a different lens, on this occasion a realist view will be taken which seeks to identify the context in which interventions have maximum impact on outcomes (Maxwell, 2012). When a complex intervention is implemented, change is expected. Within the development phase of the MRC Framework these theories need to be identified and evaluated. The modelling process may require the intervention to be tested to ensure the design is correct before it is piloted and robustly tested (Craig et al, 2008). There are four stages within the overall study however, this protocol supports only stage 2 and 3 which are the boxes in white, which will run concurrently.

Figure 3 Flow chart for larger study

Stage 1 - Realist review of the literature (timescale – May-July 2017)
This stage of the study has previously received ethical approval via Coventry University May 2017 P46289

Rationale for inclusion

- Contribute to identification of evidence base and gaps in knowledge
- Identification of theoretical frameworks
- To search for the contexts and mechanisms which influence the impact of interventions

Stage 2a – National survey of practice across within PICU's across the UK
(timescale – up to 6 months after receipt of approvals)

Rationale for inclusion

- Contribute to identification of evidence base
- What interventions are being used and have they been measured for effectiveness?

Stage 2b - Semi-structured interviews with health care professionals
(timescale up to 6 months after receipt of approvals)

Rationale for inclusion

- Address gaps in knowledge raised by realist review of literature
- Using stakeholder experience to influence design of intervention
- Exploring barriers and facilitators to acceptability of intervention to aid process modelling and increase likelihood that intervention will be successful
- Content analysis of data will identify context, mechanism and outcomes identified by stakeholders which influence the efficacy of interventions to reduce interruptions to medication administration on PICU

Stage 3 – Semi-structured interviews with parents (to seek approval autumn 2017)

Rationale for inclusion

- Address gaps in knowledge raised by realist review of literature
- Using parental experience to influence design of intervention
- Exploring barriers and facilitators to acceptability of interventions to aid process modelling and increase likelihood that intervention will be successful.
- Critical realist analysis of data will identify context, mechanism and outcomes identified by parents which influence the efficacy of interventions to reduce interruptions to medication administration on ICU

ETHICAL REVIEW:

Ethical approval will be sought from both Coventry University and approval from Health Research Authority.

STUDY DESIGN:

The protocol includes two distinct stages;

Stage 2a - a national telephone survey of current practice regarding medication administration and the management of interruptions within PICU's in England

Stage 2b - semi-structured interviews with PICU healthcare professionals which will be analysed using content analysis

The following two stages of this protocol will describe these stages in more detail.

Phase i

National survey of practice:

Aims

- To identify any interventions/strategies/practice changes targeted at reducing interruptions to medication administration or improving medication safety are or have been used in PICU's across the England
- To understand how health care professionals, assess the impact of these interventions/strategies/practice changes and identify the results
- To understand how these measurements are recorded and why they were chosen?

Sampling

A purposive sample of National Health Service (NHS) PICU's in England (n=23) will be selected (see table one). These units are identified by NHS England (2017) as designated intensive care units for children. This sampling method has been selected as the researcher is not seeking a random selection of participants but a sample which is relevant to the research questions (Bryman, 2012). It is essential that the participant can answer questions about contemporary PICU practice within the NHS. To gain a comprehensive understanding of practice within England it has been decided that all units will be invited to participate.

Inclusion criteria:

- All designated NHS PICU's within England

Exclusion criteria:

- Non-NHS PICU's
- NHS wards and units not providing intensive care to critically ill children

Table 1 – Designated PICU's in England

Included PICUs: Barts and the London NHS Trust; Birmingham Children's Hospital; Cambridge University Hospitals NHS Foundation Trust; Central Manchester University Hospitals NHS Foundation Trust; Great Ormond Street Hospital for Children NHS Trust;

Guy's & St. Thomas' NHS Foundation Trust; Imperial College Healthcare NHS Trust; King's College Hospital NHS Trust; Leeds Teaching Hospitals NHS Trust; Liverpool Alder Hey Children's NHS Foundation Trust; Great North Children's Hospital & Newcastle Freeman Hospital; Nottingham Children's Hospital; Oxford University Hospitals NHS Trust; Royal Brompton & Harefield NHS Foundation Trust; Sheffield Children's Hospital; South Tees Hospitals NHS Foundation Trust; St. George's Healthcare NHS Trust; University Hospital of North Staffordshire NHS Trust,; Southampton Children's Hospital; Bristol Royal Hospital for Children; Leicester Royal Infirmary; Leicester Glenfield Hospital.

Recruitment

'Cold calling' participants via the telephone is not recommended practice in healthcare research, they should be invited in person, by poster or letter (Ray et al, 2016:128). Therefore, all PICU's within England will be invited to participate within the study via email. The recruitment process will begin by contacting medical and nursing Clinical Leads from all Paediatric Intensive Care Units within the UK via email (see Appendix 1).

The Paediatric Intensive Care Society (PICS) is a multidisciplinary forum which represents the United Kingdom paediatric intensive care community at a national level. The email invitations will be sent by the PICS Administrator to ensure Data Protection principles of confidentiality are adhered to. It is noted by Bryman (2012) that it can be difficult to gain access to respondents, however, by contacting both medical and nursing clinical leads (Tume et al, 2017) it is hoped that the response rate will be increased. The email will contain a brief outline of the study and estimated length of the survey. In addition, to allow a convenient time for the survey to be conducted the email will request contact details for a member of the PICU management team (medical or nursing) who can describe current practice and interventions to reduce interruptions to medication administration and describe how the impact of these interventions are measured. As the invitation to participate in the study will have been made via email, a follow up telephone call from the PICS administrator to the unit to speak to the medical or nursing clinical lead will occur two weeks after the email request, to units which have not responded. The survey will be conducted within six months of ethical and HRA approval being complete.

Consent

When contact is made with the nominated professional an electronic Participant Information Sheet (PIS) and consent form will be sent prior to the telephone interviews (see Appendix 2). An appointment convenient to the participant will be made to ring back to complete the interview. Consent forms will be returned before the interview is conducted and consent will be clarified verbally at the beginning of the interview. It will be clear within the PIS and consent form that all data will be anonymised by allocating each participant an individual number.

Data collection

The survey will be completed using a telephone interview, as this method has been reported to allow for rapid collection of data (Novick, 2008). Telephone surveys are quick to administer, allow access to a wide geographical area and enable the respondent to remain in their own environment which may encourage them to answer questions more in depth (Novick, 2008).

Furthermore, they allow the interviewer to explore the responses given by the participant and ask additional questions which would not be possible within the administration of a questionnaire (Carr and Worth, 2008). In addition, telephone interviews are likely to obtain higher response rates than written questionnaires (Carr and Worth, 2001).

However, a key disadvantage of telephone interviews is initiating the call at an inconvenient time placing the participant in an uncomfortable position (Carr and Worth, 2008). Attempts to minimise this potential issue have been implemented by sending an introductory email and making an appointment for the interview should reduce this potential problem. In addition, the literature notes that it is difficult to build a rapport within a telephone interview, Novick (2008) notes that this is helped by having a scripted opening statement to outline the rationale of the study

The design of a telephone interview may be structured or semi structured (Carr and Worth, 2001). On this occasion a semi-structured approach has been selected including both open-ended and closed questions (see Appendix 3 for schedule outline). The closed questions will ensure the survey remains focused on the topic of interventions to reduce interruptions to medication administration. However, the inclusion of open-ended questions will allow the interviewer to probe responses for further clarification. This method was demonstrated to be successful, with a response rate of 78% of hospital trusts by Berry, Brink and Metaxa (2017) in their audit of bereavement care in intensive care. In addition, it will enable the participant to describe the intervention and its measurement in detail (Bryman, 2012:246).

If the participant was required to end the interview early due to a clinical requirement, data collected up to that point would be included within the analysis and an appointment would be made to complete the rest of the interview.

Analysis

All interviews will be audio recorded to ensure accuracy of data collection (Novick 2008) and will be transcribed verbatim. It is anticipated that the data generated by this survey will be both quantitative and qualitative, due to the use of open-ended and closed questions. Therefore, a mix of data analysis methods are required. The demographic data such as numbers of units and types of interventions named will be presented as percentages. Free text answers will be analysed using thematic analysis and will seek to identify what the text says as it searches for the context and mechanisms which influence the use of interventions to reduce interruptions to medication administration. This aligns with the critical realism search for the context and mechanisms which influence reality. The qualitative content analysis process is presented in the table below.

Table 2 Thematic analysis

Braun and Clarke
Familiarising Yourself with the Data

Generating Initial Codes
Searching for Themes
Reviewing Potential Themes
Defining and Naming Themes
Producing the Report

It is proposed that stage 2 and 3 run con-currently and that the findings from all stages will be synthesised as a collective at the end of stage 4.

Stage 2b

Qualitative Interviews

Aims

- To identify the context and mechanisms which enable interventions to work through the exploration of health care professionals' experiences of using interventions/ strategies/ practice changes to reduce interruptions to medication administration.
- To understand what is acceptable within an intervention and why some interventions are not acceptable to health care professionals.

Study Design

Semi structured interviews with healthcare professionals

The interview schedule will be informed by the findings of an exploratory study which explored clinical decision-making when interrupted during medication administration (Bower et al, 2017). The critical realism analysis will search for context and mechanisms which improve the efficacy of interventions. Data collection will occur for up to 6 months after the approvals process has been completed.

Sample

A purposive method of sampling will be used, described by Palys (2008) as stakeholder sampling. This method is particularly relevant within evaluation research where the researcher wants to recruit participants who are involved with the delivery of a service (Palys, 2008). Within this study a maximum of 15 professionals will be recruited, which will include healthcare professionals (nurses, medical staff, AHP's and support staff) involved in the delivery of intensive care to critically ill children as it is important that their differing perspectives on the phenomena are recorded (see table 3 for sampling framework). However, the sample will have greater representation from professional groups (medical staff, AHP's and support staff) whose experiences have been largely missed within the literature. In addition, the researcher has access to the findings of a previous study which explored nurses' decision making when interrupted during medication administration which details their experiences of this process.

Table 3 Sampling Framework

Sampling Framework

Healthcare professionals will be invited to be considered for participation in the study and they will be informed within one month of volunteering whether they have been included or not.
Ideally there will be representation from each healthcare professional group Nursing Medical team AHP's Support team (receptionists, housekeepers, health care assistants)
Recruitment will occur up to 6 months after completion of approvals process A maximum of 4 nurses will be interviewed ideally from different units across England. The other 11 professionals (at least two of each professional group) will be recruited from the other groups named above and from as many different units as possible

The sample size was selected using Morse's (2000) list of influential factors (see table 4 for a summary of these factors regarding this part of the study).

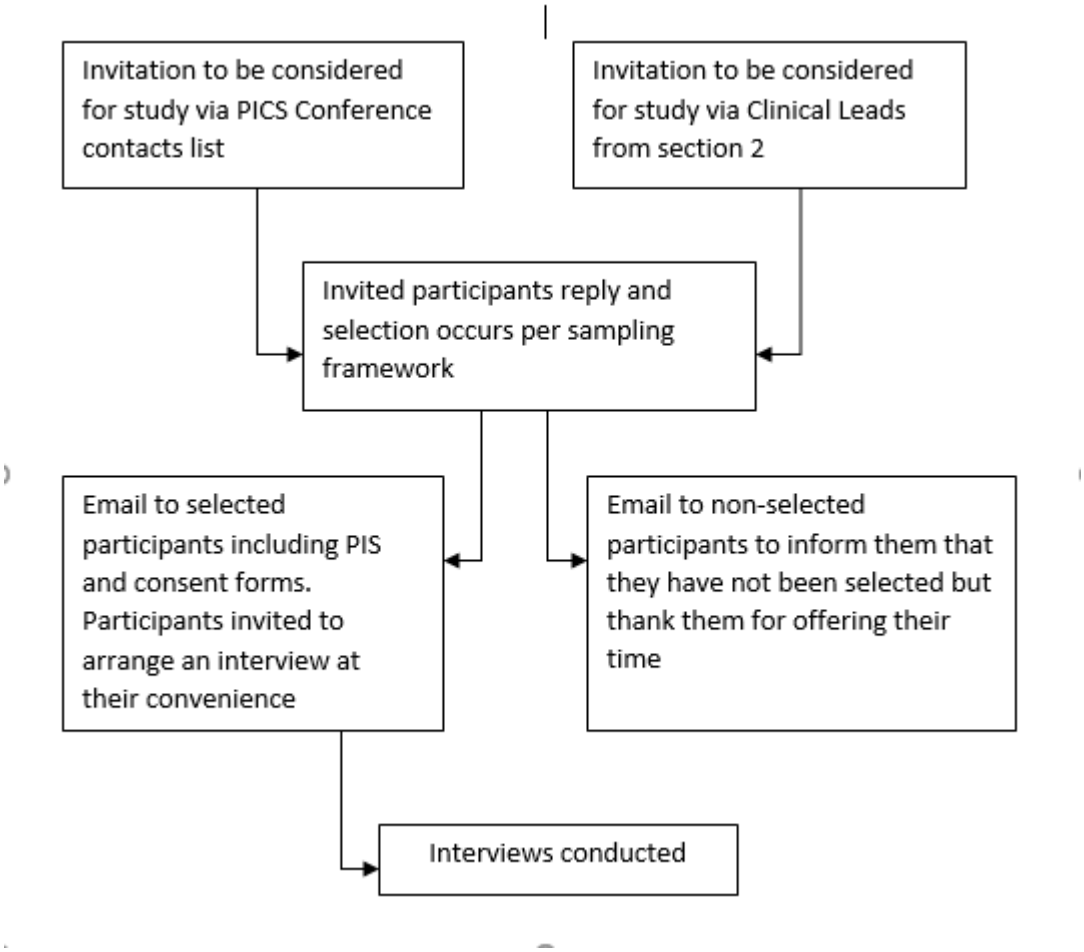
Table 4 Factors affecting sample size

Factor	
Scope	The broader the scope of the study the more participants will be required. The scope of this study was focused on interventions to reduce interruptions to medication administration. The interviews will also focus on experience, barriers and enablers to use and perceptions of efficacy.
Nature	If the topic is obvious and clear it is easily attainable and fewer participants are required. Medication administration is an activity which occurs frequently on a daily basis so participants should have increased ability to recall their experiences. However, it may raise potentially distressing issues or pressure from the work environment which may negatively impact on recall.
Quality	This relates to the ability of the participant to talk about the topic. The choice of method of interview will ensure that the participant is interviewed within a comfortable environment which may increase the willingness to share. However, sharing difficult experiences may negatively impact on this.
Design	The design of the study includes findings from a previous study and information gained in stage 2.
Use of shadow data	The concept of shadow data relates to participants talking about the experience of others. The findings from stage 1 will include shadow data which will inform the schedule of the questions for the in-depth semi-structured interviews in stage 3a.

Recruitment

Two concurrent approaches will be used to contact potential participants as detailed in the flow chart below:

Figure 4 Recruitment flow chart



- An email invitation to be considered for selection for the study (see Appendix 4) will be sent via two routes. An invitation will be sent to the multidisciplinary members of the Paediatric Intensive Care Society registered for the 2017 national conference via the administration team associated with the conference. In addition, an invitation will be circulated via the clinical leads from stage two who agreed will be asked to circulate the email. This second method of invitation will allow the request to reach a wider AHP and support team. The request will inform the member of the rationale for the study and details of the interview such as estimated length of time. In addition, each volunteer participant will be asked if they can recommend any professionals who may wish to take part. The volunteer participant will be asked to pass on a business card with the researchers contact details, to allow the recommended professional to choose whether to participate or not.
- The sample of participants will be selected as per the framework identified in the sampling section.
- An email will be sent to all volunteers, within one month to inform them whether they have been selected and to thank those who have not for offering their time. The email to the participants will include the PIS and consent form (see Appendix 5). The participant will have the choice of a telephone interview or face to face (at PICS conference) and this will be arranged at a convenient time for them

The use of two recruitment approaches with additional snowball sampling there will be access to a wider population therefore increasing recruitment rates (Bryman, 2012:424). However, if these strategies do not recruit a large enough sample a backup strategy will

be employed. The researcher is an insider with access to a professional network of contacts. These contacts will be asked to invite colleagues to participate. Nevertheless, it is hoped that the primary recruitment strategies will recruit an adequate voluntary sample of participants which will allow the researcher to explore the experiences of each professional group.

Consent

- The email will contain details concerning the rationale of the study and estimated length of interview. A PIS and consent form will be attached. Contact details will be included so the participant can contact the researcher to arrange an interview (via telephone or face to face) at a convenient time.
- Participants will be offered the opportunity to ask questions before consent forms are signed and before the interview begins.

Data Collection

The interview schedules (see Appendix 6) will be informed by the findings from a previous study (Bower et al, 2017). However, the questions will be different for AHP's and support staff who are not involved in medication administration. An example of a clear trail of question development can be seen in Appendix 7. The use of a semi-structured interview enables the researcher to use an interview schedule but also allows flexibility in its use (Bryman, 2012:471). In addition, the interviewer can follow up and explore interesting points within the answers provided by the participant. This combination ensures the interview remains focussed on the topic being researched but allows participants to express their views and experiences (Bryman, 2012:472).

Semi-structured Interviews will be conducted as requested by the participant via two different methods (face to face or telephone) at a time convenient to them. This will allow the participant to have some autonomy and choice over the modality of interview. These interviews will be in depth as they aim to explore participant's experiences and perceptions, therefore it is important that they are comfortable with the method used to conduct the interview (Carr and Worth, 2001). Therefore, allowing participants to choose from range of methods allows them to select a structure with which they are comfortable. Ensuring they are comfortable with the method will help to build rapport and produce richer data (Novick, 2008). All interviews will be audio recorded to allow transcription. Face to face interviews will occur in a quiet space to enable a clear recording to occur.

Data analysis

The data analysis process is the same as the one used for the qualitative element of the national survey of practice and is summarised in table 2.

Table 2 Thematic analysis

Braun and Clarke
Familiarising Yourself with the Data
Generating Initial Codes

Searching for Themes
Reviewing Potential Themes
Defining and Naming Themes
Producing the Report

The interviews will be audio recorded and transcribed verbatim. Familiarity with the data will be gained through transcribing and reading of transcriptions (Bailey, 2008). The data will then be coded; within critical realism (CR) there is limited guidance on the process of coding (Fletcher, 2016). The process will begin iteratively by building on a coding template and themes developed from previous research (Bower et al, 2017) which were identified during a previous study which explored nurses' decision making whilst interrupted during medication administration. However, this process will be flexible and the new data will drive the identification of new codes or themes and deletion of codes and themes which may no longer be relevant (Fletcher, 2016). Codes will then be grouped into themes which will search for the context of interventions, mechanisms which influence implementation and their impact on outcomes. These will be verified by a second researcher.

The findings from all stages of this study will be collectively synthesised using a retroductive strategy which is linked with critical realism (Blaikie, 2000:112). This discussion will aim to explain how interventions to reduce interruptions to medication administration in PICU are influenced by external mechanisms. These mechanisms may improve the impact of the intervention or prevent it from working. The synthesis will explore these effects and explain them through the application of theories from other disciplines (Blaikie, 2000:111).

DATA STORAGE:

All hard copy data will be stored within a locked cupboard within a locked office, as per the Data Protection Act. Electronic data will be stored on Coventry University password protected hard drive. Audio recordings will be destroyed after transcription. The data will be anonymised.

GOVERNANCE ARRANGEMENTS

The study sponsor is Coventry University.

Compliance with research design though the study protocol, including ethics, collecting, managing and storage of data is the responsibility of the study team. The study team is familiar with the NHS Research Governance Framework (2005). The team will have current Good Clinical Practice certification to ensure that the study adheres to the correct principles of research practice.

ETHICAL ISSUES

Insider researcher

The researcher is a PICU nurse with extensive experience in providing care to critically ill children and implementing changes to clinical practice. This knowledge and experience is beneficial in that the researcher will understand detailed descriptions of practice which may use medical and nursing terminology. However, she will use strategies do develop awareness of her own perceptions and beliefs during the study. A reflexive diary will be maintained throughout to allow the researcher to examine her own perceptions and their enable her to

have an awareness of their impact on the research (Ortlipp, 2008). The reflexive diary will be anonymised to ensure participant identity is protected.

Participant harm

One of the central principles of any research study is non-maleficence; to do no harm (Beauchamp and Childress, 2001:12). There is a potential risk that participants may become upset during the interview if issues of previous or current medication errors are raised. If this occurred, the participant would be given the choice of the following actions;

i. To continue
ii. To have time out
iii. To stop the interview
iv. To rearrange for another day
v. Referral to an NHS counselling helpline

If the participant decides to stop the interview they will be reminded that data collected up until that point will be used as indicated in the PIS.

Patient Harm

If the researcher were to hear of an actual event with associated evidence of patient harm she would comply with the following process.

i. Determine if this event had been recorded as per hospital trust incident reporting guidelines
ii. If the event had been documented no further action would be taken
iii. If the event did not involve the participant and it was an error they had observed, the nursing manager of the unit would be informed of the details of the incident
iv. If the event involved the participant and had not been reported, then the nursing manager of that unit would be informed of the details with the participants' name

This process will be documented within the PIS.

The researcher required to act within the Nursing Code of Conduct both within practice and as a researcher within the clinical field (NMC, 2015).

Informed Consent

Each participant within this study will be asked to consent as per Good Clinical Practice Guidelines (NIHR, 2013) using participant information sheets. The PIS will be given to staff with a consent form in advance to allow them to assimilate the information and provide consent without feeling pressured. The participants will be given the opportunity to ask questions about the study during the initial phone call to make the appointment to conduct the survey or interview. Consent will be clarified at the start of the survey or interview. This will ensure that all participants will be fully informed (Green and Thorogood, 2014:70). Participants will also be made aware they can withdraw at any point and there will be no consequence to this decision (Robson, 2011:297). In addition, they can withdraw their data up to a week after the survey or interview has been completed. All consent forms will be returned to the researcher either via email or as a hard copy. They will be stored securely in the site file.

The participants involved in the interview stage of the study will be given a £10 Amazon voucher as a 'thank you' for their time. The invitation email highlights the award of a voucher but it is not named and no value is mentioned. This will reduce the likelihood that participants are induced to take part in the study.

Confidentiality

Ensuring that a participants' identity is protected throughout the study is an essential ethical requirement linked to the principle of beneficence (Kaiser, 2010). The principle of beneficence seeks to ensure that the research participant is not exposed to any harm. On this occasion the researcher is required to ensure that the participant is not harmed by their interview data being identifiable and linked to them. There are potential negative risks associated with confidentiality breaches such as harm to relationships or the sharing of personal information.

This study will use a dominant approach to confidentiality, data will be collected, analysed and disseminated without compromising the participants' identity (Kaiser, 2009). This approach ensures confidentiality is protected throughout the processes of data collection, transcription, analysis and reporting. The PIS describes how the participant's identity will be protected. During transcription, all identifiable information (names, roles, geographical locations, unit descriptions) will be removed. This will create a clean data set; however, contextual data will remain, and the researcher will decide with the advice of her supervisory team whether this will be used in the reporting of the study's findings. The anonymous transcription will be returned to the participant to ensure they are happy with the clean data which it contains.

STUDY RISK MANAGEMENT PLAN

There are risks involved in any study and the table below highlights risks identified by the study team and the controls that are in place to minimise their effect.

Risk Area	Potential Impact	Management Approach
Poor practice recorded in interview	Minimal immediate harm to patient	Issues discussed with unit manager
Participant harm	Discontinuation of interview	Professional will be given the choice whether to restart interview or not. If interview is terminated permission to use data already collected will be sought. Support networks will be offered (senior nurse, counselling or chaplaincy) if required by the professional.
Poor recruitment	Limited participants	The study has been designed using two approaches to recruitment. In each arm of the recruitment the participant will be asked to agree to be considered for participation in the study. This will allow maximum recruitment to achieve the sample required. However, if over recruitment is achieved the researcher can respond and thank the participant but inform them that the sampling strategy has not included them on this occasion.

Confidentiality	Risk of identification of participants	The PICU population within England is small so a dominant approach to confidentiality will be used within the study (Kaiser, 2009). This approach attempts to remove all identifiable information about each participant. All information concerning names (of participants and co-workers), location of units and roles will be removed during the transcription phase. The anonymised transcription will be shared with the participant to ensure they are happy with the data. Only anonymised quotes will be used within the dissemination of this study.
Disclosure	Description of an event which caused harm to patient	This would be escalated as per the plan outlined in the ethical issues section.

PUBLICATION / DISSEMINATION

In the PIS, participants will be informed that while the researcher intends to publish the findings in relevant peer-reviewed journals and conferences. All identifiable information (name, role and detail of specific unit) will be removed and replaced with an identifying number to protect the anonymity of participants (see risk management plan for detail of this process). However, anonymised quotes from the interviews will be used publicly to support the analysis of the data and participants will be informed of this within the PIS.

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Appendix 1 – Invitation to participate in National Survey of Practice

Hello,

Thank you for taking the time to read this email.

I am contacting you, via PICS, as you are listed as either the nursing or medical lead for the PICU within your Trust. I would like to invite you to participate in a National Survey of Practice regarding the use of interventions to reduce interruptions to medication administration on PICU.

I am a PhD student from Coventry University who has a significant clinical experience as a senior nurse within PICU. During my time as a Clinical Development nurse in PICU I investigated a significant amount of medication errors and realised that the environment in which PICU nurses are expected to prepare and administer medications often contributed to the errors made. During the investigation process, nurses would frequently comment on the impact of being interrupted and this prompted me to explore ways in which we could improve our practice. I have started to develop a programme of research which I hope will lead to the development of an intervention which is sensitive to the complex environment of PICU. This programme began with a study which examined the frequency and type of interruptions to medication administration in PICU and then followed this by exploring the decision-making process used by PICU nurses when interrupted. Both studies have illuminated findings which indicate that there are complex relationships, communication and actions required within PICU which current interventions do not comprehend.

Before I begin to explore what is required from an intervention within PICU, I would like to identify what current practice is within England as currently this is unknown. The survey will aim to identify which interventions are used within PICU's within England and which outcomes are measured to determine what impact they have had.

The survey will last between 10 and 15 minutes and will be conducted at a time which is convenient to you. If you would prefer to nominate another member of the team who would be able to complete the survey, please can you forward this email to them and ask them to reply to the email. If you or a colleague agree to participate I will then email a participant information sheet and consent form.

Thank you again for taking the time to consider my request.

Kind regards

Rachel Bower

Appendix 2 – Participant Information Sheet and Consent for National Survey of Practice

A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Information sheet for participants undertaking telephone survey

Project lead: Rachel Bower

Introduction

I would like to invite you to participate in a study which aims to critically explore the use of existing interventions to reduce interruptions to medication administration within Paediatric

Intensive Care Units (PICU). I am undertaking this study as part of a PhD programme, supervised by Coventry University.

The design of the study includes a telephone interview which aims to understand which existing interventions to reduce interruptions to medication administration are in use within PICU's across the England. In addition, it also aims to understand what assessment has been undertaken to see if these interventions have reduced interruptions.

Before you consider taking part in this study, please take the time to read this leaflet as it is important you understand why the study is being undertaken and what is involved. If you have any questions about the study please contact the project lead, Rachel Bower, whose details are at the end of this information leaflet.

What is the purpose of this project?
Within the literature concerning reducing interruptions to medication administration several interventions have been trialled: no interruption zones, brightly coloured clothing, signs, protocols and education strategies. Systematic reviews which examine these studies highlight that there is a lack of data to support the conclusion that these interventions are sustainably effective. The design of these interventions does not allow for the necessary interruptions which may be required to ensure patients remain safe. In addition, health care professionals do not always comply with the intervention or perceive that it has any benefits.

The Medical Research Council's (MRC) Framework for the development of complex interventions states that in the development phase of the design it is important to understand the current evidence base. There is very little literature which relates specifically to PICU and no overview of current practice in England. Therefore, this telephone survey will seek to clarify what existing interventions are in use and how they have been measured for efficacy.

Why have I been chosen?
You have been identified as a valuable participant as you are the clinical lead for a PICU or have been nominated by your clinical lead to respond.

What will happen if I take part in both the interview?
If you decide that you wish to participate in this study, please sign the separate consent form and email it to Rachel Bower.

You can decide when the telephone interview so that the timing is convenient for you. The interview will be short (approximately 10 - 15 minutes), the interviewer has some set questions, however, she will respond to your answers and may explore them in more detail. The survey will be recorded to allow verbatim transcription to occur. If you are required to attend to any clinical duties whilst the interview is in progress the data collected up until that point will be automatically included in the analysis and if possible another appointment will be made to complete the interview.

What are the possible risks and disadvantages of taking part?
As the survey is seeking to clarify current practice and the call will be recorded there are minimal risks associated with the study. However, you will receive a copy of the transcription to ensure you are happy with the content before it is analysed.

You do not have to take part in the study and you can withdraw at any point in the study, however, any data collected will be used in the analysis even if you withdraw.

What are the possible benefits of taking part?
You have the opportunity of contributing to the evidence base about managing interruptions whilst administering medication. Your knowledge and perceptions will help to make the medication administration process for critically ill children safer. You will also be offered the chance to comment on the design of the intervention at the end of the study. If you wish to be involved in this review, please complete the box at the bottom of the consent form.

What if something goes wrong and I want to make a complaint?
If you wish to complain about anything within this study, please contact:
Professor Rob James
Academic Dean
Faculty of Health and Life Sciences
Coventry University
Room 111, Priory Street
Coventry, CV1 5FB
Tel 0247 7655802

This matter will be investigated by the university complaints procedure.

Will my taking part in this project be kept confidential?
All data collected during this study will be kept strictly confidential and will be stored in password protected files. No individual will be identified during the dissemination of this study.

Who has reviewed this project?
This study has been review by Coventry University ethical committee and has been approved by the Health Research Authority.

Who can I contact for further information?

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Chief Investigator
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Children and Families Research /Centre for Technology Enabled Health Research
Coventry University
Contact details: joseph.manning@coventry.ac.uk
+44 7812 275027

If you are interested in participating in both the observation and interview, please sign and return the consent form.

Thank you very much for taking the time to read this information leaflet.

A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Consent form for telephone survey participants

	Please initial
I can confirm that I have read and understood the information sheet version _ and had chance to ask questions about the study.	
I can confirm that I have chosen to participate in this study and can withdraw at any point without providing a reason.	
I understand that observation notes will be stored at Nottingham University Hospitals Trust in a locked cupboard, in a locked office. I give permission for the research team to access these files to analyse and publish findings from this project.	

I understand that the interview will be recorded by a digital voice recorder	
I understand that all data will be anonymous and stored in secure electronic files and that identities will be kept confidential.	
I agree to take part in the study as outlined in the information sheet.	

Participant name	Signature	Date
Researcher name	Signature	Date

If you wish to comment on the design of the intervention at the end of this study, please complete the section below. Please state the email you wish to be contacted by.

Appendix 3 – Schedule for National Survey of Practice

Introduction
Thank you for agreeing to take part in this survey. Can I clarify that you have consented to take part in this telephone survey? Do you have any further questions about the study or survey you would like to ask? Are you happy to continue?
Questions
Can you tell me your job title? What band/grade are you and how long have you worked in PICU? What percentage of your role involves the delivery of clinical care?
Within the clinical task of medication administration, have you implemented any interventions/ strategies/ practice changes/ medication safety initiatives which aimed to reduce interruptions? Yes/No/Unsure Please can you describe the intervention?
When was, this change made? Is it still in use now? Yes/No/Unsure If no, why is it no longer used?
Did you or do you measure what impact this change had on medication administration? How do you measure this and why did you select this outcome? What impact has or did this intervention have on the outcome?
Were any other changes made to practice at the same time which may influence this outcome?
Is there anything else you would like to add?
Thank you again for agreeing to take part.

Appendix 4 – Invitations to participate in interviews

Hello,

Thank you for taking the time to read this email.

I am contacting you as you are listed as you have been identified by your clinical lead or a colleague as working within PICU. I would like to invite you to be considered for inclusion in a study regarding the use of interventions to reduce interruptions to medication administration on PICU.

I am a PhD student from Coventry University who has a significant clinical experience as a senior nurse within PICU. During my time as a Clinical Development nurse in PICU I investigated a significant amount of medication errors and realised that the environment in which PICU nurses are expected to prepare and administer medications often contributed to the errors made. During the investigation process, nurses would frequently comment on the impact of being interrupted and this prompted me to explore ways in which we could improve our practice. I have started to develop a programme of research which I hope will lead to the development of an intervention which is sensitive to the complex environment of PICU. This programme began with a study which examined the frequency and type of interruptions to medication administration in PICU and then followed this by exploring the decision-making process used by PICU nurses when interrupted. Both studies have illuminated findings which indicate that there are complex relationships, communication and actions required within PICU which current interventions do not comprehend.

I am extremely interested in exploring with the whole team in PICU experiences of using or observing the use of any intervention which aims to reduce interruptions to medication administration.

If you agree to be considered for this study the interview will last up to 45 minutes and will be conducted either in person or via the telephone at a time which is convenient to you. Due to a sampling framework being used to try to obtain representation from different units and healthcare professionals there it is possible you may not be selected. If you are selected to participate in the study I will forward a participant information sheet and consent form, at the end of the interview you will be given a voucher to thank you for your time. If you are not selected I will contact you within a month, to inform you of this decision.

Thank you

Hello,

Thank you for taking the time to read this email.

I am contacting you as you are listed as you have registered to attend the National Paediatric Intensive Care Society Annual Scientific Meeting, 2017. I would like to invite you to be considered for inclusion in a qualitative study regarding the use of interventions to reduce interruptions to medication administration on PICU.

I am a PhD student from Coventry University who has a significant clinical experience as a senior nurse within PICU. During my time as a Clinical Development nurse in PICU I investigated a significant amount of medication errors and realised that the environment in which PICU nurses are expected to prepare and administer medications often contributed to the errors made. During the investigation process, nurses would frequently comment on the impact of being interrupted and this prompted me to explore ways in which we could improve our practice. I have started to develop a programme of research which I hope will lead to the development of an intervention which is sensitive to the complex environment of PICU. This programme began with a study which examined the frequency and type of interruptions to medication administration in PICU and then followed this by exploring the decision-making process used by PICU nurses when interrupted. Both studies have illuminated findings which indicate that there are complex relationships, communication and actions required within PICU which current interventions do not comprehend.

I am extremely interested in exploring with the multidisciplinary team, experiences of using or observing the use of any intervention which aims to reduce interruptions to medication administration on PICU.

If you agree to be considered for this study the interview will last up to 45 minutes and will be conducted during or after the PICS conference at a time which is convenient to you or via the telephone if you prefer. Due to a sampling framework being used to try to obtain representation from different units and healthcare professionals there it is possible you may not be selected. If you are selected to participate in the study I will forward a participant information sheet and consent form, at the end of the interview you will be given a small voucher to say thank you for your time. If you are not selected I will contact you within a month, to inform you of this decision.

Thank you again for taking the time to consider my request.

Kind regards

Rachel Bower

Appendix 5 – Participant Information Sheet and Consent Form (Interviews)

A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Information sheet for participants

Project lead: Rachel Bower

Introduction
I would like to invite you to participate in a study which aims to critically explore the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care Units (PICU). I am undertaking this study as part of a PhD programme, facilitated by Coventry University.

The design of the study includes an in-depth semi-structured interview which will critically explore user experiences, barriers and facilitators and impact of existing interventions to reduce interruptions to medication administration.

Before you consider taking part in this study, please take the time to read this leaflet as it is important you understand why the study is being undertaken and what is involved. If you have any questions about the study please contact the project lead, Rachel Bower, whose details are at the end of this information leaflet.

What is the purpose of this project?
Within the literature concerning reducing interruptions to medication administration several interventions have been trialled; no interruption zones, brightly coloured clothing, signs, protocols and education strategies. Systematic reviews which examine these studies highlight that there is a lack of data to support the conclusion that these interventions are sustainably effective. The design of these interventions does not allow for the necessary interruptions which may be required to ensure patients remain safe. In addition, health care professionals do not always comply with the intervention or perceive that it has any benefits.

The Medical Research Council's (MRC) Framework for the development of complex interventions states that stakeholder engagement is vital within the development of an intervention. This engagement in the design of an intervention should help to ensure it will work within the environment it has been constructed for and is acceptable to the professionals who need to use it. Therefore, these qualitative interviews aim to explore your experiences of using any of these interventions and your views regarding what is acceptable within an intervention.

Why have I been chosen?
You have been identified as a valuable participant as you are currently identified by your clinical lead, a colleague or by your membership of the Paediatric Intensive Care Society as a health care professional who works in PICU.

What will happen if I take part in both the interview?
If you decide that you wish to participate in this study, please sign the separate consent form and email or hand it to Rachel Bower.

You can decide whether you would like the interview to be conducted via telephone or face to face at the PICS conference in Nottingham, October 2017. The interview will be semi-structured, in that the interviewer has some set questions, however, she will respond to your answers and explore your experiences and views in more detail. The interview will be recorded to allow for verbatim transcription.

What are the possible risks and disadvantages of taking part?
There is a risk that the interview may highlight a medication error. If it is evident that this error caused harm to the patient, the researcher will seek to clarify whether it has been reported as an incident. If reporting has occurred, then no further action will be taken. If the participant was involved with the error and no reporting has occurred, the nurse manager of their unit will be informed of the error and person involved. If the participant was not involved but observed the error and it was not reported only the details of the error will be reported to the nurse manager. The researcher Rachel Bower is bound by the NMC Code of Conduct as she is a Registered Nurse.

You do not have to take part in the study and you can withdraw at any point in the study. However, any data already collected will be used within the study.

What are the possible benefits of taking part?
You have the opportunity of contributing to the evidence base about managing interruptions whilst administering medication. Your knowledge and perceptions will help to make the medication administration process for critically ill children safer. You will also be offered the chance to comment on the design of the intervention at the end of the study. If you wish to be involved in this review, please complete the box at the bottom of the consent form

What if something goes wrong and I want to make a complaint?
If you wish to complain about anything within this study, please contact:
Professor Rob James
Academic Dean
Faculty of Health and Life Sciences
Coventry University
Room 111, Priory Street
Coventry, CV1 5FB
Tel 0247 7655802

This matter will be investigated by the university complaints procedure.

Will my taking part in this project be kept confidential?
All data collected during this study will be kept strictly confidential and will be stored in password protected files. No individual will be identified during the dissemination of this study.

Who has reviewed this project?
This study has been review by Coventry University ethical committee and has been approved by the Health Research Authority.

Who can I contact for further information?

Researcher
Rachel Bower
Doctoral Student, Coventry University
Contact details: bowerr2@coventry.ac.uk
Tel 07528882184

Chief Investigator
Dr Joseph Manning
Chief Investigator
Clinical-Academic Senior Research Fellow in Children, Young People and Families Nursing
Children and Families Research /Centre for Technology Enabled Health Research
Coventry University
Contact details: joseph.manning@coventry.ac.uk
+44 7812 275027

If you are interested in participating in both the observation and interview, please sign and return the consent form.

Thank you very much for taking the time to read this information leaflet.

A qualitative exploration of the use of existing interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Consent form for interview participants

	Please initial
I can confirm that I have read and understood the information sheet version _ and had chance to ask questions about the study.	
I can confirm that I have chosen to participate in this study and can withdraw at any point without providing a reason.	

I understand that observation notes will be stored at Nottingham University Hospitals Trust in a locked cupboard, in a locked office. I give permission for the research team to access these files to analyse and publish findings from this project.	
I understand that the interview will be recorded by a digital voice recorder	
I understand that all data will be anonymous and stored in secure electronic files and that identities will be kept confidential.	
I agree to take part in the study as outlined in the information sheet.	

Participant name	Signature	Date
Researcher name	Signature	Date

If you wish to comment on the design of the intervention at the end of this study, please complete the section below. Please state the email you wish to be contacted by.

Appendix 6 – Interview Schedule (Nursing and Medical team)

Introduction

Thank you for agreeing to participate in this interview. Please can you clarify that you have read the participant information sheet and have no further questions to ask about the study? And you are happy to proceed with the interview which will be recorded?

1. Can you describe the process of medication administration within your PICU?

2. On a scale of 1-10 with 10 being most important and 1 being least important. How important is the task of medication administration?

3. Have you had any specific education or preparation for administering medication?

4. Have you experienced or observed interruptions within medication administration on PICU?

5. How do you respond to interruptions? / what responses have you observed when interruptions occur?

6. Is there anything which makes an interruption easier to manage? What helps you to manage interruptions to medication administration on PICU?

7. Have you observed anything else which helps nurses/doctors/AHP's respond to interruptions to mediation administration?

8. Can you describe any intervention/ strategies/ approaches/ ways of working specifically designed to reduce interruptions to medication administration?

9. Have there been any changes to practice from the implementation of this intervention?

10. What were the changes you observed?

11. How did it work?

12. Who was involved?

13. If you could create any strategy to reduce interruptions what would it be?

14. Who and what would it involve? Where would it be based? And how would it work?

Do you have any further comments you would like to make?

Introduction

Thank you for agreeing to participate in this interview. Please can you clarify that you have read the participant information sheet and have no further questions to ask about the study? And you are happy to proceed with the interview which will be recorded?

1. On a scale of 1- 10 with 10 being very important and 1 being not at all important. How important do you think medication administration is within PICU?

2. Are you involved in the process at all?

3. Do you receive any information or education about medication administration on PICU?

4. Have you observed interruptions within medication administration on PICU?

5. What responses have you observed when interruptions occur?

6. Have you ever interrupted a nurse during medication administration?

7. Can you describe how you decide when to interrupt?

8. Are there occasions when you perceive that it is more acceptable to interrupt than others?

9. Have you observed any interventions/ strategies/ approaches which may help nurses to manage interruptions to mediation administration?

10. Have you experienced or observed changes to practice from the implementation of this intervention?

11. If you could create any strategy to reduce interruptions to medication administration what would it be?

12. Who and what would it involve? Where would it be based? How would it work?

Appendix 7 Development of questions (example)

Critical realism lens	Code	Questionnaire statement	Safety attitude domain	Initial interview question	Final interview questions
Empirical (human perceptions of what's actually happening?)	Impact of Interruption	Interruptions are detrimental to medication safety. When interrupted, I can continue with the process easily	Working conditions	How do interruptions influence your medication administration practice? How do the intervention(s) you use change this?	Have you experienced or observed interruptions within medication administration on PICU? How do you respond to interruptions? / What responses have you observed when interruptions occur? Is there anything which makes an interruption easier to manage?

Appendix 3 – Transcription example

Survey 5 - 14 mins 58 secs

Researcher – so just before we begin the survey can I just double check that you are happy to continue with the survey, you are happy with the consent form and you have read the information sheet?

Participant – yes, yes that's fine

Researcher – thank you er could you describe your job and let me know how long you have been working in PICU?

Participant – Consultant intensivist in PICU and I've been consultant for 8 years

Researcher – ok

Participant – em yeah, before that I did the usual training programme through paediatrics and then sort of specialised

Researcher – yeah and what percentage of your role involves the delivery of clinical care?

Participant – er well currently because I've got a leadership role now so it's dropped a bit to about 65%. That's my normal job plan for clinical.

Researcher – ok so within your PICU within the clinical task of medication administration have you implemented any interventions or strategies or medication administration safety initiatives which aim to reduce interruptions?

Participant – er yeah so in our department we've got the red apron er initiative which erm so each bed space has diff a series of apron colours

Researcher – hmm

Participant – er and red is a signal to say do not disturb so the nurse is doing checks medications usually at the bedside erm will put on the red aprons and the objective of that is to reduce interruptions so they don't make, are less prone to drug errors

Researcher – ok

Participant – that's the idea

Researcher – and do the red aprons have it printed on 'do not interrupt' or are they just known as to?

Participant – er no there's no er there's nothing printed on them they're just just red in colour

Researcher - ok

Participant - erm they are sort of fairly distinctive but erm yeah there's no other sort of signage or anything

Researcher – and how do people outside the PICU team know that they mean drugs?

Participant – er outside the team?

Researcher – yeah

Participant – erm I'm not sure about outside the team actually so I mean I would I guess I would consider our team to include the sort of allied health professionals, physios, pharmacists, etcetera as well as all the staff who work on PIC all the time. So I think they would all be aware but I don't know for sure that's the case, but I'm pretty sure that its well known. Outside the team so visiting professionals from other teams I've got, I actually don't know how aware they are of the red aprons cause I'm not even sure if it's something that's used across the trust. I'm only telling you what I know, obviously others would know more.

Researcher - yeah that's fine, when were the red aprons introduced?

Participant - erm, I don't know I mean they must have been there at least a couple of years but again that's not, I didn't introduce them so I don't know

Researcher – ok, and have you measured the impact on interruption rates or error rates?

Participant – well the, it's not my project but the, I know that the safety team erm keep a pretty close eye on reported medication errors and obviously that's erm reviewed pretty er regularly

Researcher – yeah

Participant – so weekly meetings to look at reported stuff but that depends on errors being reported, they did a deeper dive as well so one of the nurses who led the initiative has done a time and motion study measuring interruptions erm over quite, I don't know how long she measured it over but it was a significant amount of time erm specifically measuring interruptions to nurses who were involved in delivering drugs

Researcher – hmm

Participant – but I don't think it was comparing pre and post or anything like that, it was just an observational study of what happens in the current system

Researcher – yeah

Participant – so and every time that sort of that data will sort of come up or periodically there seems to the approach to just re-inform, re-educate and re-emphasise the fact that red aprons signal do not disturb so erm which is you know I suppose a fairly typical approach to quality improvement, the first step is just to try harder isn't it?

Researcher – yes (laughs)

Participant - (laughs) it doesn't necessarily work but erm yes there are some data but I don't have them to hand

Researcher – ok , so is your personal experience that they do work? erm the aprons?

Participant – well I, yeah I mean I think they do have some effect, clearly they don't work a 100% erm they're not they don't alter behaviour to that degree but erm they I mean I can speak on my own behalf

Researcher – yeah

Participant – when I go to ask nurses to do something for my, for one of the patients I quite often will notice if they've got a red apron on

Researcher – hmm

Participant – and I have on occasionally, if it's urgent I will interrupt say you need to stop but but most of the time I'll you know apologise or just walk away and come back later erm

Researcher – hmm

Participant – so it does have, it does have an effect on me I'm not sure if it does on everyone but erm it's a bit like, we also have these prescribing areas for the

Researcher – hmm

Participant – prescribers and again the same thing the general culture is you're not supposed to talk to someone if they are sitting at one of those areas and it does, it does have an effect. Yeah it's a sort of subtle effect

Researcher – yeah

Participant – and clearly it could be better but nothing's perfect in life, I think it's a step in the right direction

Researcher – ok, my last question was going to be whether there were any other changes that sort of had as a consequence had impacted on interruptions on PICU or whether there's any other?

Participant – erm what whether we've done any other work, is that what you are asking?

Researcher – yeah

Participant – yeah I mean I think like I say the prescribing areas is the thing that immediately sprung to mind cause it's the same idea as the, you know if you interrupt a prescription it has, it has the same effect as interrupting the administration or the drug checking erm it's part of the same process

Researcher – yes

Participant – but again I think that has helped, erm the other thing,

Researcher – do you

Participant - there is a culture of not prescribing on ward rounds so erm again it's not policed r aggressively but it is, it is the norm, if something needs writing up we won't do it on the ward round and again that's sort of sends the message that interruptions are not sort of accepted.

Researcher – hmm

Participant – erm we also have pharmacists on ward rounds as I'm sure a lot of PICU's do and again their presence seems to help, just for sort of general awareness of er sort of etiquette around drugs but yeah nothing else I can think of around prescribing. Er sorry about nurse interruptions.

Researcher – and with the prescribing zones have you measured those at all?

Participant – again it's not so I think the safety team have done some work on that, I don't think they've done a robust er trial or anything along those lines. There was, there was, well we are doing a prescribing project where we are trying to the prescriptions of antimicrobials which is more of a stewardship project erm that is, erm I suppose it's a behavioural, cultural er intervention but we're not really, we're not looking at interruptions or prescribing areas in that project, we're just looking at the end product which is what the prescription looks like.

Researcher – hmm

Participant – erm there are tight links together

Researcher – ok, and who do you think leads these projects within the unit?

Participant – within our unit?

Researcher – yes

Participant – so for the interruptions I'd say ********** is our main erm lead for that she's the safety she's on the safety team, she's got a number of roles that take, but erm medication interruption has become quite a big part of her er role in the safety team. And she, I think she did that time and motion study that I was mentioning where they observed the numbers of the interruptions and like I say I can't remember the numbers but they were quite, they were quite impressive rates of interruptions even, even with the measures that have already been put in place.

Researcher – yeah

Participant – I mean it seems to me it's quite, it's quite common to go to bed spaces and drugs are being checked, it's like we use so many drugs and they all need to be checked and whether there's a more efficient system for that erm one, one wonders because you know quite often I'll go to the bedside to make a suggestion or make a change and sure enough the nurse is there in their red aprons having a drug checked (laughs). It's like it's a major part of their day

Researcher – yeah

Participant – if, if we could it the whole thing more streamlined then that would help because it would just be less time to interrupt anyway.

Researcher – yeah

Participant – erm we're about to get e-prescribing in our unit so we're behind the times and still on paper. And I think that's gonna I dunno if it's going to be good or bad. Time will tell (laughs), hopefully it will be slightly quicker.

Researcher – often it raises different issues doesn't it?

Participant – yeah, yep

Researcher – ok , is there anything else you would like to add at all?

Participant – no I've got, nothing sort of comes to mind, no nothing I don't think that's of relevance to what your studying. What's erm the intention of your data when you've sort of finished at this stage?

Researcher – well, I've sort of done a programme of research where I started out similar to where you started with the sort of observational study just looking at what interruptions there were and how frequent

Participant – yeah

Researcher – and realised you know that we did have a significant problem erm but also realised there's a significant amount of interruptions that are necessary for patient safety aw well.

Participant – hmm

Researcher – er so I felt that erm bringing in may be the red tabards, aprons or no interruption zones wouldn't necessarily address the issue, erm so my next study looked at nurse decision making when they were interrupted and sort of realised the complexity that's underneath it, so nurses don't like to be seen to be rude, they don't want to add to the stress of parents if they're asking questions

Participant – yeah

Researcher – erm em you know the communication with medical staff, if that's the only time you're gonna see them in that day then that's really important to talk to them and em sort of began to think you know the aviation theory that underpins all these wasn't sort of necessarily the right one I don't think.

Participant - hm

Researcher - It's very difficult to make a blanket statement of do not interrupt while we're doing this task because you know the ongoing care you've got for the patient doesn't allow you to just switch off from everything else.

Participant – yes

Researcher – erm so I've gone back to the literature and done a realist review which highlights the importance of things like culture and engagement and leadership so whatever

Participant – yeah

Researcher – is implemented, without that it doesn't work and most of them haven't been sustained there's very few places that manage to sustain erm those sorts of interventions erm long term

Participant – yeah

Researcher – so now I'm sort of trying to er gather data from a wider team because it's sort of trying to get, to understand the impact of our behaviour on support staff and allied health professionals. And if they see nurses talking about non-medication related things then it makes them think well it's ok to interrupt anyway. And erm

Participant – yeah

Researcher – and I'm going to try to talk to parents as well. To interview some parents next year. And try to pull it all together and see what I can make of it, so look for a new underpinning theory to support whatever I decide.

Participant – well it sounds like a challenge but I mean have you come across the safety two er concept?

Researcher – no

Participant – I don't know, but well one of my interests is, is safety basically

Researcher – hmm

Participant – in a broader sense, safety, the idea with safety two is that it's a new concept of safety that erm a safe environment or a safe unit has a condition where as many things as possible go right

Researcher – hmm

Participant - which is different from the traditional view of safety which view is that as few things as possible go wrong. Erm so it's subtly different but actually it's a big difference when you think about what it is you then study to understand

Researcher – yeah

Participant – in safety two what the proponents are trying to do is study is what's happening correctly and why is it working in these situations, so the majority of drugs are administered correctly

Researcher – yeah

Participant – so there's a wealth sort of data, or understanding amongst the successful drug administrations which might sort of be a complimentary approach to try and understand why we also make errors it's a quite interesting idea, innovative it hasn't really there hasn't really been an operational solution to it yet but we're doing a bit of work in that area which is why I brought it up

Researcher – hmm

Participant – it may it may be of interest to you?

Researcher – yeah, I'll definitely have to look at that. Ok thank you so much for your time

Participant – you're very welcome, good luck with the project

Researcher - thank you very much

Appendix 4 – Coding example with definitions

Survey 5

Data	Summary	Code	CMO
Researcher – so just before we begin the survey can I just double check that you are happy to continue with the survey, you are happy with the consent form and you have read the information sheet? Participant – yes, yes that's fine (5) Researcher – thank you er could you describe your job and let me know how long you have been working in PICU? Participant – Consultant intensivist in PICU and I've been consultant for 8 years (8) Researcher – ok	Consultant 8 years' experience Paediatric/PICU trainee	PI PI	C C

Participant – em yeah, before that I did the usual training programme through paediatrics and then sort of specialised (10-11) Researcher – yeah and what percentage of your role involves the delivery of clinical care? Participant – er well currently because I've got a leadership role now so it's dropped a bit to about 65%. That's my normal job plan for clinical. (13-14)	Leadership role 65% clinical care	PI PI	C C
Researcher – ok so within your PICU within the clinical task of medication administration have you implemented any interventions or strategies or medication administration safety initiatives which aim to reduce interruptions? Participant – er yeah so in our department we've got the red apron er initiative which erm (18) so each bed space has diff a series of apron colours (19)	Red apron initiative Different coloured aprons accessible at each bed	ID ID	C C

Researcher – hmm		ID	M
Participant – er and red is a signal to say do not disturb so the nurse is doing checks medications (21-22)	Red = do not disturb as checking medications	MP	C
usually at the bedside erm will put on the red aprons (22)	Bedside preparation	A	O
and the objective of that is to reduce interruptions so they don't make, are less prone to drug errors (22-23)	Aim to reduce interruptions and less likely to make an error (programme theory)	A	C
Researcher – ok			
Participant – that's the idea (25)	The planned aim		
Researcher – and do the red aprons have it printed on 'do not interrupt' or are they just known as to?		ID	C
Participant – er no there's no er there's nothing printed on them they're just just red in colour (28)	No writing, red in colour		
Researcher - ok		V	M

Participant - erm they are sort of fairly distinctive but erm yeah there's no other sort of signage or anything (30-31)	Viewed as distinctive		
Researcher – and how do people outside the PICU team know that they mean drugs? Participant – er outside the team? (33) Researcher – yeah Participant – erm I'm not sure about outside the team actually (35) so I mean I would I guess I would consider our team to include the sort of allied health professionals, physios, pharmacists, etcetera as well as all the staff who work on PIC all the time. (35-37)	Question clarification Unsure of wider awareness Clarification of PICU team Assumed knowledge within PICU team	Role of Team (ROT)/ AC RoT	M C M

So I think they would all be aware but I don't know for sure that's the case, but I'm pretty sure that its well known. (37-39) Outside the team so visiting professionals from other teams I've got, I actually don't know how aware they are of the red aprons (39-40) cause I'm not even sure if it's something that's used across the trust. I'm only telling you what I know, obviously others would know more. (40-41)	No communication with outside teams No knowledge of wider trust policy	Assumption of knowledge (AoK) AC/RoT PI	M M
Researcher - yeah that's fine, when were the red aprons introduced? Participant - erm, I don't know I mean they must have been there at least a couple of years but again that's not, (43) I didn't introduce them so I don't know (44)	Approximate use for 2 years Not involved in implementation	I I	C C

Researcher – ok, and have you measured the impact on interruption rates or error rates?			
Participant – well the, it's not my project but the, I know that the safety team erm keep a pretty close eye on reported medication errors and obviously that's erm reviewed pretty er regularly (46-48)	Safety team track medication errors regularly	OM/RoT	O/C
Researcher – yeah			
Participant – so weekly meetings to look at reported stuff (50)	Weekly review of reported errors	OM	O
but that depends on errors being reported, (50-51)	Alluded to possible lack of reporting	ER	C
they did a deeper dive as well so one of the nurses who led the initiative has done a time and motion study measuring interruptions erm over quite, I don't know how long she measured it over but it was a significant amount of time erm specifically measuring interruptions to nurses who were involved in delivering drugs (51-54)	Research study measurement of length of time nurses involved in interruptions during medication	Shared research (SR)	C

Researcher – hmm Participant – but I don't think it was comparing pre and post or anything like that, it was just an observational study of what happens in the current system (56-57) Researcher – yeah Participant – so and every time that sort of that data will sort of come up or periodically there seems to the approach to just re-inform, re-educate and re-emphasise the fact that red aprons signal do not disturb so erm (59-61) which is you know I suppose a fairly typical approach to quality improvement, (61-62) the first step is just to try harder isn't it? (62) Researcher – yes (laughs)	Not pre/post current picture Re-enforcement of key messages red apron = do not disturb Common QI strategy Negative view of try harder Try harder viewed as not effective	SR AC PT PT/Enf PT/Enf	C M C M M

Participant - (laughs) it doesn't necessarily work but (64) erm yes there are some data but I don't have them to hand (64-65)	Data not available	OM	O
Researcher – ok , so is your personal experience that they do work? erm the aprons? Participant – well I, yeah, I mean I think they do have some effect, (67) clearly they don't work a 100% erm (67-68) they're not they don't alter behaviour to that degree but erm they, I mean I can speak on my own behalf (68-69) Researcher – yeah Participant – when I go to ask nurses to do something for my, for one of the patients I quite often will notice if they've got a red apron on (71-72)	Aprons have variable effect Not 100% effective Personal view not enough impact to alter behaviour enough Experience of visual cue provided by apron	PoS/F OM PoS/F V/PME	C O M C

Researcher – hmm			
Participant – and I have on occasionally, if it's urgent I will interrupt say you need to stop (74)	Urgency = stop administration	U/P	M
but but most of the time I'll you know apologise (74-75)	Commonly apologise – interruption itself	Impact of politeness (IoP)/Response (R)	M
or just walk away and come back later erm (75)	Or leave bedside and return later	R	C
Researcher – hmm			
Participant – so it does have, it does have an effect on me I'm not sure if it does on everyone (77)	Personal effect but not universal	PoS/F	M
but erm it's a bit like, we also have these prescribing areas for the (78)	Identification of prescribing area	ID	M
Researcher – hmm			C

Participant – prescribers and again the same thing the general culture is you're not supposed to talk to someone if they are sitting at one of those areas and (80-81) it does, it does have an effect. Yeah it's a sort of subtle effect (82) Researcher – yeah Participant – and clearly it could be better but nothing's perfect in life, I think it's a step in the right direction (84-85)	Culture (rather than objective which was used for apron) do not talk to people when they are in the area Hidden effect Not perfect but working towards it	Identified as culture (IaC) Permeate (perm) Perf	C M
Researcher – ok, my last question was going to be whether there were any other changes that sort of had as a consequence had impacted on interruptions on PICU or whether there's any other? Participant – erm what whether we've done any other work, is that what you are asking?(89) Researcher – yeah	Clarification of question		

Participant – yeah I mean I think like I say the prescribing areas is the thing that immediately sprung to mind cause it's the same idea as the, you know if you interrupt a prescription it has, it has the same effect as interrupting the administration or the drug checking erm it's part of the same process (91-94) Researcher – yes Participant – but again I think that has helped, erm the other thing, (96) Researcher – do you Participant - there is a culture of not prescribing on ward rounds so erm again it's not policed aggressively but it is, it is the norm, if something needs writing up we won't do it on the ward round and again that's sort of sends the message that interruptions are not sort of accepted. (98-101)	Similar comparison between prescribing and administering – within the process Impact on each other Ingrained practice of not prescribing on the round - normal Re-enforcement of message interruptions not acceptable	MP Combined influences (CInf) CI Enf	C M M M

Researcher – hmm Participant – erm we also have pharmacists on ward rounds as I'm sure a lot of PICU's do and again their presence seems to help, just for sort of general awareness of er sort of etiquette around drugs but yeah nothing else I can think of around prescribing. Er sorry about nurse interruptions. Researcher – and with the prescribing zones have you measured those at all? Participant – again it's not so I think the safety team have done some work on that, (108) I don't think they've done a robust er trial or anything along those lines. (108 -109) There was, there was, well we are doing a prescribing project where we are trying to the	Pharmacist presence helps behaviour around medicines No other interventions Safety team have investigated No robust trial testing prescribing zones	IoR OM OM ID	M O O C

prescriptions of antimicrobials which is more of a stewardship project erm that is, (109-111) erm I suppose it's a behavioural, cultural er intervention but we're not really, (111-112) we're not looking at interruptions or prescribing areas in that project, (112-113) we're just looking at the end product which is what the prescription looks like. (113) Researcher – hmm Participant – erm there are tight links together (115)	Project examining antimicrobial prescriptions Focus on culture and behaviour Not interruptions Prescription standards Links between	BC ID ID PT	M C C C
Researcher – ok, and who do you think leads these projects within the unit? Participant – within our unit? (117)	Clarification		

Researcher – yes Participant – so for the interruptions I'd say ********** is our main erm lead for that she's the safety she's on the safety team, she's got a number of roles that take, but erm medication interruption has become quite a big part of her er role in the safety team. (119-121)	Led by member of safety team Completed timing study on interruptions	RoT OM	C O
And she, I think she did that time and motion study that I was mentioning where they observed the numbers of the interruptions (121-123) and like I say I can't remember the numbers but they were quite, they were quite impressive rates of interruptions even, even with the measures that have already been put in place. (123-125) Researcher – yeah	Frequent interruptions despite interventions in place	OM	O
Participant – I mean it seems to me it's quite, it's quite common to go to bed spaces and drugs are being checked, (127-128)	Drug administration is frequent	MP	C

it's like we use so many drugs and they all need to be checked and (128)	All need second checker	MP/RoT	C
whether there's a more efficient system for that erm one, one wonders because you know quite often I'll go to the bedside to make a suggestion or make a change and (129-130)	More efficient system needed	MP/PME	C
sure enough the nurse is there in their red aprons having a drug checked (laughs). (130-131)		W/V	M
It's like it's a major part of their day (131-132)	Common to see nurse in red apron	MP/W	C
Researcher – yeah	Time consuming within the nurse's day		
Participant – if, if we could it the whole thing more streamlined then that would help because it would just be less time to interrupt anyway. (134-135)	Streamlined process would reduce time to be interrupted	MP/W	C/M
Researcher – yeah		MP	C

Participant – erm we're about to get e-prescribing in our unit so we're behind the times and still on paper. (137-138) And I think that's gonna I dunno if it's going to be good or bad. Time will tell (laughs), hopefully it will be slightly quicker. (138-139) Researcher – often it raises different issues, doesn't it? Participant – yeah, yep	e-prescribing to be introduced viewed with positive and negative anticipation	PoS/F	C
Researcher – ok , is there anything else you would like to add at all? Participant – no I've got, nothing sort of comes to mind, no nothing I don't think that's of relevance to what your studying. What's erm the intention of your	Question from participant about aim of study	A	C

data when you've sort of finished at this stage? (143-145) Researcher – well, I've sort of done a programme of research where I started out similar to where you started with the sort of observational study just looking at what interruptions there were and how frequent Participant – yeah (149) Researcher – and realised you know that we did have a significant problem erm but also realised there's a significant amount of interruptions that are necessary for patient safety aw well. Participant – hmm (153) Researcher – er so I felt that erm bringing in may be the red tabards, aprons or no interruption zones wouldn't necessarily address the issue, erm so my next study looked at nurse decision making when they were interrupted and sort of realised the			

complexity that's underneath it, so nurses don't like to be seen to be rude, they don't want to add to the stress of parents if they're asking questions Participant – yeah (159) Researcher – erm em you know the communication with medical staff, if that's the only time you're gonna see them in that day then that's really important to talk to them and em sort of began to think you know the aviation theory that underpins all these wasn't sort of necessarily the right one I don't think. Participant – hm (164) Researcher - It's very difficult to make a blanket statement of do not interrupt while we're doing this task because you know the ongoing care you've got for the patient doesn't allow you to just switch off from everything else. Participant – yes (168)			

Researcher – erm so I've gone back to the literature and done a realist review which highlights the importance of things like culture and engagement and leadership so whatever Participant – yeah (171) Researcher – is implemented, without that it doesn't work and most of them haven't been sustained there's very few places that manage to sustain erm those sorts of interventions erm long term Participant – yeah (175) Researcher – so now I'm sort of trying to er gather data from a wider team because it's sort of trying to get, to understand the impact of our behaviour on support staff and allied health professionals. And if they see nurses talking about non-medication related things then it makes them think well it's ok to interrupt anyway. And erm Participant – yeah (180)			

Researcher – and I'm going to try to talk to parents as well. To interview some parents next year. And try to pull it all together and see what I can make of it, so look for a new underpinning theory to support whatever I decide.	Recommendation of safety two concept	PT	C
Participant – well it sounds like a challenge but I mean have you come across the safety two er concept? (184-185)	Personal interest in safety	L	C
Researcher – no			
Participant – I don't know, but well one of my interests is, is safety basically (187)	Looking at what goes right	PT	C
Researcher – hmm			
Participant – in a broader sense, safety, the idea with safety two is that it's a new concept of safety that erm a safe environment or a safe unit has a condition where as many things as possible go right (189-191)	Opposite to traditional view of minimising risks	PT	C
Researcher – hmm		PT	C

Participant - which is different from the traditional view of safety which view is that as few things as possible go wrong. (193-194)	Subtle change in view, but significant difference in what's studied		
Erm so it's subtly different but actually it's a big difference when you think about what it is you then study to understand (194-195)		PT	C
Researcher – yeah	Examine situations where things go well	MP/PT	C
Participant – in safety two what the proponents are trying to do is study is what's happening correctly and why is it working in these situations, (197-198)	Large percentage given correctly		
so the majority of drugs are administered correctly (198-199)	Theory may offer a different lens through which to view errors	PT	C
Researcher – yeah			
Participant – so there's a wealth sort of data, or understanding amongst the successful drug administrations which might sort of be a	Limited operational work so far	PT	C

complimentary approach to try and understand why we also make errors, (201-203) it's a quite interesting idea, innovative it hasn't really there hasn't really been an operational solution to it yet but we're doing a bit of work in that area which is why I brought it up (203-205) Researcher – hmm Participant – it may it may be of interest to you? (207) Researcher – yeah, I'll definitely have to look at that. Ok thank you so much for your time Participant – you're very welcome, good luck with the project (209)			

Definition of Codes

Code	Link To CMO	Definition
Participant information (PI)	C	Demographic information about participant
Intervention description (ID)	C	Descriptive information about the design of the intervention
Environmental factors (EF)	C	Data offering insight into the impact the PICU environment has
Additional communication (AC)	C/M	C – description of extra communication needed extra to intervention M – responses to input of extra communication
Description of medication process (DoMP)	C	Descriptive data about medication process
Un-allowed interruptions (UI)	C	Description of interruptions not allowed
Role and interruptions (RaI)	C/M	C – description of role with associated interruptions M – behavioural response to interruptions affected by role
Success elsewhere (SE)	C	Areas (not PICU) where interventions have been reported to be successful
Perceptions of success/failure (PoS/F)	C	Individual thoughts about why intervention was successful or not M- triggers of success/failure
Perceived theory (PT)	C	Explanations of how the intervention should work
Error Management Process (EMP)	C	Medication error investigation process
Workflow (W)	C/M	C – description of workflow M – workflow influencing behaviour/response to intervention
Respect (R)	C	Creating respect for medication process
Enforcement (Enf)	C	Enforcement of intervention in implementation process
Leadership (L)	C/M	C – role of leadership in intervention and implementation M – influence on response to intervention created by leadership involvement
No intervention (NI)	C	No intervention tried within PICU
Experience elsewhere (EE)	C	Experience of interventions from elsewhere
Aim (A)	C	Defined aims of intervention

Implementational challenge (IC)	C	Identified occasions when implementation becomes too much of a challenge (sus act)
Ideas about interventions (IaI)	C	Personal ideas about interventions that would work in PICU
Intervention bundles (IB)	C	Multifactorial interventions
Evidence of education (EoE)	C	Education content or strategy
Organisational influence (OI)	C	Description of resource
Linked Research (LR)	C	Shared research
Identified as culture (IaC)	C	Actions/behaviours which are described as being within the culture
Permeate (perm)	C	Infusion of change
Inconsistency (Incon)	C	C – evidence of inconsistent approach with implementation of intervention
Education (Ed)	C	C – description of education associated with interventions
Causes of error (CaE)	C	Reasons described which lead to errors
Verbalisation (Verb)	C	Description of verbalisation within medication process to prevent interruptions
Incident stimulation (IS)	C	Rationale for intervention development – incidents
Urgency (U)	M	Data relating to interruptions creating a sense of urgency which can affect how professionals respond
Personal Feelings	M	Individual feelings generated by the intervention
Engagement (E)	C/M	C- description of influencing factors on engagement M – reactions to engaging with intervention
Perfection (Perf)	C/M	C – description of perfect intervention M – reaction generated by perfection
Cultural Impact (CI)	C/M	C – description of cultural influences M – impact of culture on intervention
Empowerment (Em)	M	Mechanisms which result in the empowerment of staff
Priority (P)	C/M	C - Strategies to ensure medication is viewed as a priority M – mechanisms which result in medication as a priority or not
Error Reporting (ER)	C M	C - Reporting of errors M – impact of error levels on behaviour
Fear (F)	C/M	C - Situations which lead to staff feeling fear M – fear influencing behaviour
Protection (Pro)	M	Feeling generated by intervention
Shared learning (SL)	C/M	C – description of shared learning

		M – influence on behaviour or response to shared learning
Visibility (V)	C/M	C - Descriptive links to visibility of intervention M – visibility of intervention changes reaction
Behavioural change (BC)	M	Identification of behaviour change in others
Personal medication experience (PME)	C/M	C – description of medication experience M – occasions when personal experience influences behaviour/actions
Policy influence (PI)	C/M	C – description of policy used in intervention M – identification of response or reaction to policy
Role of team (RoT)	C/M	C – description of team/team activity/roles M – influence of team on reaction or response
Impact of politeness (IoP)	M	Behaviour stimulated by being polite
Actions (A)	C/M	Actions stimulated by intervention
Combined influences (CInf)	M	Influence from other interventions to create no interruption culture
Role of technology (RoTech)	C/M	C – description of technology in process M – influence of technology on behaviour or reaction
Patient Influence (PInf)	M	Actions required to respond to patient condition
Perpetual awareness (PA)	M	Constant responsibility and awareness of patient condition
Staffing factors (SF)	C/M	C- Issues with staffing which affect medication administration M – influence of staffing on response to interruptions
Familiarity (Fam)	M	Impact of familiarity on actions
Maintaining presence (MP)	M	Influence of staff who loiter/hover near Medication process before interrupting
Outcome failure (OF)	O	Data which demonstrates outcome failure of the intervention
Intervention limitation (IL)	O	Factors which have influenced implementation
Demonstrated outcome (DO)	O	Statistical data demonstrating outcome
Outcome measurement (OM)	O	How outcomes were measured
Shared outcomes (SO)	O	Learning and sharing of outcome data
Sustainability (S)	O	Long term outcome – sustained use
Outcome experience (OE)	O	Experience classed as an outcome

Appendix 5 – Stage 3 protocol

An exploration of parental views of interventions to reduce interruptions to medication administration within Paediatric Intensive Care

RESEARCH PROTOCOL

RESEARCH TEAM

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Rationale

In the United Kingdom (UK) the economic burden of preventable harm from medicines is estimated to be in excess of £1 billion per annum (Frontier Economics, 2014). In addition to fiscal cost, high profile reports indicate that medication errors have a demonstrable negative impact on quality of care, patient experience, outcomes and safety (The Francis Report, 2013, Patients First and Foremost, 2013, and The NHS Outcomes Framework, 2016/17).

In 2014, there were 19 760 children admitted to Paediatric Intensive Care Units (PICU) in the UK (PICANET, 2016). These children require medication as part of their treatment plan, with 33% requiring vasoactive medicines (PICANET, 2016). This demonstrates the high volume of complex medication administration which is required within PICU. In addition to these requirements, children are at increased risk of being involved in medication errors; McDowell, Ferner and Ferner (2009) identified that medication errors are higher in paediatric departments and intensive care units. Furthermore, the National Patient Safety Agency (2007) estimated that children are three times more likely to be involved in a medication error.

Medication administration for children is especially challenging due to the complexity of dosing due to large variations in weight range, the adaption of adult based medication for children and age appropriate dosing (Dickinson et al, 2012). Medication administration within PICU also requires precise, difficult calculations (Dickenson et al, 2012) which may be required at any point during the 24-hour timeframe. Adding to the complexity is the critical nature of the illness which requires constant nursing observation and promotes the preparation of medication at the bedside.

Medication administration is also a complex activity which requires prolonged periods of focus and concentration (Thomas et al, 2014). Interruptions to medication administration are often documented as having a detrimental impact on patient safety (Cooper et al, 2016) and have a negative impact on prospective memory which often leads to omissions in tasks (Grundgeiger and Sanderson, 2009). Interventions have been identified and tested within the literature since the beginning of the 21st century, which aim to reduce the frequency and impact of interruptions on medication administration. These interventions embrace concepts such as wearing visible clothing, no interruption zones, education, protocols or a combination of some or all the elements. A recent randomised controlled cluster trial (Westbrook et al, 2017) indicated that whilst the rate non-medication interruptions can be reduced from 50/100 administrations to 34/100 only 48% of nurses would the support the continued use of the intervention bundle. These results indicate the need for medical professionals to be involved in the design of these interventions to ensure they are appropriate for the environment in which they are designed for.

A local pilot observational study conducted in 2014 highlighted that within the paediatric critical care environment interruptions to medication administration are frequent (Bower, 2015). A follow up exploratory qualitative study (Bower et al, 2017) illuminated factors which are important in PICU nurse decision making when interrupted during medication administration. These factors have not been considered during the development of current interventions. The study indicated that there appears to be a culture of acceptance and that there are normal levels of interruptions. It also identified that PICU nurse decision-making when interrupted is influenced by the need to maintain interpersonal relationships with both the wider team and parents and that it is essential they are not seen to be rude. The complexity or familiarity of the medication can dictate which body language is demonstrated, which may invite or block interruptions. Providing clinical education in medication administration can generate

interruptions or it can enforce adherence to protocols. Finally, communication within a PICU is complex in nature and interventions need to facilitate essential conversations.

Nurses report and demonstrate that responding to parent need is essential in an area such as PCC due to the stresses that families feel (Bower et al, 2017). Despite a plethora of literature in relation to parental involvement in care within the critical care environment (Latour et al, 2011, and Melnyk et al, 2006), there is no published empirical research which has examined parental influences on medication administration. Colligan and Bass (2012) present the argument that the family centred approach within paediatric environments prioritises interruptions that are generated by parent. However, within the empirical research which embraces parental views of family centred care it is identified that parents would not want their needs to be the priority. Shields (2010) noted that parents wanted to know that their child was receiving the best care possible and parental needs should be dealt with after that. Butler, Copnell and Willetts (2014) documented that families value being able to trust the nurse however, receiving information is an essential aspect of family centred care. It is evident that parents do interrupt the process and there are inconsistencies in the information about medication and the process that they receive (Bower et al, 2017). Unfortunately, it is not documented within the literature what information families would like to receive and when it should be delivered. Reducing parental interruptions may enable the nurse to deliver a safer medication process which would be in the best interests of the child as paediatric nurses are expected to be an advocate for the child they are caring for (Spence, 2011).

However, despite multiple studies implementing interventions to reduce interruptions to medication administration (Pape, 2003, Anthony et al, 2010, Westbrook et al, 2017) there remains limited robust evidence which demonstrates sustainable impact on the reduction of medication errors (Raban and Westbrook, 2013). In addition, many studies highlight a lack of engagement from health professionals in adhering to the protocols and processes associated with the interventions (Verweij et al, 2015, Nelms and Treiber, 2011 and Westbrook et al, 2017). A review of the literature (Bower et al, 2015) has demonstrated that there is only one study which includes implementation of an intervention on a paediatric ward (Colligan et al, 2012) and no studies within PICU. Nevertheless, to ensure the safety of critically ill children receiving medications within PICU, medicines need to be administered accurately, within an environment which protects the nurse from unnecessary interruptions and allows maximum concentration. However, within PICU, there is an additional need for interventions to comprehend the essential communication, continual observation and parental support that are required to ensure that critically ill children and their families receive safe and compassionate care. Therefore, future research needs understand how interruptions to medication administration are currently managed and do these interventions meet the needs of this unique, complex population.

STUDY TITLE: An exploration of parental views of interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Introduction

It has been identified within the in the rationale that there is a lack of evidence available which examines interruptions to medication administration within the PICU environment. In addition, many interventions to reduce interruptions to medication administration have not involved patients and their families in their design Colligan et al, 2012, Anthony et al, 2010, Verweiji et al, 2014). However, participatory research demonstrates the benefit of including service users in the design of interventions as it allows their experiences to influence the design of the intervention. This results in the design of interventions where context is embedded and is developed from the user's perspective (Hagen et al, 2012). Another strategy, which involves users within the development of interventions, is the 'person-based approach' (Yardley et al, 2015) which identifies that in-depth qualitative research is required to understand the context and perspectives of the user. Although, parents will not be the user of the intervention itself they are the user of the service. Therefore, their perspective of proposed practice change needs to be understood otherwise engagement from clinical staff will decrease if they note a negative impact on parents.

In addition, Bower et al (2017) have highlighted that parents are an important influence on the decision-making process when PICU nurses are interrupted during medication administration. The study demonstrated that nurses strive to ensure the relationship between them, and the parent is maintained effectively at all times. Nurses do not like their behaviour to be perceived by parents as rude and they like to support the parents at this stressful time in their life. Therefore, it is essential that parental views are included within the design of an intervention as it is vital that parental support and communication is not compromised by the implementation of a change in practice.

Aim

The aim for this study is:

Explore the perceptions and experiences of parents in the medication process and interventions to reduce interruptions in PICU.

These aims and research questions are supported by the structure identified in figure 1.

Figure 1- structure of research aim and questions

Population – Parents of critically ill children
Exposure – interruptions to medication administration and interventions to reduce them
Outcome – impact on interruptions

The research question is:

How do interventions to reduce interruptions to medication administration work, for whom and under which circumstances within the paediatric intensive care environment?

Research Paradigm

The overarching research paradigm which will be used in this study is Critical Realism. In contrast to positivism, where a single concrete reality is thought to exist and to interpretivism where multiple realities are believed in, Critical Realism believes that there are multiple perceptions of one mind-independent reality (Healy and Perry, 2000). Critical Realism assumes a reality exists, because individuals behave as though this is true, however, this cannot be proven (Easton, 2010). Furthermore, within Critical Realism it is noted that there are differences between reality and the individuals' perception of it (Kraus, 2005). These beliefs indicate a contradiction within Critical Realism; that an unknown, independent reality exists and that reality is socially constructed (Easton, 2010). However, it is through the examination of social constructs (behaviours and perceptions) that reality can be described and explained. Therefore, Critical Realism is particularly useful in the examination of events which aim to explain why things are as they as they are. Critics of critical realism highlight that realist philosophers remain divided when defining the elements within the philosophy and that the ontological principles which guide it, are not required within social sciences (Magill, 1994). Furthermore, it is noted that there are differing views concerning ontology and its associated epistemology within the field of critical realism, the realist ontology can be associated with both interpretive and constructionist epistemologies (Maxwell, 2012). However, for this study the following ontological and epistemological views will be used. The ontological perspective is that a real world exists independently of perceptions, theories and constructions, with an associated constructivist epistemology that understanding of this world is a construction from individual viewpoints (Maxwell, 2012). This paradigm aligns particularly well with this study as is aims to understand why existing interventions to reduce interruptions do not always produce robust, sustainable changes on outcomes. The predominantly qualitative methodology seeks to understand parental perceptions and experiences (Bryman, 2012) of medication administration in PICU and the use of interventions to reduce interruptions during this process. These perceptions and experiences will be obtained from parents of critically ill children and will be analysed to explain the context and mechanisms (Maxwell, 2012) which may be influential in affecting the effectiveness of such interventions.

Study Framework

The design of this study will be supported by the Medical Research Council Framework for the development of complex interventions (Craig et al, 2008). As shown in figure 2, the framework has a comprehensive four staged approach. This framework supports extensive preparatory work which seeks to understand which interventions work and in which context. This preparation is thought or be vital in the design of successful interventions (Craig et al, 2008). Furthermore, interventions should be tested in feasibility of pilot studies which incorporate rigorous evaluation before being implemented in practice. The framework also supports ongoing evaluation to ensure that the intervention is effective and does not negatively impact in other areas of practice. Clarke (2008) states that the power lies with the participants using the intervention rather than the tool itself and the understanding of mechanisms which influence their actions. Applying this framework to the development of an intervention attempts to ensure that the design understands the complexity of these underlying influences.

This study will focus on the first stage of this process, ensuring that the intervention design is underpinned by robust exploratory studies. Completing an in-depth exploratory phase is essential in the design of a robust intervention (Craig et al, 2008).

Figure 2 MRC Framework for the development of complex interventions (Craig et al, 2008)

Outline of study

The following flow chart (figure 3) outlines a study design which has been formulated to identify and critically evaluate the evidence required in development phase of the MRC Framework for the design of Complex Interventions. This section of the framework requires the current evidence base to be identified and evaluated so that areas that have not been explored within the literature are highlighted. This also allows for the evidence to be reviewed using a different lens, on this occasion a realist view will be taken which seeks to identify the context in which interventions have maximum impact on outcomes (Maxwell, 2012). When a complex intervention is implemented, change is expected. Within the development phase of the MRC Framework these theories need to be identified and evaluated. The modelling process may require the intervention to be tested to ensure the design is correct before it is piloted and robustly tested (Craig et al, 2008).

There are five stages within the overall study however, this protocol supports only stage 4 which is the box in white. Prior stages have examined existing literature from a realist viewpoint, identified current practice and explored health care professionals' experiences of medication administration. This stage will explore parental experiences of medication administration on PICU. The semi-structured interviews will aim to explore what parents feel is acceptable in the organisation and content of an intervention to reduce unnecessary interruptions to medication administration on PICU.

Figure 3 Flow chart for larger study

Stage 1 - Realist review of the literature (timescale – May-July 2017)
This stage of the study has previously received ethical approval via Coventry University May 2017 P46289

Rationale for inclusion

- Contribute to identification of evidence base and gaps in knowledge
- Identification of theoretical frameworks
- To search for the contexts and mechanisms which influence the impact of interventions

Stage 2 – National survey of practice across within PICU's across the UK (timescale – up to 6 months after receipt of approvals)

Rationale for inclusion

- Contribute to identification of evidence base
- What interventions are being used and have they been measured for effectiveness?

Stage 3 - Semi-structured interviews with health care professionals (timescale up to 6 months after receipt of approvals)

Rationale for inclusion

- Address gaps in knowledge raised by realist review of literature
- Using stakeholder experience to influence design of intervention
- Exploring barriers and facilitators to acceptability of intervention to aid process modelling and increase likelihood that intervention will be successful
- Content analysis of data will identify context, mechanism and outcomes identified by stakeholders which influence the efficacy of interventions to reduce interruptions to medication administration on PICU

Stage 4 – Semi-structured interviews with parents (to seek approval autumn 2017)

Rationale for inclusion

- Address gaps in knowledge raised by realist review of literature
- Using parental experience to influence design of intervention
- Exploring barriers and facilitators to acceptability of interventions to aid process modelling and increase likelihood that intervention will be successful.
- Critical realist analysis of data will identify context, mechanism and outcomes identified by parents which influence the efficacy of interventions to reduce interruptions to medication administration on ICU

STAGE 4:

Study Design

A qualitative design has been selected because the research questions demand a method which allows the researcher to gather in-depth data regarding the parental experiences of medication administration in PICU. Using quantitative methods such as surveys would not achieve this depth of data collection (Silverman, 2000), therefore semi-structured interviews will be used to elicit parental views, experiences and perceptions as this is the best fit to meet the aims and objectives.

Sample

Robinson (2014) describes a four-point plan which is useful in the planning of a sample, i) defining a sample universe, ii) deciding on a sample size, iii) selecting a sample strategy and iv) sourcing a sample. Using this plan will contribute to the transparency, impact and trustworthiness of the study (Robinson, 2014).

iv. Sample universe

The population of the sample is defined by the inclusion and exclusion criteria (Robinson, 2014), which can improve the homogeneity of the sample (see table 1). The parameter to be used within this study is life history homogeneity (Robinson, 2014) as the sample aims to recruit parents whose child has been an inpatient on PICU and received medications.

Table 1 Inclusion/Exclusion criteria

Inclusion Criteria	**Rationale**
Parents who understand and speak English	the researcher is unable to gain access to an interpreter
Parents who are admitted to PICU for at least 24 hours	To enable parents to have significant exposure to the medication process
Parents who have legal responsibility of the critically ill child	To ensure parental views, experiences and perceptions are collected
Exclusion Criteria	
Parents whose children are receiving end of life care	To reduce the emotional burden on parents (Latour et al, 2011)

v. Sample size

Within qualitative research large generalisable samples are generally not achievable (Silverman, 2000). The following table (2) demonstrates the factors which have been taken into consideration when determining the sample size for this study (n15). A sample of this size will allow for rich data analysis and enable individual participant views to be located within the data (Robinson, 2014).

Table 2 Factors affecting sample size

Factor	
Scope	The broader the scope of the study the more participants will be required. The scope of this study was focused on parental experiences, perceptions and views of medication administration and interventions to reduce interruptions.
Nature	If the topic is obvious and clear it is easily attainable and fewer participants are required. Medication administration is an activity which occurs frequently over the day so parents should be able to recall their experiences. However, it may be difficult for them to isolate the medication administration process from other care delivered to their child. Therefore, the interviews will be conducted whilst the child is an inpatient either on PICU or on the ward to allow them to recall recent experiences. Information shared before the interview will indicate the topic under discussion allowing parents to think about the topic beforehand if they wish. The interview may raise distressing topics which may affect the parent's ability to talk about the subject or may influence the parent to stop the interview early. The parents will be allowed to operate the recording of the interview so that they may feel more in control.
Quality	This relates to the ability of the participant to talk about the topic. The choice of method of interview will ensure that the participant is interviewed within a comfortable environment which may increase the willingness to share. However, sharing difficult experiences may negatively impact on this.
Design	The design of the study includes findings from a previous study and information gained in stages 1, 2 and 3.
Use of shadow data	The concept of shadow data relates to participants talking about the experience of others. Parents are only being asked about their own experiences, not their observation of other parents. However, they will be commenting on their observations of the care delivered to their child.

vi. Sample strategy

As previously mentioned, a study completed by Bower et al (2017) highlighted that parents have a significant influence on PICU nurse-decision making when interrupted during medication administration. This prior theoretical knowledge has determined that a purposive method of sampling will be used as these participants have a unique understanding of the phenomena under examination (Robinson, 2014).

Quota sampling is a purposive method which allows the researcher to have a flexible but multi-case approach to obtaining a sample (Robinson, 2014). This will be employed within this study to ensure multiple specialities from different types of units are included as interruptions to medication administration is a phenomenon which is experienced across a range of patients and units. It has been noted that medication regimes and workload can vary, dependent on diagnosis. In addition, the input from the wider multidisciplinary team is speciality dependent, the presence of these teams is associated with increased rates of interruptions (McGillis Hall et al, 2010). Therefore, the sample will aim to include at least one participant from each speciality to a maximum of four (see table 4) The specialities are those which PICANET (2015) identified as the most common diagnostic reason for admission to PICU.

Table 4 Sampling Framework

Diagnosis
Cardiovascular
Neurological
Respiratory
Gastro-Intestinal
Infection
Musculoskeletal

vii. Sample source

The participants will be recruited from three different NHS Trusts (Hospital A, Hospital B two units within Hospital C). Table 5 indicates the distinct differences between the four PICU environments. Accessing the four different units will help to achieve the sampling strategy identified in the previous section. (see Appendix 3 for letters of confirmation)

Table 5 Sample source framework

Site	Rationale for inclusion
Hospital A	Standalone children's hospital Cares for children of all specialities Supra-regional PICU (30 beds)
Hospital B	Part of a large teaching trust Does not admit children with cardiac conditions (14 beds) Specialities include neuro, major trauma, renal, oncology, spinal, general surgery
Hospital C (site 1)	Part of a large teaching trust Specialist cardiac centre Not attached to an Emergency Department (9 beds)
Hospital C (site 2)	Part of a large teaching trust Specialities include general surgery and respiratory medicine (6 beds)

Recruitment

Due to the differences within the four PICU environments, each unit has a bespoke recruitment process, these are summarised within the following diagrams (figures 3 and 4). These have been negotiated individually with the clinical teams to ensure that the process compliments existing workflows and maximises recruitment opportunities.

Figure 3 Hospital B and C recruitment process

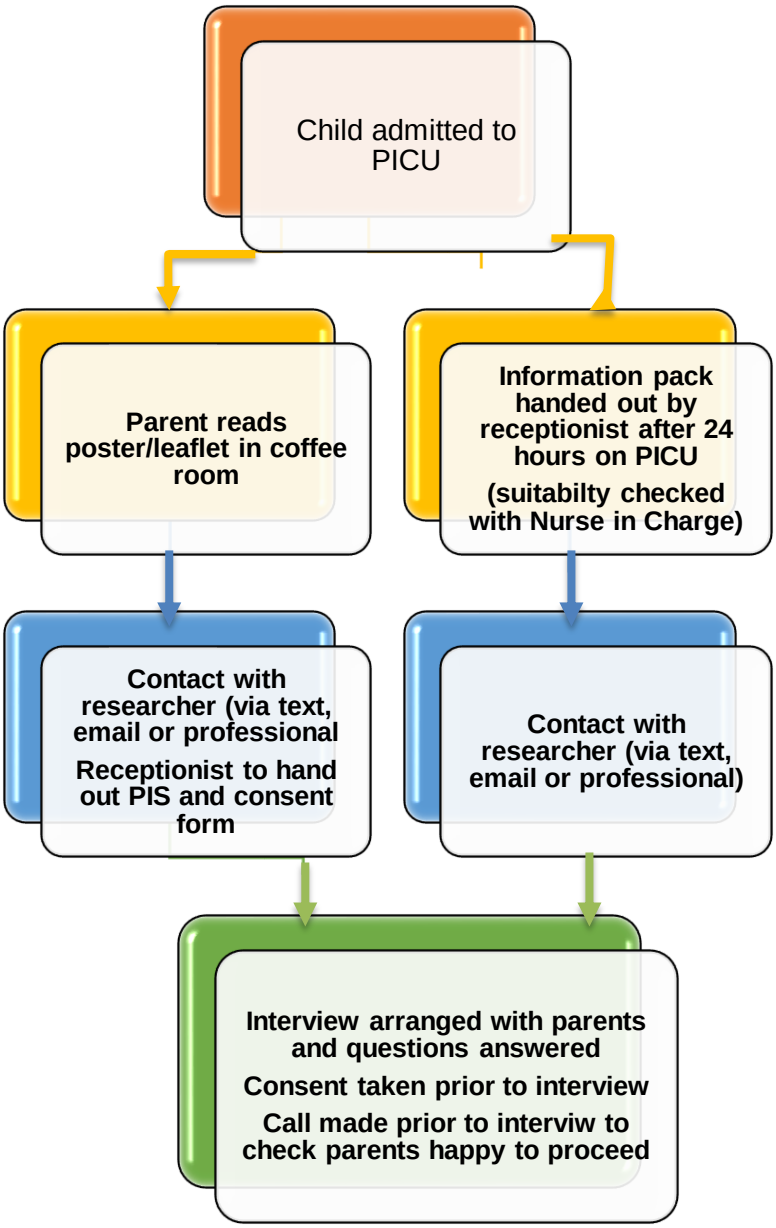
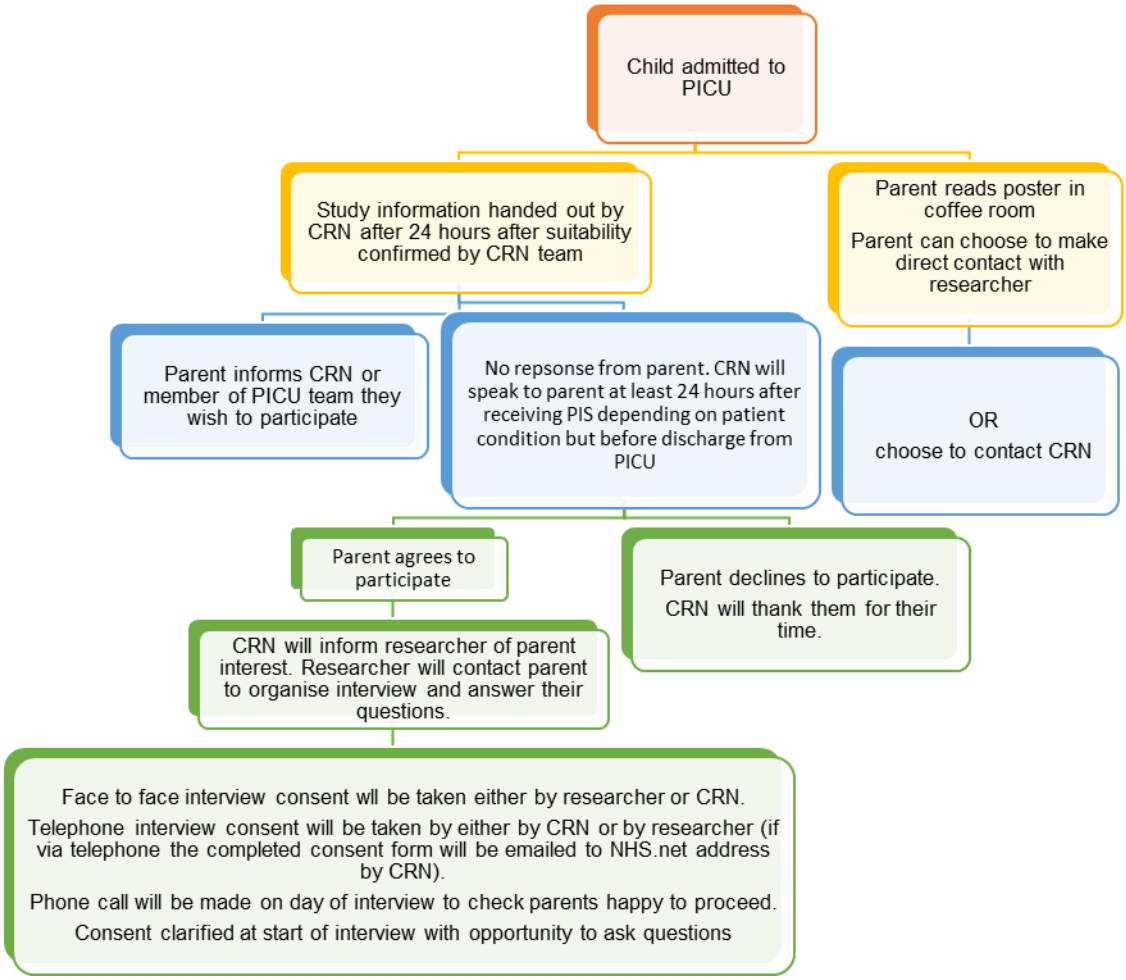


Figure 4 Hospital A recruitment flow chart



Parents will be recruited via posters/leaflets or information sharing from the clinical team. Investigations into the barriers and facilitators of recruitment in paediatric studies highlight that parental engagement is reduced if too much information is given out (Keightly et al, 2014). It was therefore decided that the poster/invitation leaflet (see Appendix 1) would use graphics with a small amount of text to invite parents to participate.

However, other studies have highlight the importance of information in ensuring informed consent is gained (Burgess et al, 2003). Therefore, it is important that study information is reviewed by parents during the design phase and that the clinical team or the researcher is available to answer questions and support parents in their decision whether to participate or not (Keightly et al, 2014). To achieve this within the study design a more detailed Participant Information Sheet (see Appendix 2) offered more detail about the study and during the consent process parents will be encouraged to ask questions. In addition, an email will be sent to the nursing and medical team highlighting the rationale for the study and what will be required from participants, this will enable staff to promote and share key information about the study.

Feedback from a parent also indicated that it would be beneficial to conduct the interviews whilst the child is an inpatient as, once parents are discharged they feel that it is time to move on. Therefore, parents will be approached whilst their child is in PICU, this will also allow them to think about the process and their real-life experiences. However, the interview will be arranged at the parents' convenience, before they are discharged from hospital.

This will need to be discussed with each site and may be slightly different for each site depending on their requirements. Diagram inserted for NUH currently, being negotiated at other sites.

Patient and Public Involvement (PPI)

Public involvement is an increasing requirement in the research process, with the NIHR (2012) INVOLVE briefing defining the term as research being carried out 'by' or 'with' patients and their families. Investigations into the impact of PPI in healthcare research (Brett et al, 2012) acknowledge that patients or service users can impact on the design resulting in both benefits and challenges for the researcher. Benefits were found to be the offer of pragmatic advice, criticism about protocols and instruments, improved recruitment, increased data collection particularly in interviews, interpretation of data from lay point of view and better dissemination. The main challenge highlighted was the clash of views between science and service user knowledge which was demonstrated when scientific methods had to be compromised, for example the removal of a placebo arm of a trial. However, it could be argued that this change may have improved the ethical design of the study or aided recruitment.

Within this study, it is evident that the design of the study was planned with the input of parents who have had experience of admission to PICU. Informal discussion with parents within PICU highlighted that they were happy with a study which was designed to use either questionnaire or semi-structured interview. However, one parent noted that an interview would be better as there may be medical terminology used within the questions that would be more understandable if explained.

In addition, a parent of a patient who was an inpatient on a PICU in the past shared her experience of being involved in research. When questioned about the best way to approach parents to participate she advocated the use of different methods due to there being significant differences between families. There are many different pathways into a PICU and significant differences in experiences, all of which can affect their ability to retain information. Therefore, staff, posters and leaflets will be used to promote the study and engage parental involvement. The timing of the interview was also discussed as the researcher was unsure whether to offer interviews post-discharge from hospital. The parent felt recall about medication administration would be affected and that for some families discharge home signifies a time to move on. When asked about the risk of parents becoming upset during the interview, she felt that this may be a possibility and that the researcher would require a plan to address this.

All leaflets, posters, participant information sheets (PIS) and consent forms were reviewed by a mixed group of parents, both with and without PICU or hospital experience.

Informed Consent

Informed consent is essential criteria within the Good Clinical Practice Guide for Research ((NIHR), 2013).To ensure that this occurs a clear process of consenting will be followed. When contact is made by the parent(s) the researcher will ensure they have a hard copy of the PIS and consent form (see Appendix 2). A telephone call will occur to arrange the interview and ensure that the parent(s) understand the information contained within the PIS and any questions are answered. Consent will also be reclarified at the beginning of the interview and consent signed if not done so already.

Data Collection

Semi structured interviews with parents of critically ill children

Semi-structured Interviews will be conducted as requested by the participant via two different methods (face to face or telephone) at a time convenient to them. This will allow the participant to have some autonomy and choice over the modality of interview. These interviews will be in depth as they aim to explore participant's experiences and perceptions, therefore it is important that they are comfortable with the method used to conduct the interview (Carr and Worth, 2001). Therefore, allowing participants to choose from range of methods allows them to select a structure with which they are comfortable. Ensuring they are comfortable with the method will help to build rapport and produce richer data (Novick, 2008). All interviews will be audio recorded to allow transcription. Face to face interviews will occur in a quiet space to enable a clear recording to occur.

The interviews will be conducted at the parents' convenience in a location of their choice. A telephone call will be made on the day of the interview to ensure the child was well enough for the parents to feel comfortable with the interview taking place. The interview will occur while the child is still an inpatient (either on PICU or in a ward), and a quiet room within the locked doors of PICU or the ward will be used. The nurse looking after the child will be informed of the location or a phone number agreed so that if the parent is required at the bedside they can be easily located. The PIS and consent interview emphasised that any data collected before an interruption would be included in the study and plans to resume or reorganise the interview will be made.

The interview schedule will be informed by the findings of an exploratory study which explored clinical decision-making when interrupted during medication administration (Bower et al, 2017) and the realist review from stage 1. The critical realism analysis will search for context and mechanisms which improve the effectiveness and efficacy of interventions. Data collection will occur for up to four months after the approvals process has been completed with a further two months (until 30th September) for final data analysis.

The interview topic guide (see Appendix 4) has been informed by the findings which focus on parental influence from a previous study (Bower et al, 2017) and the realist review. An example of a clear trail of question development can be seen in Appendix 5. The use of a semi-structured interview enables the researcher to use a topic guide but also allows flexibility in its use (Bryman, 2012:471). In addition, the interviewer can follow up and explore interesting points within the answers provided by the participant. This combination ensures the interview remains focussed on the topic being researched but allows participants to express their views and experiences (Bryman, 2012:472).

Data analysis

The interviews will be audio recorded and transcribed verbatim. Familiarity with the data will be gained through transcribing and reading of transcriptions (Bailey, 2008). The data will then be coded; within critical realism (CR) there is limited guidance on the process of coding (Fletcher, 2016). The process will begin iteratively by building on a coding template and themes developed from previous research (Bower et al, 2017) which were identified during a previous study which explored nurses' decision making whilst interrupted during medication administration. However, this process will be flexible and the new data will drive the identification of new codes or themes and deletion of codes and themes which may no longer be relevant (Fletcher, 2016). Codes will then be grouped into themes which will search for the context of interventions, mechanisms which influence implementation and their impact on

outcomes. These will be verified by the supervisory team. The data analysis process is the summarised in table 6.

Table 6 Thematic analysis

DATA STORAGE:

All hard copy data will be stored within a locked cupboard within a locked office, as per the Data Protection Act. Electronic data will be stored on Coventry University password protected hard drive. Audio recordings will be destroyed after transcription. The data will be anonymised. The participant log which will include parent details will only be accessed by the research team and will be stored on the Coventry University password protected hard drive. As per Coventry University's Code of Conduct the data will be stored for ten years after the end of the project and archived at Coventry University's archives.

GOVERNANCE ARRANGEMENTS

The study sponsor is Coventry University.

Compliance with research design though the study protocol, including ethics, collecting, managing and storage of data is the responsibility of the study team. The study team is familiar with the NHS Research Governance Framework (2005). The team will have current Good Clinical Practice certification to ensure that the study adheres to the correct principles of research practice.

ETHICAL REVIEW:

This study will involve participation from parents/legal guardians of NHS Patients that will be recruited through NHS trusts. Therefore, ethical approval will be sought from both Coventry University and NHS Research Ethics Committee, and governance approvals from the Health Research Authority.

ETHICAL ISSUES

This section will discuss the potential ethical issues which should be considered within the design of the study. The section will begin by examining the issues which may affect

participants, followed by those which may be experienced by the researcher. Clear management plans are outlined where necessary to minimise the risk of the issues raised. It is important that ethical issues are considered within the design of a study to ensure research integrity is maintained (Guillenim and Gillan, 2004).

Participant harm

One of the central principles of any research study is non-maleficence; to do no harm (Beauchamp and Childress, 2001:12). There is a potential risk that participants may become upset during the interview.

Face to face interviews

Parents will be allowed to control the recorder so that they are able to easily stop the interview if they become upset. If this occurred, the participant would be given the choice of the following actions:

vi. To continue
vii. To have time out
viii. To stop the interview
ix. To rearrange for another day
x. Referral to an NHS counselling helpline

If the participant decides to stop the interview they will be reminded that data collected up until that point will be used as indicated in the PIS.

Telephone interviews

Prior to commencing the interview, the researcher will confirm with the participant that if they become upset during the interview they can stop or pause the interview at any time.

The researchers recognise that identifying distress during a telephone interview maybe more difficult, however, the researcher will respond to any verbal or audible signs of distress by offering to pause or terminate the interview. If this occurs the same strategy will be used as outlined in the section for face to face interviews:

i. To continue
ii. To have time out
iii. To stop the interview
iv. To rearrange for another day
v. Referral to an NHS counselling helpline

Furthermore, at the close of a telephone interview the researcher will clarify with the parent that there are no outstanding issues of upset or concern and will ensure they are signposted to any additional support services (such as the local PALS) if required.'

Patient Harm

If the researcher were to hear of an actual event with associated evidence of patient harm she would comply with the following process.

v. Determine if this had been shared with the parent as part of the incident reporting process
vi. If the information had been shared as part of the incident reporting process no further action would be required

vii. If the event being described was an observation made by the parent, they would be asked if this information and patient details could be shared with the nurse manager of the unit to ensure it had been reported.
viii. If consent to share patient detail declined an anonymous description would be shared with the nurse manager.

This process will be documented within the PIS.

The researcher required to act within the Nursing Code of Conduct both within practice and as a researcher within the clinical field (NMC, 2015).

Informed Consent

Each participant within this study will be asked to consent as per Good Clinical Practice Guidelines (NIHR, 2013) using participant information sheets. The PIS will be given to staff with a consent form in advance to allow them to assimilate the information and provide consent without feeling pressured. The participants will be given the opportunity to ask questions about the study during the initial phone call to make the appointment to conduct the survey or interview. Consent will be clarified at the start of the survey or interview. This will ensure that all participants will be fully informed (Green and Thorogood, 2014:70). Participants will also be made aware they can withdraw at any point and there will be no consequence to this decision (Robson, 2011:297). All consent forms will be returned to the researcher either via email or as a hard copy. They will be stored securely in the site file.

The participants involved in the interview stage of the study will be given a £10 Amazon voucher and a £10 Toys r Us voucher as a 'thank you' for their time. The poster and leaflet highlight the award of a voucher but it is not named and no value is mentioned. This will reduce the likelihood that participants are induced to take part in the study.

Confidentiality

Ensuring that a participants' identity is protected throughout the study is an essential ethical requirement linked to the principle of beneficence (Kaiser, 2010). The principle of beneficence seeks to ensure that the research participant is not exposed to any harm. On this occasion, the researcher is required to ensure that the participant is not harmed by their interview data being identifiable and linked to them. There are potential negative risks associated with confidentiality breaches such as harm to relationships or the sharing of personal information.

This study will use a dominant approach to confidentiality, data will be collected, analysed and disseminated without compromising the participants' identity (Kaiser, 2009). This approach ensures confidentiality is protected throughout the processes of data collection, transcription, analysis and reporting. The PIS describes how the participant's identity will be protected. During transcription, all identifiable information (names, roles, geographical locations, unit descriptions) will be removed. This will create a clean data set; however, contextual data will remain and the researcher will decide with the advice of her supervisory team whether this will be used in the reporting of the study's findings. The anonymous transcription will be returned to the participant to ensure they are happy with the clean data which it contains.

Insider researcher

The researcher is a PICU nurse with extensive experience in providing care to critically ill children and implementing changes to clinical practice. This knowledge and experience is beneficial in that the researcher will understand detailed descriptions of practice which may

use medical and nursing terminology. However, she will use strategies do develop awareness of her own perceptions and beliefs during the study. A reflexive diary will be maintained throughout to allow the researcher to examine her own perceptions and their enable her to have an awareness of their impact on the research (Ortlipp, 2008). The reflexive diary will be anonymised to ensure participant identity is protected.

STUDY RISK MANAGEMENT PLAN

There are risks involved in any study and the table below highlights risks identified by the study team and the controls that are in place to minimise their effect.

Risk Area	Potential Impact	Management Approach
Poor practice recorded in interview	Minimal immediate harm to patient	Issues discussed with unit manager
Participant harm	Discontinuation of interview	Parent will be given the choice whether to restart interview or not. If interview is terminated permission to use data already collected will be sought. Support networks will be offered (counselling, PALS or chaplaincy) if required by the parent.
Poor recruitment	Limited participants	The study has been designed using two methods of recruitment in 3 different centres. In each method of the recruitment the participant will be asked to agree to be considered for participation in the study. This will allow maximum recruitment to achieve the sample required. However, if over recruitment is achieved the researcher can respond and thank the participant but inform them that the sampling strategy has not included them on this occasion.
Confidentiality	Risk of identification of participants	The PICU population within England is small so a dominant approach to confidentiality will be used within the study (Kaiser, 2009). This approach attempts to remove all identifiable information about each participant. All information concerning names (of participants and teams involved in their care), location of units and diagnosis will be removed during the transcription phase. The anonymised transcription will be shared with the participant to ensure they are happy with the data. Only anonymised quotes will be used within the dissemination of this study.
Disclosure	Description of potential or actual patient harm	This would be escalated as per the plan outlined in the ethical issues section.

PUBLICATION / DISSEMINATION

In the PIS, participants will be informed that while the researcher intends to publish the findings in relevant peer-reviewed journals and conferences. All identifiable information (name, diagnosis and detail of specific unit) will be removed and replaced with an identifying number to protect the anonymity of participants (see risk management plan for detail of this process).

However, anonymised quotes from the interviews will be used publicly to support the analysis of the data and participants will be informed of this within the PIS.

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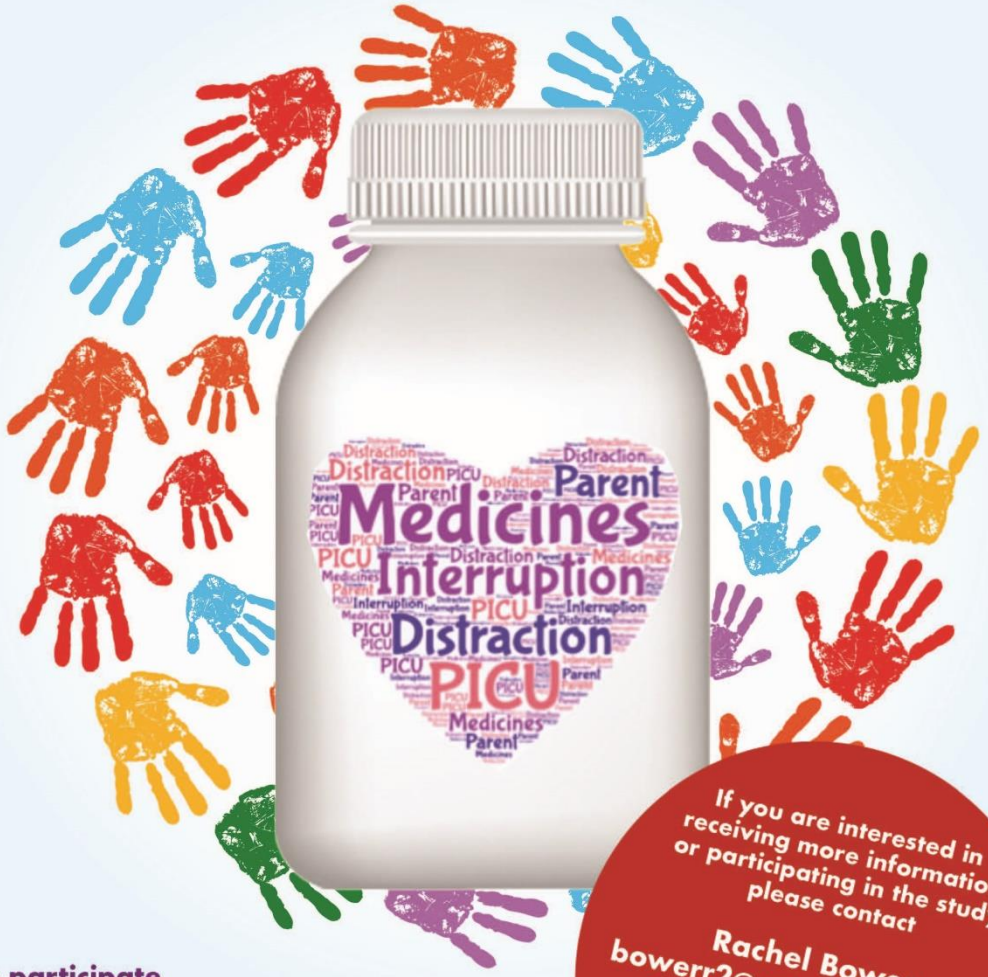
Appendix 1 – Invitation leaflet and poster

Coventry University

RESEARCH PARTICIPANTS WANTED

Would you be interested in taking part in an interview which will explore your experiences and/or views of interruptions to medicine administration in the Paediatric Intensive Care Unit



To participate
You must be able to understand and converse in English.

The study will involve
One interview which can be arranged at your convenience whilst your child is an inpatient in hospital. The interview can be conducted in person or over the telephone. It is expected that the interview will last up to 45 minutes (participants will receive vouchers for their time).

If you are interested in receiving more information or participating in the study please contact

Rachel Bower
bowerr2@uni.coventry.ac.uk
Tel ??????????????

or speak to the nurse caring for your child and they will contact the researcher

IRAS 237172

all-free-download.com: BSGStudio & freedesignfile

Appendix 2 – Participant Information Sheet and Consent Form

Information sheet for participants

An exploration of parental views of interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Project lead: Rachel Bower

INTRODUCTION

I would like to invite you to take part in a study that will explore medication administration and interruptions within Paediatric Intensive Care Units (PICU). I am undertaking this study as part of a research programme, supervised by Coventry University.

The design of the study includes an interview which aims to understand how and why interruptions to medicine administration occurs. I am inviting parents of critically ill children to take part in an interview to answer my questions about the medicine process within PICU (this can be face to face or by telephone). Before we can develop and change practice to reduce interruptions to medication administration we need to understand parental experiences of medication administration. It has been identified by nurses that supporting parents is important in the delivery of care to critically ill children.

Before you consider taking part in this study, please take the time to read this leaflet as it is important you understand why the study is being undertaken and what is involved. If you have any questions about the study please contact the project lead, Rachel Bower, whose details are at the end of this information leaflet.

ANSWERS TO YOUR QUESTIONS

What is the purpose of this project?

The purpose of this study is to gather information about parental experiences of medicine administration in PICU. I am inviting 15 parents across 3 hospital Trusts to take part in the study. You have been invited because your child is being cared for in one of the PICUs that have agreed to take part in the study, and your child has been in PICU for at least 24 hours.

I am only able to invite parents who speak English to take part.

Why have I been chosen?

The unit where your child is being cared for has agreed to take part in the study and parents are being invited to consider sharing their experiences. If you would like to take part in the study please contact Rachel Bower (**********) or please let one of the members of the PICU team know.

What will happen if I take part in the interview?

- Before the interview starts you will be asked to complete a consent form.
- The interview will be conducted in a quiet room in the hospital or over the telephone at a time that is most convenient for you. The interview will be audio recorded. If you chose to have a face to face interview you will be able to stop and start the recording as you feel comfortable.
- The nurse caring for your child will know where the interview is being conducted so that if you are needed by your child you can attend. You will be able to choose whether to continue the interview after a break, rearrange it to another convenient time or stop. However, the data collected up until that point will be automatically included in the analysis.
- The interview will last no longer than 45 minutes.
- The interviewer will ask you a number of set questions about medicine administration and she may respond to some of your answers to explore them further.
- Once the interview is completed, the recording will be transcribed but your name and location will be removed to maintain your confidentiality**.**

Do I have to take part?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What are the possible risks and disadvantages of taking part?

As you are talking about your child and their current illness there is a risk that you may become upset. If this occurs, you will be able to stop the recording. The interview will be stopped so that you can have a break. You can then choose whether to continue the same day, try to rearrange for another convenient time or finish at that point. However, any data collected up until that point will be included in the study. If after talking to the researcher you feel you require more time to talk, she will organise with team looking after you access to a support professional such as a chaplain.

You do not have to take part in the study and you can withdraw at any point in the study, however, any data collected will be used in the analysis even if you withdraw.

What are the possible benefits of taking part?

Parental experiences of medicine administration in PICU are very important. They will help us understand how parents can influence and help to improve the process.

Data protection and confidentiality

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Coventry who are organising the research. They

may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (email address, telephone number) will be kept for 12 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other research data will be kept securely for 10 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen to the results of the study?

The results be published in my PhD thesis, scientific journals, and presented at conferences. In all publications and presentations anonymity and confidentiality will be maintained. Participants can get a short summary of the findings, if you wish to receive it, when the project has finished. Please complete the section on the consent form.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [name of committee will be added] Research Ethics Committee.

What if something goes wrong and I want to make a complaint?

If you wish to complain about anything within this study, please contact:

Dr Gurnam Singh

Principal Lecturer in Social Work and Research Degrees Lead

Faculty of Health and Life Sciences

Coventry University, Priory Street,

Coventry CV1 5FB, UK

Tel 024 7765 7886

This matter will be investigated by the university complaints procedure.

Key researcher details

Rachel Bower

PhD Student

Coventry University

Priory Street

Coventry, CV1 5FB

Tel **********

An exploration of parental views of interventions to reduce interruptions to medication administration within Paediatric Intensive Care

Consent form for parents

	Please initial
I can confirm that I have read and understood the information sheet version _ and had chance to ask questions about the study.	
I understand that I also have the right to change my mind about participating in the study at any time, but the information collected so far cannot be erased and that this information may still be used in project analysis.	
I understand that interview notes will be stored at Nottingham University Hospitals Trust in a locked cupboard, in a locked office. I give permission for the research team to access these files to analyse and publish findings from this project.	
I agree to the interview being audio recorded as part of the research project.	
I understand that all data will be anonymous and stored in secure electronic files and that identities will be kept confidential.	
I agree to take part in the study as outlined in the information sheet.	

Participant name	Signature	Date
Researcher name	Signature	Date

Please tick the box if you wish to:

- Receive a copy of the findings ☐
- comment on the proposed design of the intervention at the end of this study ☐

Please state the email you wish to be contacted by.

Appendix 3 – Interview Schedule for Parental Interviews

Thank you for agreeing to take part in this interview. Please can I double check that you have read the information sheet? Signed the consent form? And have no more questions that you wish to ask?
I really appreciate you taking time away from (child's name)'s bedside. I will be recording this interview (If parents in face to face interview chose to operate the recorder, instructions on to do this will be given). Please do not hesitate to stop and start the recording as you feel comfortable.
Settling in question and demographic information To start our conversation, are you able to tell me a little bit about …….? How old are they and why have they been admitted to PICU? How long have you been in PICU?
Medication administration • Can you describe an episode of medicine administration that you have seen whilst your child is/was in PICU? • How did you know when nurses were beginning to administer medicines? • Can you describe generally what you do while the nurses are involved with preparing and giving medicines? • If you needed help whilst the nurse was preparing medicines what would you do?
Interruptions to medication administration • Have you seen the nurse stop preparing or giving the medicines at all? • Can you describe any occasion when medicine administration was interrupted? • Are you able to describe how the nurse responded to the interruption? • How did you feel at that time? • Are there any interruptions which you feel are more important than medicine administration?
Interruptions initiate by parents • Have you as a parent felt you needed to interrupt the nurse while he/she was working? • If so can you describe the occasion? • How did the nurse respond? • How did you feel? What makes you feel that way?
Interventions

Can you describe anything which may have encouraged you not to interrupt medicine administration?

- Can you describe how you responded to it?
- How did you feel at this time?
- Did you see any benefits or consequences to this intervention?

Can you describe anything which may help to reduce interruptions when nurses are preparing medicines?

Sharing medication information

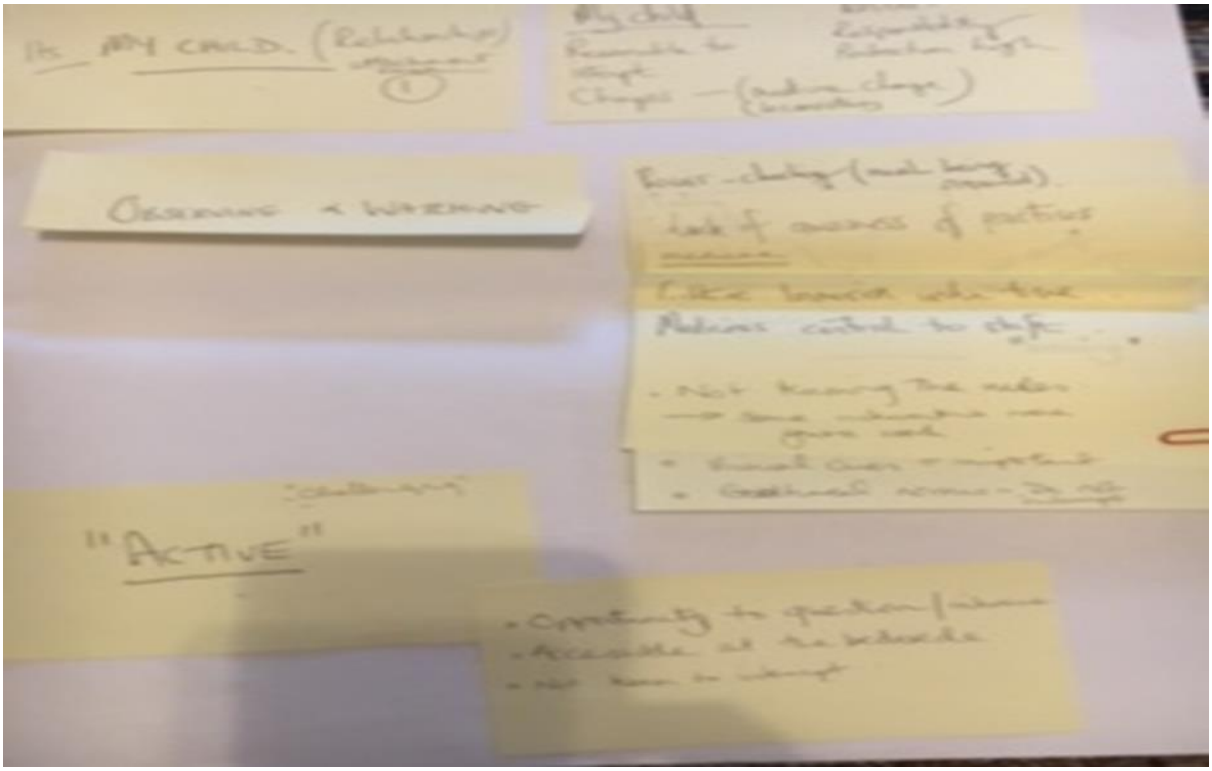
- As a parent when would it be best to share information about medicines with you?
- How should we share this information?

Appendix 4 Development of questions (example)

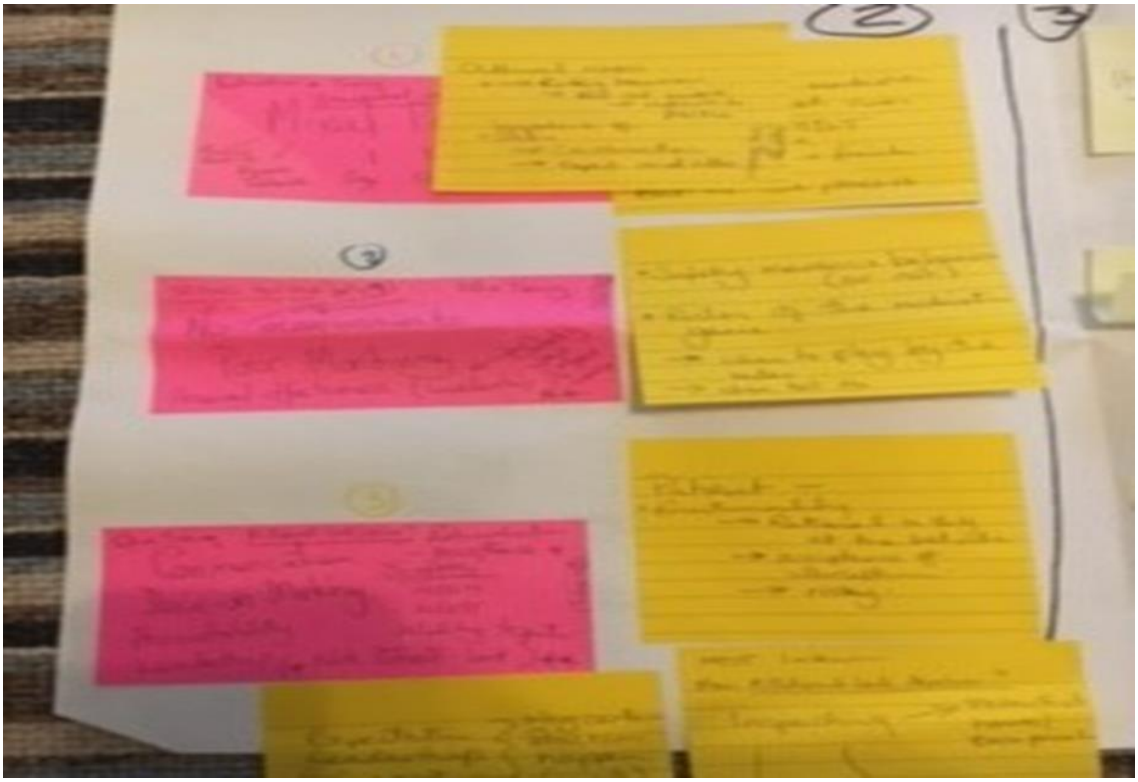
Code from previous research	Detail	Possible interview question
Being Seen as Rude	Ignoring an interruption from a colleague would make me feel uncomfortable Ignoring an interruption from a parent would make me feel uncomfortable	Can you describe an occasion when you have seen a nurse being interrupted whilst preparing medicines for your child? How do you feel if the nurse ignores the interruption?
Maintenance of Professionalism	Maintaining a professional image is important in medication administration	What behaviour do you expect from a nurse while they are administering medicines to your child?
Conversational Influence	Conversations including personal content should not occur during medication administration Conversations concerning patient condition should not occur during medication administration	Can you describe any occasions when conversations have been held during medicine administration? Were any of them not related to the administration of medicine? If present did these conversations influence how you responded to medicine administration?
Responding to Patient Condition	Responding to changes in patient condition is more important than medication administration	Did you observe any interruptions which were more important than medicine administration?
Parental Influence	Parents frequently interrupt medication administration The presence of parents reduces interruptions to medication administration It is important to respond to parental interruptions during medication administration Parental consent is required before the administration of each medication Parents require detailed information about medications	Did you as a parent feel you needed to interrupt medicine administration at all? If so can you describe the occasion? Do you think your presence changed how nurses responded to interruptions? When is it best to share information about medicine administration?

Appendix 6 - Thematic review discussion

Parent/carer themes – active decision-making, observation, ‘my child’

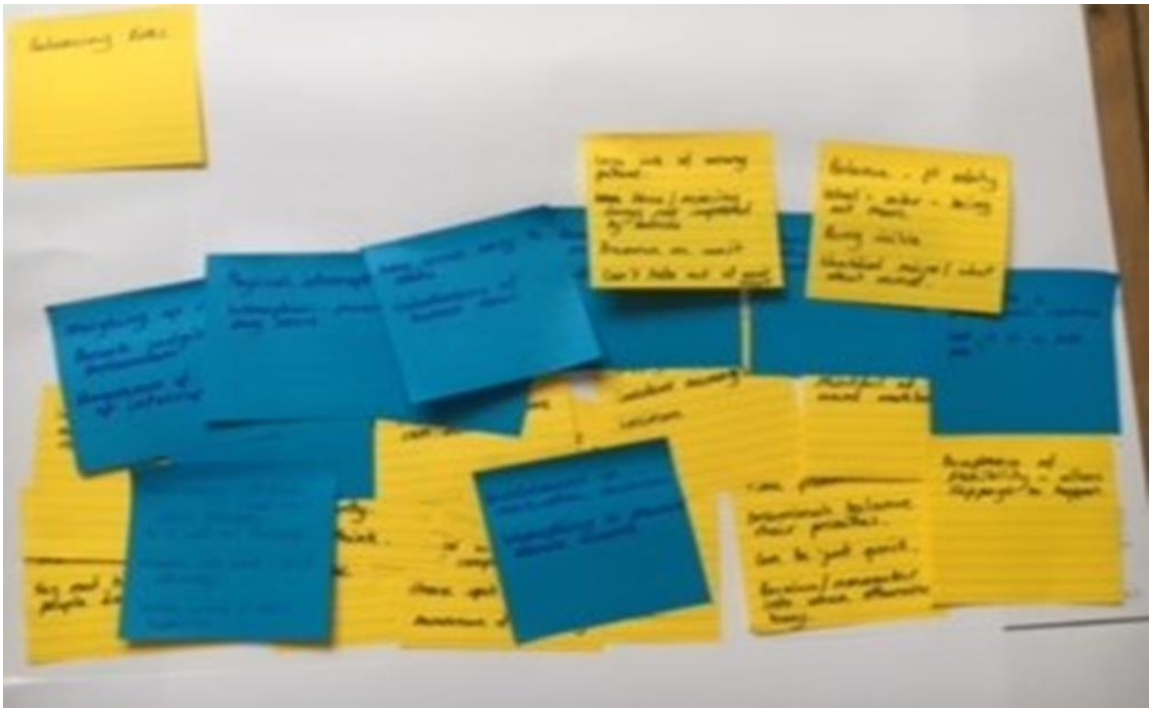


MDT themes – communication, decision-making, leadership, mavericks

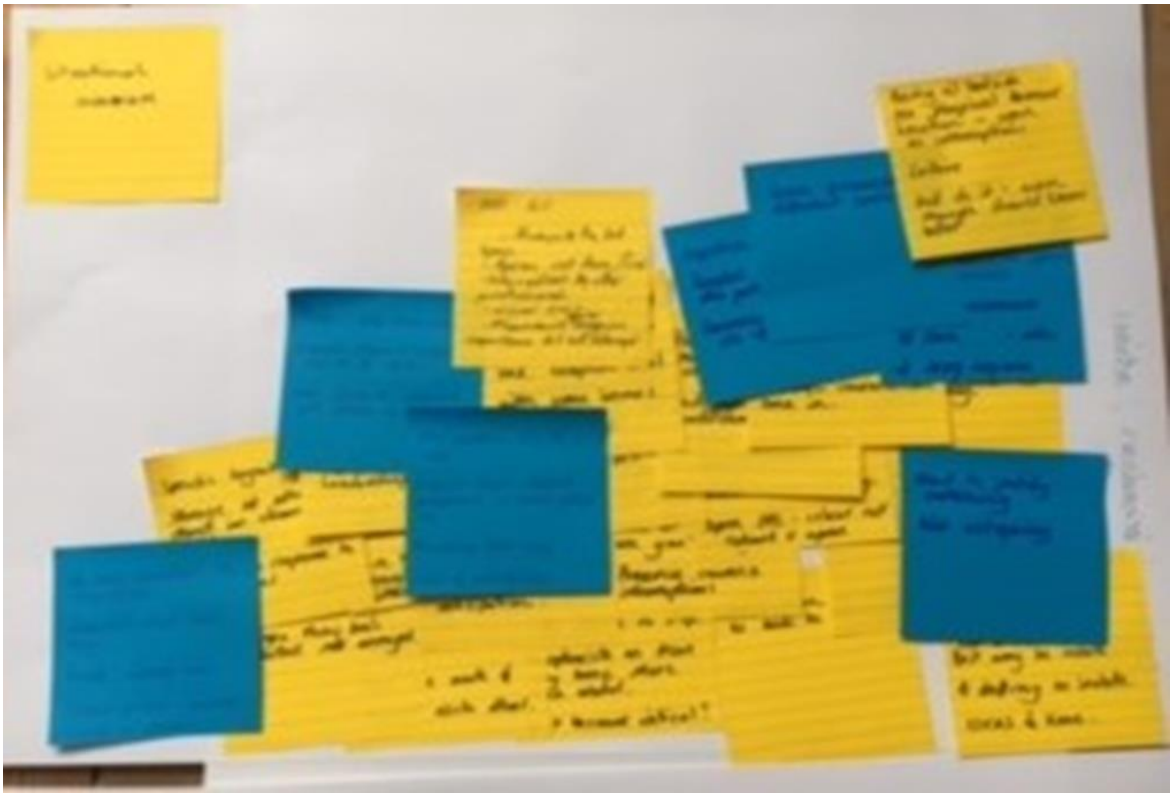


Appendix 7 - Colleague Review

Balancing Risks



Situational Awareness



Conflict