UNIVERSITY OF BIRMINGHAM

INTERRUPTIONS AND MEDICATION ERRORS: A MIXED METHODS FEASIBILITY STUDY

by

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ABSTRACT

Background

Medication errors have been found to have numerous contributing factors and interruptions and distractions have been identified as a key cause. A scoping review was conducted to identify and evaluate educational interventions that have been employed to reduce medication interruptions and improve medication safety. Eight studies were found to have employed educational interventions often using multifaceted interventions making it difficult to determine the effectiveness of education alone.

The aim of this study is to determine if an educational intervention can change the way nurses manage interruptions in a Paediatric Intensive Care (PICU) setting, with a focus on the number of interruptions handled appropriately by nurses.

Methods

The study was conducted in a 31-bed PICU in the United Kingdom. An educational intervention, informed by the scoping review, was designed and developed, consisting of a teaching session on appropriate behaviour management strategies, a simulation session to practice strategies, and an eLearning module. A randomised, un-blinded trial design was selected, where participants were randomised to either receive the educational intervention alongside the standard training provided by the unit (intervention group) or to just receive the standard training (control group). Band 5 nurses new to the unit were invited to participate. Observational data was collected at two months to identify the management strategies used by the nurses and then participants were invited to take part in interviews to explore their experiences of the learning and the perceived impact this had.

Ethical, governance and Health Research Authority approval was sought and gained for this study.

Results

A total of 27 nurses were recruited to the study, with 11 randomised to the intervention group and 16 to the control group. Due to sickness and unavailability when the intervention was implemented, two participants randomised to the intervention group had to be switched to the control group.

A high rate of interruptions was found in the observational data, with 89% of medication episodes interrupted at least once. The main source of interruptions were nursing staff communications, ranging from questions about breaks, social conversations to clinical communication. Observation of the medication episodes showed that the main strategy used by both groups was multitasking, which was never adopted appropriately. The blocking strategy was found to be used least. Upon analysis, no statistical difference was found between the intervention and control groups in the strategies they adopted to manage their interruption.

Six themes emerged during the interviews: 1) Situational awareness, 2) Empowerment, 3) Simulation sessions, 4) Team cohesion, 5) Embedded in the culture and 6) Shared learning. All the participants reported they would recommend the educational intervention to their colleagues. The interview data supported findings from the with the observational study, where the nurses reported they didn't always utilise the appropriate strategy but had an increased awareness of the interruption. A fear of being perceived as rude and lack of embedded education in the culture, were identified as the main barriers to using the blocking strategy.

Discussion

A high rate of interruptions was found to occur in PICU, with nurses one of the main sources of these. A need for a consistent approach among all professionals emerged from the interviews, allowing behaviours such as choosing to block an intervention to be understood in the moment and accepted. The main management strategy utilised by all participants was multitasking.

The high interruption rates observed and the nurses' desire for change needs to be further explored. Although there was no statistical difference between the intervention and control groups, the education increased awareness of the issue and highlighted the need for this to be made more widely available within the organisation to encourage wider cultural change. This would make strategies to block interruptions more acceptable.

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OWEN,S., MENZIES, J & PONTEFRACT, S. 2022. Nurses' experience of an education intervention to help effective management of medication interruptions. *HEE Future Directions Midlands wide Conference.* The Studio Birmingham, UK (oral presentation)

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GLOSSARY OF ABBREVIATIONS

WHO	World Health Organisation
NHS	National Health Service
PICU	Paediatric Intensive Care Unit
ADR	Adverse Drug Reactions
UK	United Kingdom
PPIE	Patient and Public Involvement and Engagement
HCP	Healthcare Professionals
MDT	Multidisciplinary Team
ENT	Ear, nose and throat
NG	Nasogastric
NJ	Nasojejunal
IV	Intravenous
US	United States
IoM	Institute of Medicine

Chapter 1 EDUCATIONAL INTERVETIONS TO REDUCE MEDICATION INTERRUPTIONS: A SCOPING REVIEW

This chapter explores the published literature around interruptions to the medication administration process and educational interventions to help manage these. The results of this chapter will be used to inform the design of the educational intervention for the mixed-methods study.

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Introduction

Preventable harm from medicines is a global problem which creates a huge economic and social burden (Dickinson, 2012). The World Health Organisation (WHO) has recognised the issue and in 2017 developed a strategy to reduce avoidable medication errors by 50% by 2022 (Donaldson et al., 2017). Donaldson et al.(2017) estimated that the annual global cost of medication errors is US$42 billion, which represents approximately 1% of the global expenditure on health. In 2018, Elliott et al found that each year in England, an estimated 237 million medication errors occur at some point during the medication process, with 66 million of these being potentially clinically significant errors. Medication errors cost the National Health Service (NHS) an estimated £98.5 million per year, with £14.8 million due to them increasing patients' length of stay and contributing to approximately 1081 deaths a year (Elliott et al., 2018).

The complexity of a Paediatric Intensive Care Unit (PICU) can mean medication errors or Adverse Drug Reactions (ADRs) are more likely. There are environmental factors that can cause a higher risk of medication errors including the acuity of patients, the frequency of

medicines administered and the complexity of the calculations associated with these (Bower et al., 2015). A single medication error will have several contributing factors, many of which are human in nature. Nurses often work in a busy and stressful environment, where interruptions frequently occur (Myers and Parikh, 2019). Interruptions and distractions are both key contributing factors leading to medication errors globally (Kwon, Kim & Choi., 2021; Davidson et al., (2022).

Interruptions can occur frequently in clinical environments. One study in medical-surgical and critical care wards in Australia, found that 99% of observed medication episodes (55/56) were interrupted (Johnson et al, 2017). Research suggests that there is a cognitive cost of interruptions, such as reducing concentration, causing confusion and reduction in work efficiency (Cole et al., 2016). Research can also delay time critical jobs such as patient assessments and cause a decline in effective communication leading to a deterioration in patient's health (Weigl et al., 2016). Interruptions can include self-distraction, loss of focus, patients, other healthcare providers, phone calls and texts (Hayes et al., 2015). Kalisch and Aebersold (2010) found that nurses spend approximately 30% of their time at work multi-tasking, which can have both positive and negative effects. It can allow nurses, who often are constrained on time, to use their time more effectively. On the other hand, it can also affect their workload which can impact patient's safety (Kalisch and Aebersold, 2010).

Studies have associated interruptions with clinical errors and procedural failures (Eid, Machudo & Eid, 2022), however, the link has never been directly proven. A review of 38,063 medication errors in America, identified that interruptions were the most common contributing factor (Santell et al, 2003). Distractions or interruptions were identified in nearly half of the reports into the medication errors. Many of the studies investigating medication interruptions found that the most frequent cause of medication interruptions were nursing colleagues (Alteren et al., 2018; Schroers, 2018). Westbrook et al (2010) also found that the 85% of medication episodes that were interrupted during their observations, resulted in either clinical or procedural errors. Furthermore, a local audit conducted at Birmingham

Children's Hospital on the PICU (Longman, 2017), showed that 81% of medication episodes were interrupted at least once and 65% of administration episodes were interrupted two or more time. This added, on average, an additional 17 minutes to the medication rounds. Some interruptions are unavoidable, necessary and occur for patient safety reasons, for example, important communication about a patient or alerting to a risk (Westbrook et al, 2010). In view of this, it is important that interventions to reduce interruptions can distinguish between those that are avoidable and those that are necessary.

There are currently no standardised guidelines or interventions to reduce medication interruptions (Tomietto et al., 2012). However, the main intervention for tackling this problem in the last decade has been "Do Not Disturb Vests" or "No Interruptions Zone". These interventions have been adapted from the aviation industry. However, there is weak evidence to support the effectiveness of these types of interventions (Hall et al., 2010). A recent multicenter cluster randomised controlled trial in France, found that a 'do not interrupt' vest intervention had no impact on administration errors or interruptions (Berdot et al., 2021). Hayes (2014) suggests that these interventions deny the complexity of the healthcare environment, the medication task, and the nurse-patient interaction. Furthermore, another study found registered nurses characterised the vests as uncomfortable and time consuming, and only 48% supported the vests becoming hospital policy (Westbrook et al., 2017). A previous literature search into interventions to reduce medication interruptions was conducted by Raban and Westbrook in 2014. They found ten research papers eligible to include in their review. Employed interventions included signage, quiet zones, checklists and more. All interventions had a poor impact on reducing the rate of medication interruptions and there was weak evidence for their effectiveness and no study employed targeted education interventions. Other research has suggested that interventions should focus on addressing the culture of the organisation towards managing interruptions (Machen et al., 2019). In recent years there has been a shift from tackling the phenomenon of interruptions directly towards educational interventions that teach staff to employ techniques to manage

these situations better, with a focus on non-technical skills of situational awareness, task management and coping with stress.

Aim: The aim of this scoping review is to identify and evaluate published literature describing employed educational interventions to reduce medication interruptions and improve medication safety.

Method

A scoping review was conducted to answer the research question; 'Are educational interventions that are employed to overcome problems associated with medication interruptions, effective?'. The aim was to examine the extent, range and nature of research activity into medication interruptions as suggested by Arskey and O'Malley (2005). A scoping review was more appropriate than a systematic review, as the area under investigation is broad and no specific study design was required to answer the question. Furthermore, as this is part of a larger study, the limited time also made it more appropriate to conduct a scoping review, as stated by Arskey and O'Malley (2005).

Six databases were searched: PubMed, Embase, Cochrane Library, CINAHL, PyschInfo and Medline. Manual searches of reference lists and grey literature were also conducted. The inclusion criteria were created to be able to answer the research question. Articles were included if they were written in English and published between 2010–2020. The articles met the inclusion criteria if they employed an education intervention (including bundled interventions) aimed at reducing medication interruptions. For the purpose of this review, interruptions are defined as a halt in the medication process due to a secondary task (Hopp et al, 2005). Education interventions were defined as interventions that included an element of teaching, introduction of new knowledge or personal feedback. Exclusion criteria included: review articles, research that did not specifically focus on medication interruptions. research

focused on medication errors rather than managing or overcoming medication interruptions. Studies were also excluded if they were not written in English or if the full-text was not available. The decision was made to include other healthcare professionals that have similar roles to nurses in the medication process. This included healthcare workers and student nurses, as they often participate in the medication process with nurses in the same environment. They are therefore exposed to the same interruptions and often contribute to these interruptions. Education interventions needs for these healthcare professionals will be the same as for nurses.

Databases were searched using individual keywords identified from background literature and using the OR/AND function to combine keywords such as “medication interruptions” AND “Education” AND “Interventions”. A combination of medical subject headings (MeSH) and free-text keywords were used alongside keywords identified from other published articles during the initial search. The keywords were tested in different combinations before the final strategy was identified for the search. The subject headings were exploded to included narrower related terms, which were added to the search as ‘free-text’. Data from each article was independently reviewed and extracted into a data extraction table. Descriptive characteristics were collated in a table by the main author, which was reviewed by the co-author. Assessment of risks of bias were undertaken for non-randomised intervention studies using the ROBINS-I tool (Sterne et al., 2016) and the RoB 2 tool for randomised trials (Sterne et al., 2019). Thematic analysis was completed to identify key themes by the main author, which was presented to the co-author for review. The PRISMA extension for scoping reviews was followed during this scoping review (Tricco, 2018).

Table 1.1 Keywords used in the literature search

Medication	**Interruption**	**Education**	**Intervention**
Medicine Drug	Interruption	Training Teaching ELearning Online learning	Program Programme

Results

A total of 1,144 articles were identified from the initial search in November 2020 (Figure 1.1). Duplicates were removed and articles were screened by title, abstract and full text to ensure eligibility (Figure 1.1). Eight articles met the inclusion criteria. Key information was captured to examine each of the interventions and the reported impact. The eight articles were published during a 9-year period of 2010-2019, in a range of countries including Australia (n=3), Italy (n=2), Switzerland (n=1), Egypt (n=1) and Ireland (n=1) (Figure 1.2)

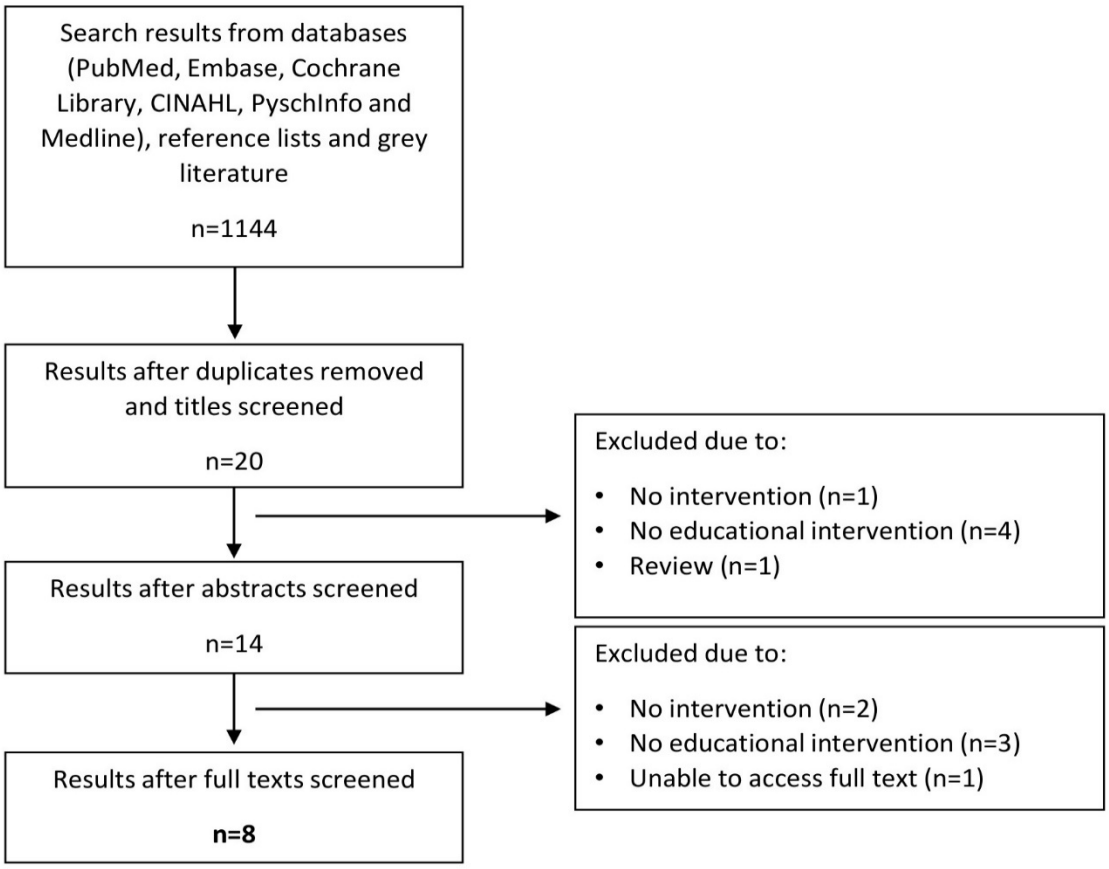

Figure 1.1. Screening the literature for educational Interventions to reduce medication interruptions

Table 1.2 Descriptive characteristics of studies included

Authors ,Year (Country)	Aim	Sample	Setting	Design	Intervention	Outcomes Measure	Key findings
Mortaro et al. 2019 (Italy)	To explore main reasons for interruptions on a geriatric ward in an Italian secondary hospital and test the effectiveness of a combined interruption.	24 nurses	geriatric ward (n=1)	Pre and post observation study Qualitative and Quantitative	**Combined intervention:** Education Intervention (n=3) Other Intervention (n=3)	Number of interruptions Reason for interruptions Duration of interruptions Interruption management	Number of interruptions significantly improved Time wasted on interruptions significantly reduced.
Johnson et al. 2019 (Australia)	To conduct a feasibility cluster randomised controlled trial of an educational intervention that taught behavioural strategies to nurses	68 nurses	medical-surgical wards (n=8) from 4 hospitals	Parallel cluster randomised controlled trial Pre and post observations Qualitative and Quantitative	**ELearning module**	Number of Interruptions Observed clinical errors/procedural failures Distribution and frequency of nurse-initiated behavioural management strategies	Reduced multi-tasking and increased engaging strategies No statistical differences in number of interruptions and clinical error/procedural failures
Johnson et al. 2018 (Australia)	To describe and evaluate the perceptions of nurses of an authentic e-learning module that demonstrates behavioural management strategies for interruptions	9 healthcare workers 9 nurses	palliative ward (n=1) acute ward (n=1)	Focus Groups Qualitative	**ELearning module**	Framework guided thematic analysis E.g. questions about the education program and if it changed their behaviours	Many needed prompting to remember the program Felt it was definitely important and should be viewed by other staff Felt the content made sense and was effective

Authors ,Year (Country)	Aim	Sample	Setting	Design	Intervention	Outcomes Measure	Key findings
Dall'Oglio et al. 2017 (Italy)	To assess the effectiveness of an improvement programme to reduce interruptions during medication preparation and administration in a paediatric hospital	486 medication cycles were observed Number of participants was not stated	medical surgical wards (n=2) cardiac wards NICU wards (n=2) medical wards (n=3)	Quasi experimental study Pre and post observations Qualitative and Quantitative	**Combined Interventions:** Education Interventions (n=2) Other Interventions (n=3)	Frequency of interruptions Cause of interruptions Medication Administration Distraction Observation Sheet (MADOS)- adapted for Paediatrics Debriefing session after the intervention	Length of medication cycles significantly decreased after intervention Significant decrease in interruptions post-intervention
Huckels-Baumgart et al. 2017 (Switzerland)	To evaluate the impact of staff training and safety vests on interruptions during medication preparation and double checking	26 nurses	medical ward (n=1)	Pre and post observation study Quantitative	**Combined Interventions:** Education Intervention (n=1) Other Intervention (n=2)	Frequency of interruptions Cause of interruptions Duration of interruptions Medication Administration Distraction Observation Sheet (MADOS)	Decreased interruptions by 23% After combined intervention time taken for medication preparation and double checking reduced by 52%
Hayes et al. 2017 (Australia)	To describe undergraduate student nurse responses to a simulated role-play experience focussing on managing interruptions during medication administration	528 2nd year nursing students 8 academic teaching staff	2 campuses within a large Australian University	Thematic analysis of reflective responses Qualitative	**Simulation role-play**	Structured reflective responses	Learning experience improved their confidence, taught them how to prioritise and plan care and time management Improved awareness of management strategies.

Authors ,Year (Country)	Aim	Sample	Setting	Design	Intervention	Outcomes Measure	Key findings
Zakira et al. 2017 (Egypt)	To assess the effectiveness of interventions to limit errors and interruptions during medication administration in medical and surgical units	48 nurses	general medical wards (n=2) surgical wards (n=2)	Quasi-experimental study Questionnaires Pre and post observations Quantitative	**Education programme**	Postintervention test to assess nurses' knowledge Frequency of errors Frequency of interruptions Cause of interruptions	Statistically significant improvement on knowledge of interruptions and medication safety Statistically significant decrease in errors and interruptions post intervention
Relihan et al. 2010	To assess the impact of a set of interventions in reducing the interruption/distraction rate during medication administration	31 nurses	Acute Medical Admissions Unit (AMAU) (n=1)	Pre and post intervention observational study Quantitative	**Combined Interventions:** Education Interventions (n=2) Other Interventions (n=3)	Frequency of interruptions/distractions Sources of interruptions/distractions Medication Administration Distraction Observation Sheet (MADOS)	Interruption/distraction rate significantly decreased post intervention Substantial behavioural changes were observed in staff, patients and visitors post-intervention

Study demographics

Most of the research in the eight studies was conducted in general hospitals, with two studies set in a paediatric hospital and one within a university. The studies were mainly conducted in medical wards (n=4), surgical wards (n=2), and medical-surgical wards (n=2). Most of the participants included were female nurses and the level of nursing experience ranged from less than 6 months to 20 years. Sample sizes for the studies ranged from 18 (Johnson et al, 2018) participants to 536 (Hayes et al, 2017).

Half of the studies identified used a combined intervention (n=4), whilst the others focused exclusively on implementing an education intervention (n=4). Those that used a combined intervention employed strategies such as no interruption zones, sashes, signs on the wards and red aprons. Most of the studies evaluated the effectiveness of the intervention using a pre- and post-intervention observational design (n=6), with two studies using reflection and focus groups post-intervention. Only one study used a randomised controlled trial design (Johnson et al., 2019). Various strategies were adopted to implement the education interventions, including lectures/group sessions (n=4), role play and simulation (n=2) and e-Learning modules (n=2). One study used a combination of both group sessions and simulation/role play. Two of the studies did not provide a working definition for interruptions (Hayes et al., 2017, Johnson et al., 2018) six studies provided a definition, although these were all similar, there were subtle differences between each, for example whether interruptions are purely caused by external factors or both external and internal factors. Despite research being conducted in this field for many years, there was no standardised definition of an interruption.

Six of the studies used a pre- and post-intervention design. The other two studies used focus groups and reflection to determine the effectiveness of the interventions. All the studies collected their data within six months of the intervention being implemented, the majority collected data between 1–3 months.

All the non-randomised intervention studies scored a moderate or serious risk of bias using the ROBINS-I tool (Table 1.3) (n=7). The majority of the bias was due to the lack of controlled interventions resulting in bias due to confounding factors. There was also often little information regarding participant selection, meaning it was difficult to identify if processes were biased. On the other hand, the majority of the randomised controlled trial conducted by Johnson et al. (2019), was deemed low risk using the ROB2 tool (Table 1.4). The final result scoring ‘some concern’ due to a lack of information about participant attrition rates and missing outcome data.

Table 1.3: Risk assessment of bias for the non-randomised interventional studies using the ROBINS-I tool.

	Pre-Intervention		At Intervention	Post-Intervention				
Author, Year	**Bias due to confounding**	**Bias in selection of participants into the study**	**Bias in classification of interventions**	**Bias due to deviations from intended interventions**	**Bias due to missing data**	**Bias in measurement of outcomes**	**Bias in selection of the reported result**	**Risk of bias judgement**
Mortaro et al. 2019	Low	No Information	Moderate	No Information	No Information	Moderate	Low	Moderate
Johnson et al. 2018	Low	No Information	Low	Low	Low	Moderate	Low	Moderate
Dall'Oglio et al. 2017	Serious	Low	Low	Low	No Information	Low	Low	Serious
Huckels et al. 2017	Serious	No Information	Low	No Information	No Information	Low	Low	Serious
Hayes et al. 2017	Low	Low	Low	Serious	Low	Low	Low	Serious
Zakira et al. 2017	Low	No Information	Moderate	Low	Low	Low	Low	Moderate
Relihan et al. 2010	Serious	No Information	Low	Low	Serious	Low	Low	Serious

Table 1.4: Risk assessment of bias for the randomised trials using the RoB 2 tool.

Domain 1a: Risk of bias arising from the randomization process			
Signalling questions	**Lower risk of bias**	**Higher risk of bias**	**Other**
1.1 Was the allocation sequence random?	Y		
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	PY		
1.3 Did baseline differences between intervention groups at the start of the first period suggest a problem with the randomization process?	PN		
Risk-of-bias judgement *(Low / High / Some concerns)*	Low		
Bias due to deviations from intended interventions			
2.1 Were participants aware of their assigned intervention during the trial?		Y	
2.2 Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y	
2.3 If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	PN		
2.4 If Y/PY/NI to 2.3: Were these deviations likely to have affected the outcome?			
2.5 If Y/PY to 2.4: Were these deviations from intended intervention balanced between groups?			
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y		
2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomised?			
Risk-of-bias judgment *(Low / High / Some concerns)*	Low		
Bias due to missing outcome data			
3.1 Were data for this outcome available for all, or nearly all, participants randomised?			NI
3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	PY		
3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?			NI
3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?			NI
Risk-of-bias judgment *(Low / High / Some concerns)*			Some concern
Bias in measurement of the outcome			
4.1 Was the method of measuring the outcome inappropriate?	N		
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N		

4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	PN		
4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?			
4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?			
Risk-of-bias judgment *(Low / High / Some concerns)*	Low		
Bias in selection of the reported result			
5.1 Were the data that produced this result analysed in accordance with a prespecified analysis plan that was finalised before unblinded outcome data were available for analysis?	PY		
Is the numerical result being assessed likely to have been selected, on the basis of the results, from:			
5.2 ... multiple eligible outcome measurements (eg, scales, definitions, time points) within the outcome domain?	N		
5.3 ... multiple eligible analyses of the data?	N		
Risk-of-bias judgment *(Low / High / Some concerns)*	Low		
Overall bias			
Risk-of-bias judgment *(Low / High / Some concerns)*			Some Concern

Intervention themes

Several themes of interventions were identified including general medicine safety, education for other staff, patient and visitors, role play and simulation, behaviour management strategies and generic techniques. General medicine safety was highlighted to staff in several studies (Mortaro et al., 2019, Dall'Oglio et al., 2017, Huckels-Baumgart et al., 2017, Hayes et al., 2017, Zakria and Mohamed, 2017). Some studies used the education intervention to discuss medication safety and to reiterate the importance and discuss the five rights of medication administration (right patient, right drug, right dose, right route and right time). Education about general medication safety was always implemented in conjunction with other areas of education. Many studies utilised previous study findings to demonstrate to staff, or students, the epidemiology of interruptions (Johnson et al., 2019, Johnson et al., 2018, Huckels-Baumgart et al., 2017, Zakria and Mohamed, 2017). Data on the frequency, types and causes of interruptions were portrayed to staff to highlight the severity of the

problem. Strategies to reduce interruptions were also common in many of the education interventions. Different strategies were identified in all eight of the studies. Some studies focused on behavioural management strategies, employing techniques such as engaging, multi-tasking, mediating and blocking (Johnson et al., 2019, Johnson et al., 2018). Whilst others adopted more generic techniques such as ensuring the medication trolley was fully stocked (Mortaro et al., 2019, Relihan et al., 2010), alerting colleagues that you are conducting the medicines administration round so others can be on hand to answer phones and patient/staff queries (Dall'Oglio et al., 2017, Relihan et al., 2010). Some studies also included education for other staff, patients and visitors (Mortaro et al., 2019, Dall'Oglio et al., 2017, Zakria and Mohamed, 2017, Relihan et al., 2010). One study utilised role play to help undergraduate students appreciate the negative impact of interruptions and learn how to navigate them successfully (Hayes et al., 2017). Students were given case studies to prepare, for which they had to administer medication or cause interruptions dependent on the role they were playing. They would also have a student in the observer role to identify interruption management strategies utilised. They then facilitated reflection to help the students identify both good and bad practices.

Study outcomes

Number of interruptions

Most of the studies found a significant improvement in the number of interruptions post-intervention (n=5) (Mortaro et al., 2019, Dall'Oglio et al., 2017, Huckels-Baumgart et al., 2017, Zakria and Mohamed, 2017, Relihan et al., 2010). However, one of the larger studies with an exclusive education intervention did not find a significant difference between the control and intervention group, and the control group's baseline and follow up data (Johnson et al., 2019). However, they did find that more nurses engaged with the intervention at follow-up and fewer attempted to multi-task. The intervention was an eLearning module and nurses reported finding it difficult to have the time to complete all the learning. During the focus group session, it also became apparent that the nurses struggled to recall the

eLlearning programme. This could explain the contrasting finding for this study with the lack of improvement post-intervention. However, the nurses also commented on the importance of the eLearning programme during the focus groups (Johnson et al., 2019, Johnson et al., 2018). They stated that the content made sense and was effective. They also felt that other healthcare staff should view it. The only change they wanted to make to the programme was to add consequences of medication interruptions, for example, show medication errors caused by interruptions.

Duration of interruptions

Many studies not only reported on the number of interruptions post-intervention, but also looked at the duration of the interruptions post-intervention (Mortaro et al., 2019, Dall'Oglio et al., 2017, Huckels-Baumgart et al., 2017, Zakria and Mohamed, 2017). Significant reductions were found in the studies that looked at the duration of interruptions, and these were also perceived by the participants.

Other changes

Two of the studies observed changes in the nurses' behaviour (Johnson et al., 2019, Relihan et al., 2010). One study observed behavioural changes in all groups; nurses, other healthcare staff, patients and visitors (Relihan et al., 2010). However, it was unclear whether this change was due to the education intervention or other interventions. For example, one of the changes described was visitors walking towards the medication trolley to interrupt the nurse, but then being discouraged away by signs and posters. One study worked with the nurses to create the interventions, which they found resulted in a greater uptake of the intervention (Zakria and Mohamed, 2017). A study that employed role play and simulations with students, found that after the intervention students demonstrated an understanding of how medication interruptions affect clinical decision making (Hayes et al., 2017). The simulation improved their confidence and increased their ability in time management and prioritising and planning their care. The students reported that for the role play to be effective and successful, the students need to feel they are in a safe and supported environment

where they are able to make mistakes freely. Several studies reported that nurses were the most common cause of interruptions (Johnson et al., 2018, Dall'Oglio et al., 2017, Huckels-Baumgart et al., 2017, Relihan et al., 2010). This is similar to previous research into medication interruptions colleagues (Biron et al, 2009; Johnson et al, 2017), however, the staff still reported surprise that nursing colleagues created the most interruptions.

Implications for research

Colligan and Bass (2012) stated that an education and a cultural change are needed with a specific focus on nurses, as nurses showed a willingness to engage in interruptions, and Westbrook et al. (2010) also highlighted the importance of using simulations within education interventions. Raban and Westbrook (2014) state that the lack of studies that implement a control group makes it difficult to assess whether any other factors affected the change in interruptions seen. During their literature review Raban and Westbrook (2014) criticised the lack of randomised controlled trials and stated for research to provide evidence of the effectiveness of the intervention, more studies with these designs need to be conducted. Considering this scoping review was completed nearly 10 years later, it highlights the lack of progress in this area and how imperative these designs are, to allow us to better understand and manage the complex relationship between medication and interruptions. As the majority of the studies included in this scoping review were feasibility studies and therefore had small sample sizes, more research needs to be conducted on a larger scale. Most of the studies did not control for bias, which brings the quality of the research conducted to date into question. Furthermore, most of the studies took place in general medical or surgical wards. More research needs to be conducted to assess the appropriateness of an educational intervention for medication interruptions in more specialised wards such as intensive care (Bower et al., 2018).

Previous interventions have been heavily criticised for a lack of nurse buy in (Bower et al., 2015, Hayes et al., 2014, Federwisch et al., 2014). Previously, many nurses found the

interventions added work, increased the time it took to complete the medication episodes and were not successful. Only two of the studies sought nurses' opinions and experiences after the implementation of the intervention. Therefore, we are unsure as to whether nurses are more accepting of educational interventions than those previously implemented such as no interruption zones or safety vests. Furthermore, one study conducted previously, found that when the intervention decreased the number of interruptions, a reduction in communication and co-ordination was observed, which was essential for effective teamwork (Anthony et al., 2010). This emphasises the need to understand the implications of these interventions on both the number of interruptions but also the healthcare staff and workflow. The studies that used focus groups and reflection to allow nurses to evaluate the interventions, found that the nurses believed the education was important and would be useful for other members of staff (Johnson et al., 2018, Hayes et al., 2017). The simulation/role play was found to increase nurses' confidence and taught them how to prioritise and plan patient care (Hayes et al., 2017). Nurses found it difficult to have the time to complete the e-learning module, and the study did not investigate whether participants completed the whole of the online module (Johnson et al., 2019, Johnson et al., 2018). The largest study that solely employed an education intervention did not find a significant difference in interruptions which could potentially cast doubt as to whether employing exclusive education interventions is the way to go. However, this was the study that implemented the e-learning module and as stated, although they had positive qualitative data from their research, the engagement in the whole of the programme was lacking. Future research could explore the effect if both role play and simulations were implemented simultaneously with an e-learning programme, to allow both the benefits of the easy to access and quick e-learning module with the increased confidence and management skills from the role play.

None of the studies identified in this scoping review, attempted to identify the long-term effects of the interventions. The majority of the studies identified the Hawthorne effect as a

limitation to their research, which has also been identified as a limitation in previous research (Prakash et al., 2014). With the limited time between the implementation of the intervention and the post-intervention observations, it increases the likelihood of the Hawthorne effect impacting the participants' behaviour. Furthermore, considering we are unsure on the nurses' level of acceptance of the intervention, it is difficult to determine whether the improvement seen is due to the Hawthorne effect or whether the intervention has triggered a culture change towards interruptions. Similarly, other studies found that participants struggled to recall aspects of the intervention, potentially meaning that there is a 'ceiling effect' to the effectiveness of interventions (Prakash et al., 2014). More longitudinal research is needed to explore whether the initial improvements observed in most studies were sustained over time.

A question raised from this review, is whether researchers were using the correct outcome measures to evaluate the educational interventions. The study that exclusively focused on an education intervention did not find a significant difference in reduction of interruptions between baseline and follow up, and control and the intervention groups. However, the education was aimed at teaching nurses how to effectively manage interruptions, and not to stop interruptions altogether. They did find more nurses used the engaging strategy at follow up more than the multi-tasking strategy. There is a question over whether the aim of the interventions is to eliminate all interruptions, despite being aware that some interruptions are needed, or whether it is to eliminate the risk that is associated with engaging in interruptions during medication administration. If the latter, duration of interruptions or management strategies may be a more effective outcome measure to evaluate the impact of the interventions.

Conclusion

The scoping review found very few studies utilised an education intervention for medication interruptions. The eight studies identified often combined the intervention with other

strategies, making it difficult to determine the effectiveness of the educational intervention alone. Research into strategies to reduce medication interruptions needs to be carried out in a wider range of clinical settings, with appropriate outcome measures selected. Research should explore the combination of educational strategies, such as role-play and eLearning to allow the participants to gain benefits of both techniques. It is important in future research that allocated time is given to participants to allow them to complete the training. More longitudinal studies are needed to see if any impact is sustained over time. Nurses' experience and acceptance of the learning and impact on their work should be investigated to identify any unintended effects that could impact on communication and coordination of care, which can ultimately impact on patient safety.

Chapter 2 STAFF AND A PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (PPIE) GROUP'S FEELINGS ABOUT MEDICATION INTERRUPTIONS: A QUESTIONNAIRE STUDY

This chapter describes a questionnaire study conducted to inform the educational intervention for the mixed-methods study. It describes the development of the questionnaire to explore staff's opinions and experiences of medication interruptions and to determine an appropriate phrase for the intervention. The survey findings will be used to develop an educational intervention.

Background

A local UK PICU audit (Longman, 2017) identified interruptions in 81% of medication episodes. There has been a recent shift in focus, where interventions are now implementing behaviour management strategies to reduce the consequences of medication interruptions. Johnson et al. (2018) identified four main strategies nurses can use to manage interruptions; blocking, mediating, engaging and multitasking. Blocking is where the individual would ignore the interruption to focus on the medication episode. Mediating is when actions to aid memory recall are taken before dealing with the interruption. Engaging is favouring the interruption by stopping the medication process immediately to deal with the interruption. Finally, multitasking is simultaneously trying to complete the medication episode and the interruption. To create effective interventions, it is essential to understand healthcare professionals' and patient and public involvement and engagement group's (PPIE) perspectives on medication interruptions. The scoping review highlighted that there is a paucity of research exploring this. Understanding whether medication interruption research is viewed as a priority and interventions/behaviour strategies are deemed as appropriate will be beneficial when combatting this issue.

Aim: The aim of this study is to explore the feelings of PICU staff and PPIE members about medication interruptions and to determine the level of acceptance for a verbal phrase to be utilised to manage interruptions throughout blocking.

Methods

The survey was created and informed from the results of the scoping review. It was developed online and disseminated via email to all PICU HCP (n=408) working in a 31-bedded UK PICU, with promotion and reminders via a private staff Facebook group. The survey was also disseminated to a local young research champions group during a regular meeting. The survey was created via the online platform JISC and questions were developed and informed by the scoping review. Questions included Likert scales, with the opportunity for free-text (Appendix 1). The phrase "*I'm sorry I'm preparing medication. Unless it is an emergency, I will speak to you when I have finished*", was created locally by a multidisciplinary team to include in the questionnaire to determine level of staff acceptance, as part of a medication audit in 2017 (Longman, 2017). The work was registered and approved with the University of Birmingham research ethics committee and local NHS governance, as part of the ethics approval for the whole study [IRAS ID: 292511; OID: RG_20-166].

Results

A total of 54/413 (13%) responses were received, two thirds of which were nurses (n=41/54, 76%). Other respondents comprised consultants, doctors, health care assistants, pharmacists, other nurse group (e.g. HCA's) and PPIE group (Table 2.1).

Table 2.1 Roles of survey participants

Role	Total	Percentage
Nurse	41	76%
Consultant	2	4%
Doctor	3	6%
Health Care Assistant	1	2%
Pharmacist	1	2%
Nurse (other)	1	2%
PPIE Group	5	9%

Experience of the participants ranged from <1 year - > 5 years. Over half the participants (57%, n=36/54) were involved in clinical checking of medication prescriptions, preparation and administration. All participants agreed that medication safety research is important, 81% (n=44/54) strongly agreeing. Most of the participants (83%, n=45/54) recognised interruptions were a significant issue. However, many of the participants (65%, n=35/54) admitted that they had previously interrupted staff members during the medication process, with another 7% (n=4/54) stating that they have probably unknowingly interrupted.

There were mixed views about when it was appropriate to interrupt the medication process, with 16% (n=12/74) of respondents identifying ward round and 16% (n=12/74) when asking a clinical question (Figure 2.1). Some nurses (16%, n=12/74) stated that there was never an appropriate time to interrupt, and 32% (n=24/74) left the question blank. The data does not allow us to determine whether the question was intentionally left blank or whether this was utilised to emphasise there is no appropriate situation.

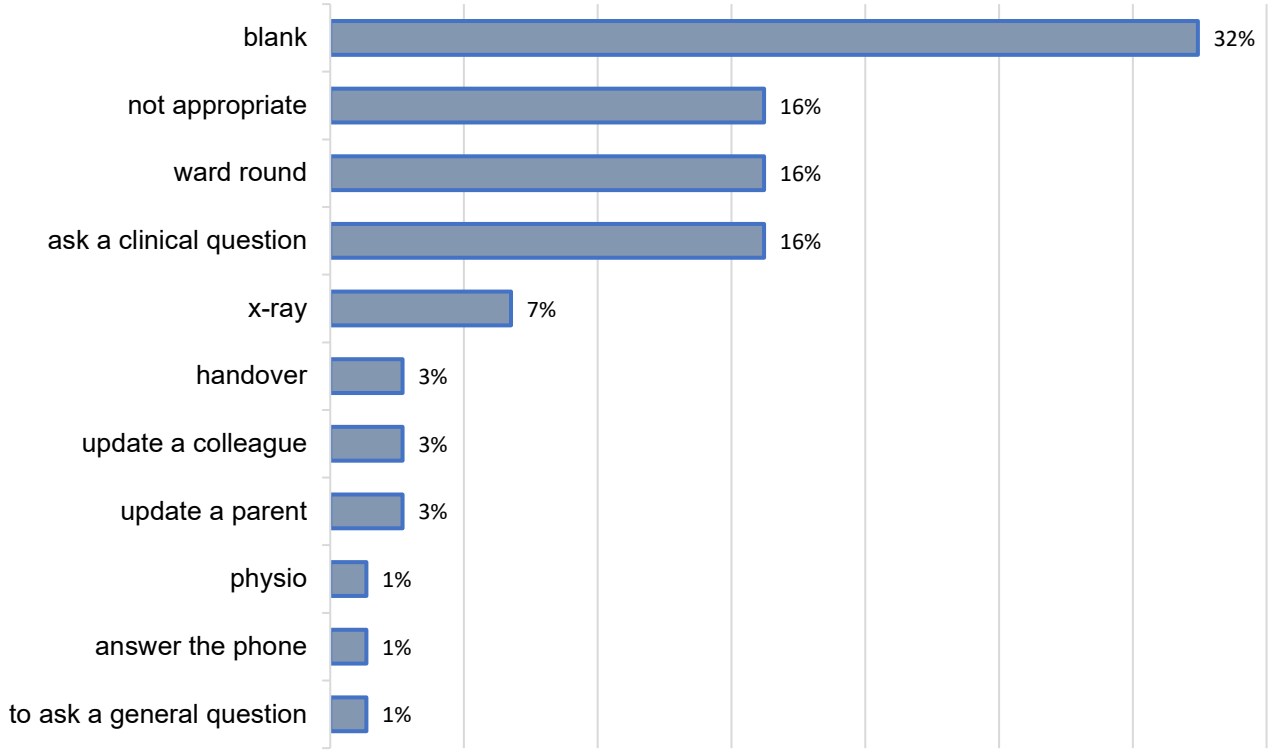

Figure 2.1 Situations where it appropriate to interrupt the medication process, as identified by participants

The locally developed phrase was identified as appropriate to use to block interruptions by 81% (n=44/54) of the participants. The main reasons for not agreeing were that it was "*too long*", "*you should not be interrupting in the first place*" and that the "*phrase should be unique to the individual and the situation*". Participants used the final comment box to suggest that interruptions are never appropriate or only in emergency situations. Participants reported *"the evidence is clear – unless it is life threatening emergency there should be no interruptions"* and *"we should aim for zero tolerance to medication interruptions in routine*

circumstances". Participants also identified red aprons and information around the unit as useful interventions. Assertive behaviour to block interruptions was described as useful to overcome challenges posed by interruptions. There was a sense of frustration from staff about constant interruptions. One participant recalled they had been "*asked for the drug chart/drug chart taken mid drug check!"* and another stated *"there is just no respect re somebody trying to do something".*

Discussion

Participants were clear that interruptions were a priority problem on PICU. However, the lack of consensus around the classification of appropriate interruptions is worrying. High rates of interruptions have been cited in many studies, however, there is little research exploring nurses' understanding and awareness of interruptions. Sasangohar et al. (2015) identifies that some interruptions are needed and appropriate (such as the communication of important information about a task/patient), but there has been a lack of research looking at defining appropriate and inappropriate interruptions. The participants lack of understanding and consensus, could reflect both the culture and lack of research in this area. Future interventions to reduce medication interruptions, should provide participants clear definitions to optimise effectiveness.

In the survey, some participants described frustration around interruptions, which is supported in other research. Sørensen and Brahe (2014) identified all interruptions are a source of frustration for staff, whether they were avoidable or unavoidable. This could reflect the *'zero tolerance'* to interruptions desired by staff. Many studies have demonstrated the negative emotional impact on staff that interruptions cause. Feelings of ineffectiveness, pressure, constant re-prioritising, reduced job satisfaction and stress-related symptoms have been cited in research studies (Tucker and Spear, 2006). Previous research to reduce interruptions has shown little success specifically in reducing emotional consequences for staff. It is essential that interventions focus on how staff can manage interruptions.

Chapter 1 identified that interventions have failed due to a lack of nurse buy-in. The majority of participants agreed with the phrase to block interruptions, indicating this intervention may overcome this barrier. Future educational materials should include the use of this phrase to optimise effectiveness, reinforcing that the phrase had been agreed by consensus opinion by staff working within the setting.

Limitations

This survey had a low response rate of 13% and only included a small sample of participants, of which the majority were nurses and all from the same unit. Therefore, the results may not reflect the wider population of the hospital, or other hospitals and other PICU settings. However, most participants were nurses, who are the target group for educational interventions.

Conclusion

The survey results highlighted that both PICU staff and PPIE respondents believed that medication interruptions are a problem and to prioritise this type of research. The lack of agreement about when it is appropriate to interrupt nurses reflects the rate of interruptions seen clinically. A locally developed phrase was viewed as acceptable by the majority of participants. The sense of frustration from staff also emphasises the need to involve staff in future research to help reduce medication interruptions and ensure they feel heard and that we are prioritising the problem. Further work is required to standardise and embed best practice.

Chapter 3 STUDY DESIGN AND INTERVENTION

This chapter describes the design of the randomised controlled intervention study. It describes how the design was informed by the scoping review and the survey discussed in Chapters 1 and 2 respectively, and why an unblinded feasibility randomised controlled trial has been selected. Furthermore, it also describes why a mixed-methods approach will be used to investigate the impact of the intervention. Finally, it summarises the results of the recruitment to the trial and engagement with the intervention.

Aims and Objectives

The aim of this study is to determine if an educational intervention can change how nurses manage interruptions in a PICU setting, with a focus on the number of interruptions handled appropriately by nurses. The objectives of the study are to:

1. Identify protective behaviours that nurses engage with to manage interruptions
2. Quantify the frequency and length of interruptions during medication administration rounds
3. Understand participants' experience of an educational intervention

A secondary aim of this study is to determine whether the educational intervention implemented is accepted and therefore feasible to be rolled out to multiple sites with a larger participant sample.

Setting

The study was conducted in a busy 31-bed United Kingdom (UK) Paediatric Intensive Care Unit (PICU). The PICU provides care for 35 specialties including respiratory, cardiac, liver, general surgery, ENT, spinal, orthopaedics, metabolic, endocrine, neurology and neurosurgery. It is the lead centre for paediatric care and major trauma in England and is one of the largest in Europe. Nurses on PICU are automatically enrolled on a Foundation

course, which is standard mandatory teaching delivered by the local PICU for new nurses and lasts the first 18 months of their employment. The training includes teaching about the conditions and diseases they may see on the PICU, different processes and paperwork on PICU, general care of patients and the medication process including checking medication charts and drawing up intravenous medication.

Intervention

The educational intervention for this study has been informed by and developed with organisational behaviour change theories in mind. Lewin's theory of change identifies steps necessary before action is taken to facilitate the process of change (Lewin, 1997). Initially the problem should be analysed and understood (Burnes, 2004). The local audit conducted in 2017 (Longman, 2017) provided information improving understanding of the problem by identifying the cause, frequency and consequences of interruptions. The second phase identifies an understanding of a need for change to be adopted by the organisation. The survey results (Chapter 2) showed that healthcare professionals believed medication interruption research is needed and is considered a priority. There were also feelings of frustration about the current situation implying that healthcare professionals are ready for a change. Batras et al. (2016) states that the ultimate aim for an organisation is to move from Model 1 to Model 2 theories by using double-loop learning. Model 1 is often described as a competitive and defensive stance, in which people want to maximise wining and minimise losing (Dick and Dalmau, 2000). It can often produce poor relationships and learning. However, Model 2 is more collaborative valuing valid information and free and informed choice (Dick and Dalmau, 200). This often allows more effective relationships and learning. Double-loop learning is gained by giving the learners freedom and allowing them to make an informed choice (Rogers, 2010). The style of intervention to be implemented needs to give

learners, in this case nurses, the understanding of the problem and strategies that they can implement but also the freedom to choose how and when to implement.

The education intervention has also been informed and developed based on research conducted by Johnson et al in Australia (Johnson et al., 2019, Johnson et al., 2018). Johnson et al (2018 & 2019) created an online learning module to deliver to nurses on wards in metropolitan hospitals in Australia. Their work identified four main strategies used by nurses during medication interruptions: blocking, medicating, multi-tasking and engaging. Blocking is where the individual would ignore the interruption to focus on the medication episode. Mediating is when actions to aid memory recall are taken before dealing with the interruption. Engaging is favouring the interruption by stopping the medication process immediately to deal with the interruption. Finally, multitasking is simultaneously trying to complete the medication episode and the interruption. The education programme delivered factual information to nurses on medication interruptions and errors, a series of videotapes depicting negative and positive responses to medication interruptions and interviews with senior management teams to reinforce positive behaviour.

The scoping review showed that many studies adopted multifaceted interventions to change behaviour, rather than a single component. There were also a lack of studies focusing on a single education intervention, with the majority employed alongside other interventions such as red aprons worn by nurses. This made it difficult to determine the impact of education on behaviour change. During an evaluation of systematic reviews of multifaceted interventions to change healthcare professionals behaviour, Squires et al (2014) found that there was no evidence that multifaceted interventions are more effected than those who employ a single intervention. In view of this, it was decided to employ only one education intervention to truly understand the effect.

Table 3.1 describes the education intervention, which has three phrases: a teaching session, simulation and eLearning. Since nurses on PICU already complete a structured education programme (the Foundation course), the educational intervention was in addition to this

standard learning. Those in the control group received the standardised training from the Foundation course, and those in the intervention group received both the foundation course and the intervention (Figure 3.1). The Foundation course does not include learning about consequences of errors and medication interruptions.

Table 3.1. Education Intervention Structure

Phase	Intervention	Description
1	Teaching session	Day 1 Focused on understanding the epidemiology and consequences of medication errors and interruptions. • Lecture • Interview with a nurse The education session will be online to adhere to COVID-19 protocols
2	Simulation	Day 1 To allow participants to practice the protective behaviours identified in the education session
3	eLearning	Day 14-28 To consolidate learning, implemented two weeks after phase 1 and 2, and to be completed in a 14-day window

The educational intervention focuses on understanding local, national and international epidemiology of medication errors and their consequences. The theory of planned behaviour explains that intention and personal motivation are the most important variables in behaviour change (Grizzell, 2007). To facilitate change, positive information about the change is required, for example, why the change is needed, why the current behaviour is wrong and why the change is positive. Providing nurses with information on the severity of the current situation and why this positive change is needed, will help facilitate change according to the planned behaviour theory. The education session included an interview with a nurse from the unit who made a medication error. The interview talked about factors perceived by the nurse to contribute to the medication error, such as the interruptions that stopped thorough checks from being completed that may have identified the mistake. The interview also included their personal experience of telling the parents about this error and the stress and psychological trauma suffered after the error was made.

Moyen et al. (2008) states that critically ill patients are likely to have twice as many medications prescribed as those on other wards. The large volume of medications to be administered increases the chance of medication errors (Rashed et al., 2012) potentially because the nurse becomes desensitised to the serious risks of medication errors. Two key elements Witte (1996) identified to facilitate behaviour change are 'threat' and 'fear'. Participants must be aware of the threat and consequences of the negative behaviour that the researchers are seeking to change (Witte, 1996). They need to fear the consequences to make this change and they are more likely to fear these if it is personally relevant and seen as a significant threat (Witte, 1996). The rationale for including the nurse interview was to overcome the effect of nurses being desensitised to medication errors. The intention was to increase their sense of threat and fear by increasing their understanding of potential consequences and making the possibility of a medication error a reality. The session then focused on teaching the four strategies identified in Johnson et al's (2018 and 2019) work. The positive and negative effects of the strategies was described and explained. Examples seen in the local unit was used and open discussion between the researcher and participants was encouraged.

A simulation session was utilised to give the participants a safe learning environment where they can practice behaviours, make mistakes, and learn (Kalanati and Douglas, 2015). The simulation session utilised local role players with experience in healthcare simulation scenarios. Local simulation experts were sought and consulted to help create scenarios and ensure appropriate facilitation and debriefing of the session. The simulation scenarios allowed the participants to practise using the protective behaviours identified in the education session. Scenarios where participants may be less likely to use the appropriate protective behaviours were used (Appendix 2). These included examples such as a cross or frustrated parent/consultant interrupting a medication episode. The simulation gave the participants a chance to practice employing the behaviours and allowed them to discuss the strategies with the role players, with the aim of giving participants more confidence to use

them in clinical practice. A phrase was given as an example of using the blocking strategy (Chapter 2). The simulation session allowed learners to practice this phrase and adapt it to suit each individual, allowing them to feel more comfortable and confident.

eLearning was utilised in the last phase of the education intervention. eLearning has become increasingly popular in universities and NHS settings (Ruiz et al., 2006) due to low cost and ease of delivering effective learning to multiple students (Ruiz et al., 2006). Research shows that eLearning allows learners to learn more effectively and with better retention (Gibbons and Fairweather, 1998). The online module was used to consolidate learning from the education session and was made available two weeks after the education and simulation session. An existing national eLearning programme (SCRIPT, https://www.safeprescriber.org/) was used as the platform, as this is easily accessible by those working in the NHS, has an existing portfolio specifically for nurses, and focuses on medication safety. The modules were designed with a pre- and post-test, used to assess the participants baseline knowledge, and knowledge acquisition on completion of the learning. The online module then followed a similar structure to the education session, discussing the epidemiology and consequences of medication errors and interruptions and the strategies that can be used to manage them.

Randomised Unblinded Trial

Randomised controlled trials (RCTs) have been viewed as the 'gold standard' of research study designs for many years (Murad et al, 2016). RCTs reduce bias by evenly distributing participants between an intervention/treatment and control group. Soloman and Nezami (2023) stated that RCTs are often the most accurate design for understanding the true effect of an intervention. Due to the superiority of RCTs and the lack of these types of trials in this area of research highlighted by the scoping review, a randomised controlled trial design has been selected. There is a school of thought that RCTs cannot be carried out in educational research, however a systematic review of RCTs in educational research by Connolly, Keenan and Urbanska (2017) found that not only are RCTs

possible in this type of research they also contribute to new knowledge. Kendall (2003) stated that a double blind study design is seen as the ideal trial design as it reduces the impact of confounding factors, however, it is often difficult to achieve. The aim of the study will be made clear to all participants and will therefore be unblinded. Disclosure of the intervention is necessary to facilitate the teaching and learning. Participants will be randomised to either the control or the intervention group (see Figure 3.1).

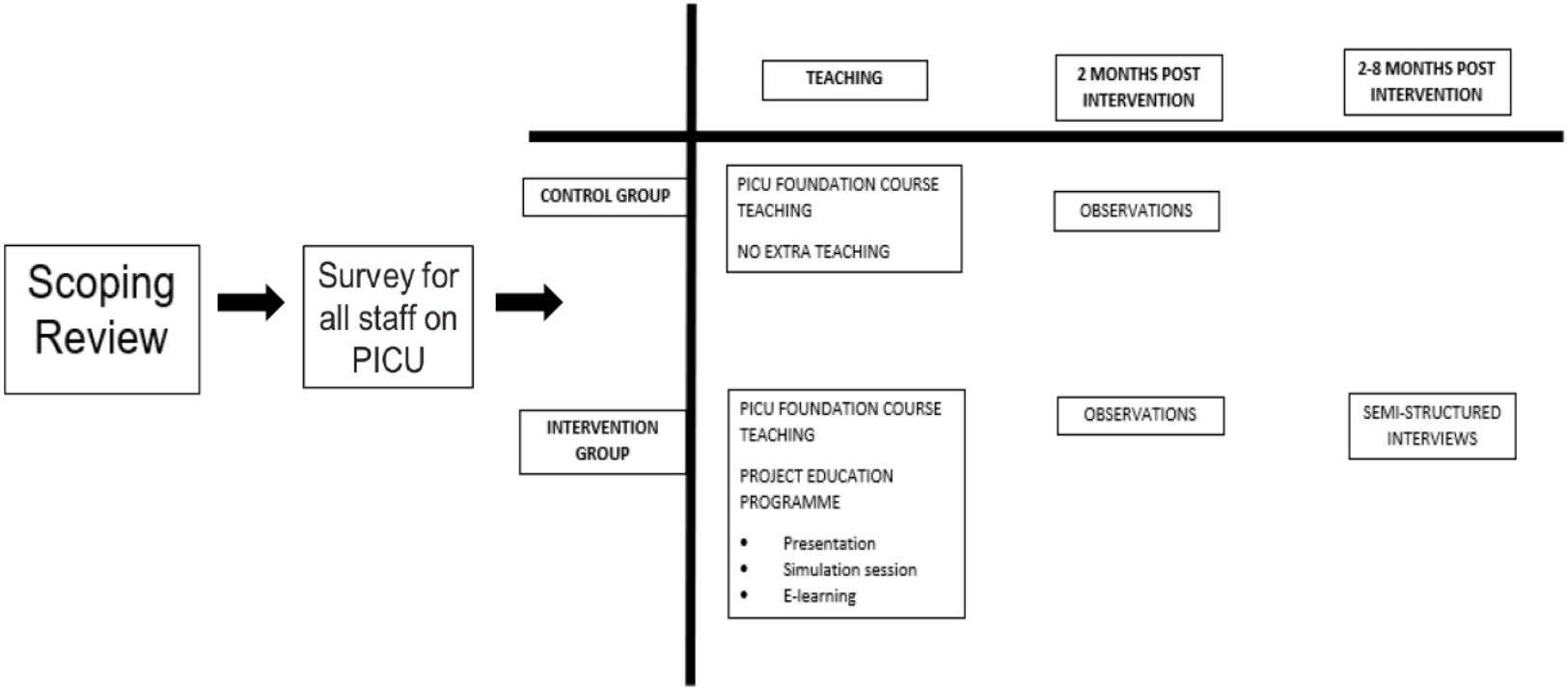

Figure 3.1. Study structure for both intervention and control group

Participant Recruitment

The educational intervention was implemented to a cohort of new nurses attached to a single PICU with the objective of reducing medication errors caused by interruptions. The aim was to provide standardised education at the beginning of a nurses' professional career before they are immersed in a culture where medication interruptions may become the norm.

Eligibility to participate in the study was defined as follows:

- NHS Band 5 nurses who are new to the local PICU and enrolled on the Foundation course.

Some Nurses had prior experience on wards or international PICUs, so participants were not eligible to participate if:

- They had prior experience of working in a UK PICU setting or are employed on the identified PICU prior to the study.
- Were a clinical support worker or nursing training associate due to their different roles and responsibilities with medication.
- Were NHS Band 6 or higher-grade nurses as this feasibility trial will focus on those new to the culture.

Ethics and Consent

The researcher (SO) who works in PICU, worked with the PICU education team to identify eligible participants. SO approached nurses during their Foundation course, to provide a background to the study with a participant information leaflet (Appendix 3). The information leaflet was given to explain the observational aspect of the study. A separate information sheet was given to explain the qualitative workstream (Appendix 4). Separate consent forms for the quantitative and qualitative work streams were provided (Appendix 5 and 6). The two consent forms were signed at the beginning of the study before participants are randomised.

Verbal consent was reconfirmed before every aspect of the study including the education intervention, the observations and the interviews. Participants were able to withdraw at any point in the study however, the data collected at that point will be included in any analysis.

Approvals before the outlined protocol and associated documentation were gained from both the University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee, Governance and the NHS Health Research Authority. Please see the appendix (3-11) for the approved Patient Information Leaflet, Consent forms and Protocol [IRAS ID: 292511; OID: RG_20-166]

Investigating the Impact

A mixed-methods design was adopted to allow for a more in-depth understanding of what protective behaviours are used and why they are used by nurses. Tashakkori and Creswell (2007) stated that mixed-methods research is when both qualitative and quantitative methods are used to collect and analyse the findings in one single study. A mixed-methods design was chosen as quantitative or qualitative research alone may not provide an in-depth understanding of the effectiveness of an education intervention and nurses' level of acceptance (Creswell and Clark, 2017). An explanatory sequential mixed-method design was used, where the research is conducted in two stages (Passey, 2020).

1. Quantitative methods, through collecting observational research two-months post-intervention
2. Qualitative interviews, through individual participant semi-structured interviews

This methodological approach provides an opportunity for the qualitative data to explain the findings from the quantitative approach, and vice versa. In this study the semi-structured interviews were used to explain the protective behaviours observed (Creswell and Plano

Clark, 2011). The semi-structured interviews provided a greater understanding of participants experience of the education intervention and why they may utilise certain protective behaviours and not others, as seen in the observational data. An advantage of an exploratory sequential mixed-methods approach is the ease of implementing this type of design especially for a single researcher, however, this type of design can often take longer to implement (Creswell and Plano Clark, 2011). The weighting is often placed upon the quantitative results during this design and the data is connected between the two phases (Creswell and Plano Clark, 2011). In this study the quantitative results helped inform the questions and structure of the interviews.

The qualitative workstream included semi-structured interviews to explore the nurses' feelings and beliefs about the intervention. They investigated how useful the nurses felt the intervention had been in helping them identify and deal with medication interruptions. It is essential to understand the nurses' perceptions as studies have shown that interventions such as red aprons add burden and have not been utilised. These interviews took place 2-8 months post intervention. The qualitative workstream was essential to understand whether nurses 'buy into' the intervention. Nurses' lack of 'buy in' was identified as a major contributor to previous unsuccessful interventions (Chapter 1). As many of the previous studies did not seek to understand nurses' opinions and experiences, the aim of this study was to reduce this gap in knowledge.

Results

Participant recruitment and engagement

A total of 32 nurses were identified as eligible to participate in the study, of which 27 nurses consented to participate (n=27/32, 84%). One nurse declined participating in the study and

four were unavailable to approach. The cohort comprised of both male and female nurses with a range of experiences (see Table 3.2).

Table 3.2 Demographic data for participants

	Male	Female	Newly Qualified Nurse	Experienced Nurse	International Recruit
Number	3	24	20	2	5
Percentage (%)	11	89	74	7	19

The study took place between April 2021 and June 2022. The nurses recruited to the study started the Foundation course on PICU between August 2020 and January 2021. In total, 13 nurses were randomised to the control group, however only 11 received the educational intervention. Of the two that did not participate, one was on sick leave during the education intervention and the other was on shift on both dates when the session was delivered. Both nurses agreed to continue in the study and were transferred to the control group. Unfortunately, when this was discovered, there was not enough time to re distribute the groups evenly, so the end allocation was 11 nurses in the intervention group and 16 in the control group.

Simulation

The simulation session took place over Zoom as part of the education intervention. It lasted 2 hours with 2–3 scenarios and debriefs conducted. Scenarios were first completed with the whole group (1 nurse and 1 role player, whilst the others observed) and then the nurses split into break out rooms so more could complete them. Visual aids of the drug charts were displayed on the screen, and the nurses were asked to work through the drug calculations out loud before the interruption occurred. Two role players from the University of Birmingham Interactive Studies Unit were utilised. The role players have experience of working with healthcare students to facilitate simulation sessions to help with communication skills.

Scenarios were created from interruptions seen in a previous audit (Longman, 2017), they included parental, visiting consultants and nurse interruptions (Appendix 11). The other nurses would observe and then they would debrief and reflect in both their smaller groups and the main group. Both the researcher (SO) and the role players facilitated the debriefs.

eLearning

The eLearning module was informed by the scoping review. The epidemiology and consequences of medication interruptions are discussed, as well as behaviour management strategies nurses can use to manage them and their appropriateness (Appendix 12).

Pre-intervention implementation, participants were going to be granted protected time to complete the education intervention, however due to the exacerbated clinical demands from the COVID-19 pandemic, this was not available when the research was conducted.

All the participants in the intervention group completed the online learning (Appendix 12). Only 36% of the participants completed this eLearning on time and overall, they were completed between 1–3 months post intervention. The participants took on average 29 minutes to complete the online module (range from 20 seconds to 3 hours and 4 minutes). The participant who took 20 seconds scored 100% in both the pre- and post-test. The short time may be due to an error in the learning management system. Those who took longer tended to score lower on the pre-test, for example the participant who took over 3 hours scored 6/10 on their pre-test. The length of time may suggest the eLearning was open, but not being engaged with for the duration of the time. On average the participants scored 7.5 out of 10 on the pre-test, however this was increased to 9.3 out of 10 on the post test. Four of the participants scored 100% in the pre-test (see Table 3.3).

Table 3.3 Intervention participant results

Participant	Pre-Test	Post Test	Time Spent
01	5/10	9/10	00:11:26
02	10/10	10/10	00:17:08
03	5/10	9/10	00:25:25
04	4/10	8/10	00:04:22
05	10/10	10/10	00:00:20
06	6/10	10/10	00:29:04
07	6/10	8/10	03:04:52
08	9/10	9/10	00:13:49
09	10/10	10/10	00:11:38
10	10/10	9/10	00:17:29
11	8/10	10/10	00:13:04

Discussion

Although a small sample was decided upon for this feasibility study, the consent rate was high with 96% participants approached to participate gifting their consent. This could reflect participants desire to reduce medication interruptions as identified in Chapter 2. This desire to continue learning has been shown in other research (Govranos and Newton, 2014), however, time and clinical demands are often barriers, implying the lack of time afforded to this study's participants may prove problematic.

The forced change from face-to-face teaching to eLearning became the norm for many education providers during the pandemic. eLearning for healthcare professionals

dramatically increased during this period with many observed benefits (Rouleau et al., 2019). Difficulties in accessing traditional educational methods, such as geographical isolation and limited opportunities for face-to-face learning due to heavy clinical demands, have been seen by healthcare professionals for years (Bennett et al., 2014, Lenthall et al., 2011, Doorenbos et al., 2011). eLearning is often also seen as a low-cost option that allows easy access to multiple participants (Ruiz et al., 2006, Ehlers and Pawlowski, 2006). All participants completed the eLearning implying that this method of delivering the educational intervention is acceptable and achievable by participants The majority of participants passed the eLearning test on their first attempt, and all participants passed by the end of the eLearning session, showing that the participants knowledge of this area increased. Reviews into eLearning identified that improved knowledge does not always lead to a change in behaviour and more eLearning research needs to use behaviour change as a measure of effectiveness (Sinclair et al., 2016). The results from the quantitative and qualitative workstream will provide an in-depth understanding about the impact of this educational intervention and whether it has facilitated a change in behaviour.

Chapter 4 NURSE MANAGEMENT OF INTERRUPTIONS: AN OBSERVATIONAL STUDY

This chapter describes the rational for conducting an observation study and the aims of this research. It describes the method and discusses the results of the observational data through quantifying the protective behaviours and identifying any difference in behaviours between the control and intervention groups.

Aims and Objectives

The aim of this study was to identify and quantify the protective behaviours used by nurse participants when being interrupted to determine any difference between the control and intervention groups. The objectives were to:

1. Observe nurse participants and document protective behaviours utilised to manage interruptions
2. Time the length of interruptions that occur during medication administration rounds

Method

Data Collection

A data collection tool was developed to collect the number and length of interruptions observed and the types of behaviour nurses used to manage these interruptions (Appendix 14). This was adapted from a previous unpublished local study based in the same setting. Prior to data collection, the tool was piloted and refined by members of the PICU research team and student observers, to ensure information captured was comprehensive and would meet the research aim.

The main information gathered by the data collection tool is shown in Table 4.1. Interruptions were coded to facilitate the observation process (Table 4.2). The tool was also designed to

allow free-text comments to be added by the observer to facilitate accurate debriefing with other observers.

Table 4.1 Data collected and the categories used in the data collection tool

Variable	**Description**
Medication Name	Generic name of medicine
Medication Route	oral/NG/NJ/PR IV continuous infusion IV intermittent infusion IV Bolus Topical Injections
Time of Day	min:sec:mm
Length of Medication Episode	min:sec:mm
Type of Interruption	Code (Table x.)
Length of Interruption	min:sec:mm
Behaviour observed	Engaging Multitasking Mediating Blocking
HCP who administered the medication	Nurse Second checker Doctor Parent/guardian Other

Table 4.2 The types of interruptions and the codes used for the observations

Types of interruption	**Interruption code**
Patient care need	A
Own patient emergency	B
Silencing alarms	C
Neighbouring bed emergency	D
Telephone/Vocera* call *mobile communication device	E
Parental Communication	F
Nursing staff interruption	G
Consultant/registrar interruption	H
Senior PICU staff interruption	I
Pharmacy staff interruption	J
Other staff interruptions (e.g. physio, family liaison, student nurse)	K

Observers comprised of volunteer student nurses and pharmacists from the University of Birmingham and researcher SO. Observers were provided with an induction to PICU

including emergency processes and fire exits. They were trained to identify specific strategies from the education intervention prior to the observation period and were provided with guidance information sheets. To ensure inter-rater reliability was achieved, observers first started observing in pairs discussing the coding and data collection. Once they felt comfortable, observers then changed to independently observing the same nurse and comparing their results. Once they achieved over 85% inter-rate reliability they changed to completely independent observations.

Understanding the long-term effects of an education intervention was highlighted as a necessity for future research work (see Chapter 1). Originally observations were going to be conducted at two months and then six months to assess the longitudinal effect of the intervention, however, issues with observers coming into the hospital during the pandemic caused this to be abandoned. Observations were therefore conducted over a 15-day period in November 2021. Observation periods were designed to last a maximum of two hours to reduce the risk of observer fatigue and covered day and night shifts, weekdays and weekends. Participants agreed to be available for a minimum of three observations during the observation period.

Participants previously signed consent to be observed (Chapter 3), and verbal consent was also sought before each observation. Participants were reminded that they could refuse being observed and remain in the study. For example, if they felt their workload was too high or it was not an appropriate situation to observe. Observers were aware they could stop observations and leave at any point if situations arose on PICU that were upsetting or triggering. Verbal consent was sought from families on the ward prior to the observations. The nurse in charge of PICU was consulted each day to ensure it was appropriate for the observers to be in the allocated bedspaces and to avoid disruption to daily procedures. At the start of each day, observers identified the study participants on shift, gained consent and checked their shift plan for preparing and administering medications. Each observer started

observations at least 30 minutes before medication rounds commenced to ensure they were present to observe the process. Multiple observation periods were completed each day. After each day of observations, observers attended a debrief meeting to discuss their experience, the data they had collected, and the appropriateness of the strategies observed. This was used as an opportunity to discuss potentially upsetting events observers may have observed. Debriefing allows observers to make sense of what they have seen, to process it, and by reflecting on their observations and techniques, develop increased efficient observations (Gardner, 2013). A member of staff from both the clinical and research team were available to facilitate any questions or concerns observers had.

Data Analysis

Data was collected on the type of interruption, the discipline of the interrupter, the behaviour strategy adopted by the nurse and the observer's perception of the appropriateness of the strategy. Debrief sessions between the observers and researcher were used to discuss the documented appropriateness of the strategies implemented and consensus was agreed. The final appropriateness was documented. All data were transcribed into Excel for analysis. The periods of observations were categorised into morning (05:01-11:00), afternoon (11:01-17:00), evening (17:01-23:00) and night (23:01-05:00).

The complexity of the medicines administered were evaluated by identifying the number of steps required in the administration phase, ranging from 1–5. For example, medicines requiring a specific volume to be drawn out of the vial only had one step, would have a complexity level of 1. Alternatively, medicines such as intravenous (IV) antibiotics where a diluent needed to be added to reconstitute a powder, a volume drawn up and then diluted further was a 3-step process and given a complexity level of 3. Data were analysed using the Chi-squared test to determine any significant difference in appropriate strategies used by the intervention verse control group. The Chi-squared test was favoured over the Fisher exact

test as the sample size was deemed too large to conduct the Fisher exact test (Kim, 2017). A p-value of 0.05 was used to determine significance.

Results

Observations took place over a 3-week period in November 2021 with a total of 63 observations with an even split between the control and observation groups (51% control and 49% intervention group). The observations were mainly conducted during the nurses' clinical day shifts, with one observation period occurred during a night shift. Nearly three quarters of the participants were observed (n=20/27, 74%). Those who were not observed were due to reasons such as annual leave, being moved to different wards, long-term sick, no medicines during their shift or continuous night shifts. No participants refused observations or withdrew from the study. Both groups had similar demographic data and were observed for similar numbers of observations. Both groups were observed on the acute, cardiac and long-term stay side of the PICU (Table 4.3).

Table 4.3. The number of observations observed in each area of the unit

	Acute Side	Cardiac Side	Long-Term Side	Total
Control	6	18	8	32
Intervention	4	9	18	31

Medicines Administration

A total of 100 medications were administered during the 63 observations, ranging in the route and formulation including nebulisers, topical, enteral, and parenteral injections, including intermittent and continuous intravenous (IV) infusions and boluses. The average number of medicines per episode for both the intervention and control group was 1 (n=40/63, 63%, range = 1-8). Medications per episode ranged from 1–8 in the intervention group and 1–4 in the control group. The most frequent type of medicine observed was enteral (54%), particularly oral omeprazole (n=5/100, 5%). The average medicine complexity level was 1,

however as the episodes often contained more than one medicine, the average complexity level of the episodes for both groups was 3 (range of 1-10). The average length of time for medication episodes were 13 minutes (range of 2-35mins).

Interruptions

During the 63 episodes, 171 interruptions were observed with an average of three interruptions per episode. At least one interruption occurred in 89% of the episodes (n= 58/65). The average length of an interruption was 40 seconds for the intervention group and 41 seconds for the control group. The longest interruption was observed for 15 minutes and 39 seconds. More interruptions were observed for the intervention group 66% (n=113/171) versus 34% (n=58/171). A total of 10 different types of interruptions were observed (Table 4.4.). Communication interruptions were significantly more frequent, accounting for 85% (n=145) of all interruptions. The most common interruption was caused by nursing staff, which accounted for 51% (n=88/171) of all interruptions. Nursing interruptions were observed at similar rates in both the intervention and control group (intervention = 54%, control = 47%). Silencing alarms was the next most frequent for the control group (16%, n=9/58) and other staff interruptions for the intervention group (17%, n=19/113). Pharmacy interruptions were not seen in either group.

Table 4.4 The types of interruptions observed for both the intervention and control group

	Intervention	Control	Total
Patient care needs	2	3	5
Own Patient Emergency	1	1	2
Silencing Alarms	8	9	17
Neighbouring Bed Emergency	0	2	2
Telephone/Vocera Call	3	0	3
Parental Communication	8	7	15
Nursing Staff Communication	31	27	88
Consultant/Registrar Interruption	10	4	14
Senior PICU Staff Interruption	1	1	2
Other Staff Interruption	19	4	23

Figure 4.1 shows the complexity level of the medicines administered and the number of interruptions. There was no correlation observed between the number of interruptions and the complexity.

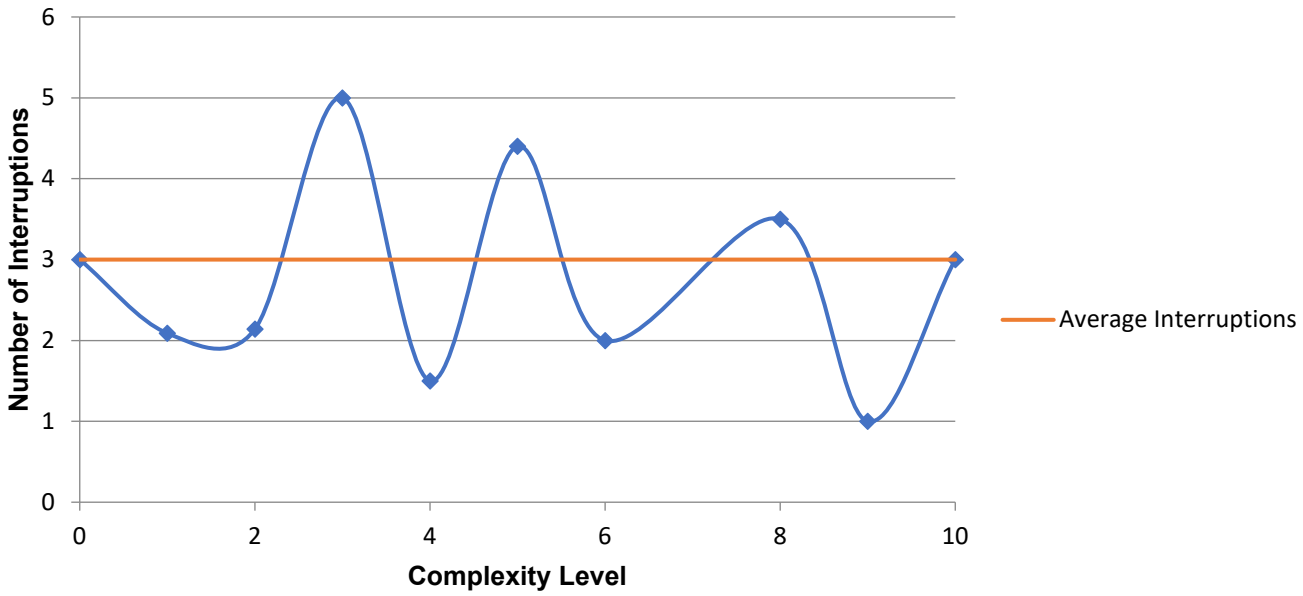

Figure 4.1. The number of interruptions compared to the complexity level of the medicines administration episode

Strategies to manage interruptions

The participants were observed for their use of one of four strategies: engaging, multi-tasking, mediating and blocking. Multi-tasking was the strategy observed most frequently, identified in 35% (n=60/171) of interruptions. Blocking, was used the least, observed in only 11% of interruptions (n=19/171). Blocking and mediating strategies were the strategies that were used most appropriately (Table 4.5).

Table 4.5. The number of appropriate and inappropriate behaviour strategies observed

	Engaging	Multitasking	Mediating	Blocking
Appropriate	2	60	41	19
Inappropriate	49	0	0	0
Total	51	60	41	19

Multitasking was the main strategy used for parental communication, patient emergencies and nursing staff communication (Figure 4.2).

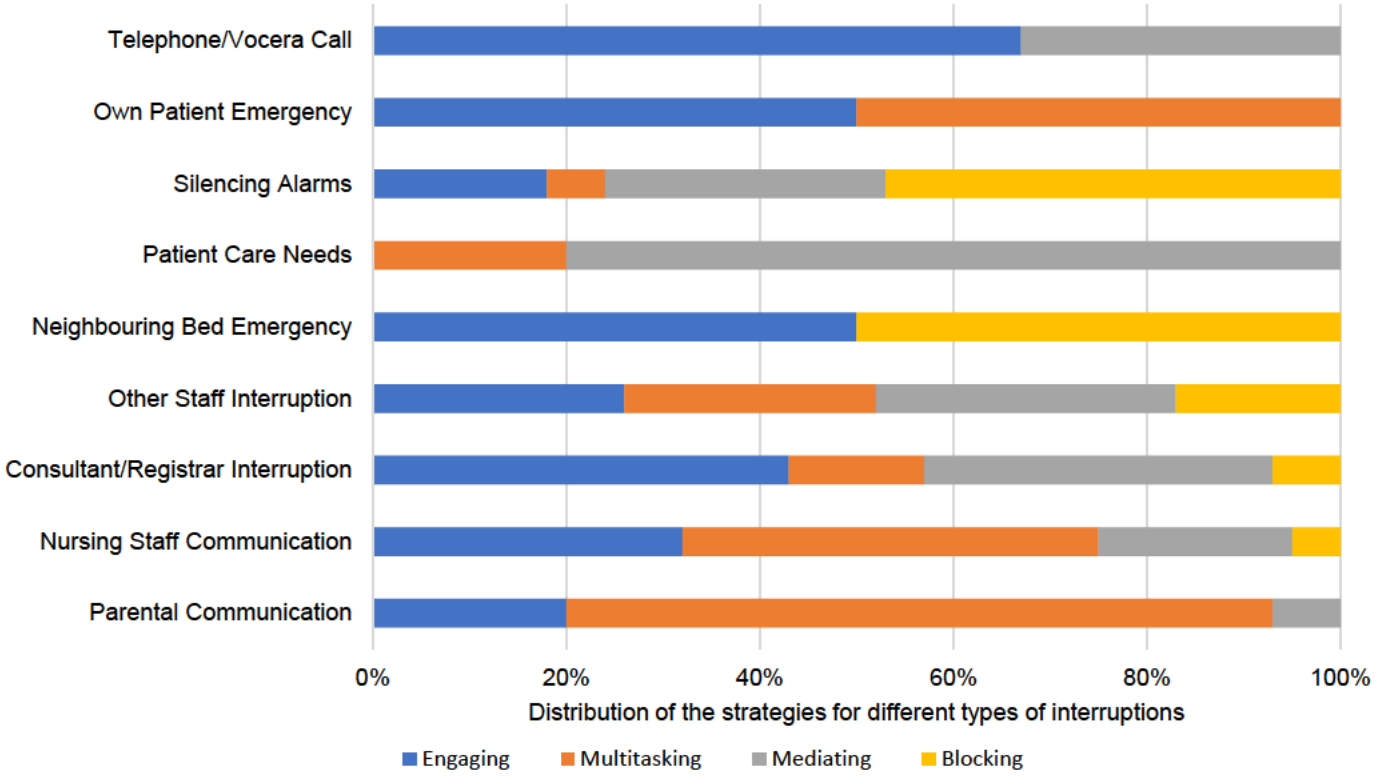

Figure 4.2. The protective behaviour adopted for the different types of interruptions observed

Nurses were observed to use appropriate strategies when the distraction was clinical, such as silencing alarms, however the level of appropriateness was reduced when the interruption was communication (Figure 4.3). The number of medicines per episode and therefore the nurses' workload, did not impact on the use of multitasking. However, during the episode with the highest number of medicines (n=8), multi-tasking was the strategy chosen. This was also reflected with the complexity level. Multitasking was still frequently used when the complexity level of the medicines was increased. In 75% (n=3/4) of the episodes where the complexity level was above 8, multitasking was observed. The average level of complexity observed when blocking was utilised was three.

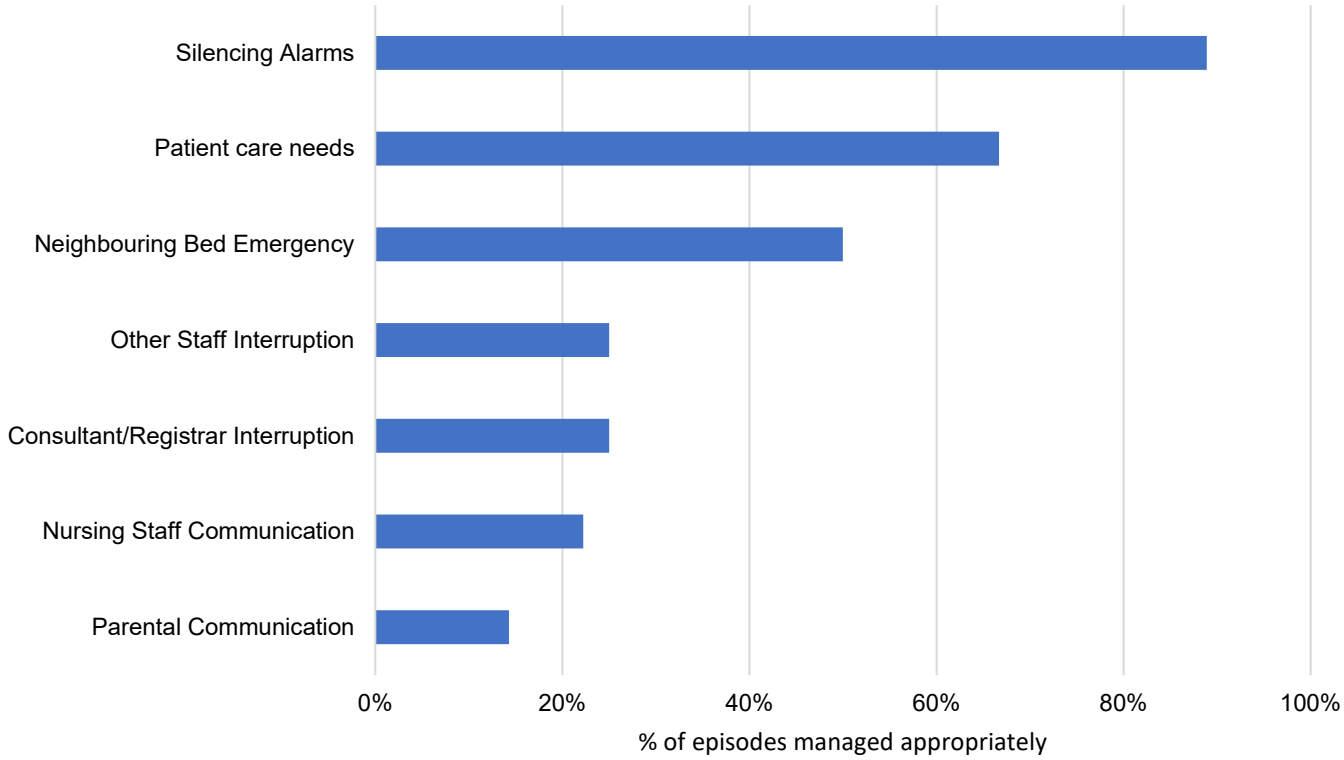

Figure 4.3. How appropriately each type of interruption was managed by nurses

Intervention VS Control

Multitasking was preferred strategy of the control group (41%, n=24/58). The intervention group were more likely to use the engaging strategy (35%, n=39/113) (Table 4.4). Both

groups were observed to use blocking the least. The analysis resulted in a Chi-Square statistic (x^2) of 0.05, with 1 degree of freedom. Therefore, there was no significant difference between the intervention and control groups in any of the strategies ($p>0.05$). Both groups dealt with patient emergencies appropriately 100% of the time. Communication interruptions were most likely to be dealt with inappropriately. Interruptions from senior PICU staff were not observed to be dealt with appropriately in either group. The intervention group did not deal with parental communications appropriately in any episode, whereas the control group dealt with this type of interruption appropriately 14% of the time (n=1/7). Consultant/registrar and other staff interruptions were handled appropriately by the intervention group 48% of the time (n=14/29), compared to the 25% (n=2/8) of episodes observed in the control group. There was no significant difference between the appropriate use of the different strategies ($x^2(3) = 1.51, p = .68$). Both groups used blocking and mediating appropriately 100% of the time and multitasking inappropriately 100% of the time. The intervention group only used the engaging strategy appropriately 2% of the time (n=1/39), and the control group never used it appropriately.

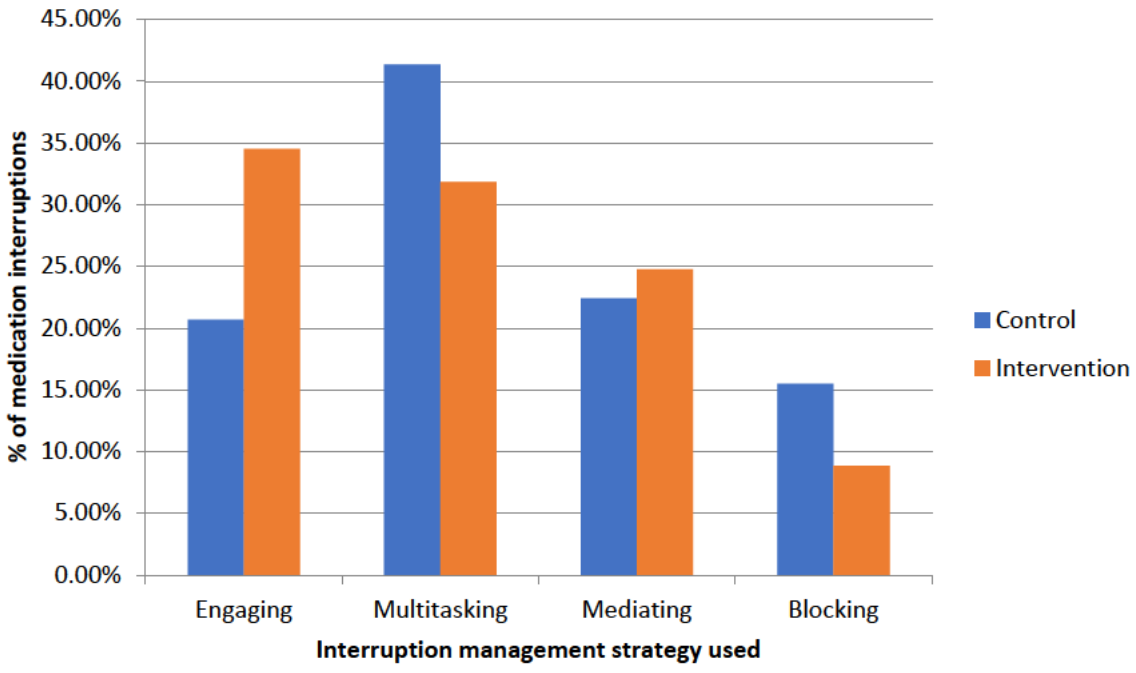

Figure 4.4. Comparing the use of each medication interruption strategy between the intervention and control group

Discussion

The aim of this study was to identify and quantify the protective behaviours used by nurse participants when interrupted to identify any difference between control and intervention groups. No significant difference was observed between the groups in the strategies adopted by participants. Both groups were found to adopt similar use of appropriate and inappropriate behaviour management strategies when interrupted.

One objective of this study was to quantify the number of interruptions facing nurses on PICU. The findings from the observation data emphasise the significance of interruptions on PICU. During the observations, 89% of episodes were interrupted at least once, consistent with results seen in the medication audit in the same PICU in 2017 (with an interruption rate of 81%) (Longman, 2017). High interruption rates have been found in several studies (Kliger et al., 2009, Relihan et al., 2010, Anthony et al., 2010). The interruption rate reported in this study and the previous audit is much higher than the 25–55% reported in other studies (Kalisch and Aebersold, 2010, Palese et al., 2009, Westbrook et al., 2010). The scoping review identified that interruptions could cause errors (Chapter 1). The high rates of interruptions observed suggest there is potential risk of errors, however, this has not been investigated in this study. The high rates of interruptions reinforces the need for an effective local intervention to reduce these occurring and minimise risk of harm. Hayes et al. (2015) stated that due to the inevitability of interruptions, it is essential for patient safety, to ensure nurses learn how to manage these interruptions appropriately.

In this study, nursing staff communications accounted for over half of the interruptions observed. This ranged from questions about breaks, social conversations and clinical communication, reflecting results found in other studies (Kalisch and Aebersold, 2010, Hall et al., 2010, Anthony et al., 2010, Tomietto et al., 2012, Dante et al., 2016). The high volume of

interruptions initiated by nursing staff emphasises the need to initially focus education on nurses rather than other healthcare professionals or visitors. This position is also supported by Colligan and Bass (2012), who stated that education and cultural change should be centred around nurses due to their frequent involvement in interruptions.

The blocking strategy was the strategy least likely to be used by nurses during the observation period. This has been identified in other research, for example Bower et al. (2018) found nurses reported being worried about blocking interruptions believing it would have a detrimental effect on their working relationships. Chan (2013) agreed as they found that silence can be misconstrued as being rude. It is essential that we understand why nurses are reluctant to block as this has been identified as one of the safest interruption management strategies.

During the observational research multitasking was the main strategy observed. Multitasking is a strategy that is considered inappropriate in all situations and therefore it is concerning that this is the main strategy used by both groups. Multiple studies have found that nurses are often required to multitask when fulfilling their clinical responsibilities (Kalisch and Aebersold, 2010, Yen et al., 2018). Westbrook et al. (2011) found similar use of multitasking strategies during the medication process. They observed 57 nurses for over 190 hours and found that during 25% of the medication processes, nurses engaged in multitasking. Although, multitasking was not always initiated by interruptions, the rate is high. Studies have commented on the relationship between multitasking and medication errors (Kalisch and Aebersold, 2010, Hayes et al., 2015). A high rate of multi-tasking could therefore increase error prone situations.

This study aimed to measure participants behavioural strategies rather than the number of interruptions. The scoping review (Chapter 1) concluded that the ‘number of interruptions’ as an outcome measure may not be useful, especially when the focus of an intervention is on

managing the interruption and not necessarily reducing them. In this study no statistical difference was found between the control and intervention group for the strategies adopted by nurses to manage interruptions. Similar results were observed when implementing a similar intervention in Australia (Johnson et al., 2019). It maybe that the nurses found it difficult to implement the strategies when only a few had received the training and therefore implementing the strategies may have involved challenging their colleagues' beliefs and values. To be able to understand whether these results truly reflect the effectiveness of the intervention, interviews will be conducted to appreciate participants experience of both the education and implementation of the strategies on PICU.

Limitations

A small sample was used in this feasibility study. A larger sample would be needed to confidently identify if there is a difference between the groups and produce generalisable results. These results may not reflect the effectiveness of an intervention if delivered to the whole unit.

There were limitations to conducting the observations. Some participants were not available for observations during the allocated period or would be allocated in roles with no medication responsibilities, such as the resource role. The resource role means that the nurse does not have their own allocated patient and therefore had no specific medication responsibilities, and the students were unable to observe them. However, 75% of the participants were still represented and an even number of observations were seen between the groups.

Due to the pandemic the students were not permitted to be on the unit at the time of the second observation period. Time limitation of the study made delaying the observation period not possible as the qualitative phase of the study needed to commence.

Nursing communication was identified as the main cause of interruptions for participants, however, this study did not investigate how many of these interruptions were self-initiated, as in previous work of Anthony et al. (2010). Information about how many interruptions were self-initiated may be needed to help nurses understand and appreciate when they are interrupting and therefore potentially increasing the risk of error.

Medication errors were not investigated in this study as only a small sample size was used and therefore understanding if the medication error rate was affected on the unit would be difficult to ascertain. This should be investigated if the study is to be rolled out to more sites and participants.

Conclusion

The observational research aimed to determine what interruptions were occurring and how they were dealt with by nurses on PICU. The findings from this data show that nurses did not manage interruptions appropriately on the majority of occasions. The main strategy used by both groups was multitasking, which was never used appropriately. Additionally, it was observed that nurses used the blocking strategy the least, with no difference between the intervention and control group. It is essential that we understand any barriers to nurses utilising the education that was delivered in the intervention and in particular the use of the blocking strategy. Acquiring and exploring participants perceptions and experiences is essential for an in-depth understanding to further explain the findings observed.

Chapter 5 NURSE PERCEPTIONS OF THE INTERVENTION STUDY: A SEMI-STRUCTURED INTERVIEW STUDY

This chapter describes the methodological approach taken to conduct the semi-structured interviews with study participants. It explains how the findings from the observational study (Chapter 4) informed the design of the interview questions. Finally, it discusses the themes that emerged from the data following an inductive and deductive analysis.

Aims and Objectives

The aim of this study was to determine PICU nurse participants perceptions of their experience of the education provided in the study, and their strategies to manage interruptions prior to and after the educational intervention. The objectives were to:

1. Conduct interviews to understand participants perceptions of the educational intervention
2. Use thematic analysis to understand the facilitators and barriers to using the proposed strategies to manage interruptions.

Methods

A qualitative methodology was adopted to enable exploration of the quantitative observational findings (Chapter 4) and to better understand the behaviours observed. As this was a feasibility study, it was essential to identify areas of the intervention that were perceived to be useful or not. Qualitative methods allow better understanding of the participant's experience of the intervention.

Focus groups were originally planned to answer the qualitative research aim. This approach was selected because it can promote group discussion and facilitate generation of new ideas through sharing in a group setting (Rook et al., 2007). Due to participants time constraints

and the system pressures following the pandemic, it was not possible to organise focus groups and therefore individual semi structured interviews were conducted. Semi-structured interviews allow for flexibility and in-depth conversations between the interviewer and participant (Kakilla, 2021). They have been found to be effective at stimulating new ideas due to their generative nature (Kakilla, 2021). An interview guide was developed to capture nurse opinions and beliefs about the educational intervention and its effectiveness (see Appendix 13). The interview guide was informed by the quantitative findings of the protective behaviours observed and discussed in Chapter 4. The scoping review (Chapter 1) showed that some interventions to reduce medication interruptions can place more burden on nurses, therefore the interviews were designed to understand the level of 'nurses buy in'. The interviews were designed to allow flexibility in the structure and used open-ended questions allowing the interviewer to adapt the questions in response to each participant's answers and experiences.

All the participants who were randomised to the intervention group were invited to take part in an interview. Invites were sent via email with a copy of the Participant Information Leaflet (Appendix 4) and Consent form (Appendix 6). If no response was received via email, participants were contacted by the research team whilst on their shift. All participants were reminded of their voluntary participation and right to withdraw. As participants had already signed the interview consent form at the beginning of the study, verbal reconfirmation of consent was gained at the start of each interview.

The interviews were conducted online on Zoom due to the COVID pandemic. This increased ease of access and facilitated distancing and allowed flexibility when organising the interviews. The interviews were all conducted at a time suitable for participants (e.g., during their days off). Originally participants were allocated work time to participate, unfortunately this was subsequently not possible due to COVID-19 pressures on the unit. The semi-

structured interviews took place between 2-8 months after the observations. The interviews were all conducted by the researcher and were audio-recorded and transcribed verbatim.

Data Analysis

Thematic analysis is a popular form of qualitative analysis, where themes, meanings and concepts are derived from the data (Clarke and Braun, 2021). The interview guide contained targeted questions from the quantitative data and scoping review results. Although questionnaires were asked in regard to a framework, the results were not organised in this manner. Due to the complexity of the process being researched and the effectiveness of the approach being reliant on the experience of the researcher, an inductive thematic analysis was utilised instead of the original idea of framework analysis. Themes were allowed to emerge during the process of analysis. Clarke and Braun (2021) phases of thematic analysis were followed. Initially the transcripts were read in full to allow familiarity with the data, and then codes were created to describe the data, which were then organised into themes in Excel. These themes were reviewed and refined. to ensure descriptors were accurate to the context of the data.

Results

Of the 11 participants randomised to the intervention group, eight interviews were conducted. Of the three that did not participate, one participant had left their job, one was on long-term sick, and one did not respond to the interview invitation. The transcripts were first coded and then organised into themes (Table 5.1). Six themes emerged from the data; 1) Situational awareness, 2) Empowerment, 3) Simulation sessions, 4) Team cohesion, 5) Embedded in the culture and 6) Shared learning.

Table 5.1 Codes and themes from the transcripts

Situational Awareness	Empowerment	Simulation
Awareness	Increased/Change in Confidence	Beneficial
New Knowledge	Understanding	Realistic Scenarios
Change of Practice	Justified	Understanding
High Risk	Freedom	Relatable
Consequences	Encouraged	Translation to Clinical Practice
Reduced Mistakes	Authority	Fear/Apprehension
Recognition		Learning
Pro-active		

Team Cohesion	Embedded in the culture	Shared learning
Relationships	Implementing the Intervention	Educating Others
Desire to be Liked	Widespread Training	Explaining their Actions
Rude	Standard Training	Learning from Others
Fear	Easy Implementation	Reassurance
Teamwork	Same Goals	New Ideas
Breakdown in Relationships	Dissemination of Teaching	Championing the Training
Blocking	Parental Training	Shared Experiences
Anger		

During the interviews, all participants stated that they believed medication interruptions were a problem and many had experienced an interruption that they felt was high-risk at some point in their career. They felt the main cause of interruptions on PICU were doctors, surgeons, parents (or guardians), patients, X-rays (portable x-rays take place on the unit) and ward rounds. Only two of the participants mentioned nurses as a cause of interruptions. Many stated that the environment contributes to the incessant number of interruptions. Medicines prepared in the bedspace compared to a perceived controlled environment of a medication room, was felt to be significant contributing factor. The different specialities on PICU can mean that nurses are unfamiliar with the medicines prescribed. The unfamiliarity and the potentially dangerous side-effects were felt to increase the risk of the medication process on PICU.

All the nurses reported that they would recommend the education intervention for their colleagues, however, they found having to complete the training in their own time problematic. Originally, they were meant to be given time away from clinical duties to participate in the research, unfortunately due to the pandemic this was not an option.

Situational Awareness

During the interviews participants showed an increased awareness of medication interruptions risks. This resulted in increased knowledge and behaviour change post intervention according to the participants themselves. Participants acknowledged that they did not always use the most appropriate strategy for the situation, but the learning had changed their behaviour and they have implemented internal risk assessments of interruptions. One participant, discussed using the blocking strategy when interrupted, stated that the learning had;

> *"Definitely changed my practice to a certain extent . . . I definitely still get interrupted and engage, but I would say more so, especially when I am doing drugs that are a bit high-risk"* (Participant 07)

They stated that;

> *"with high-risk drugs I would say I've been a bit more like trying to not get interrupted . . . because I know how risky these drugs can be".* (Participant 07)

Interruption lag is the time that occurs between the interruption and the nurses' decision of how to deal with the interruption. Since the intervention, nurses reported that this lag was being used to weigh up the risks and consequences of interruptions and the strategies they can use to manage them. Previously this interruption lag was more passive for nurses and their responses automatic. Participants expressed increased awareness of the consequences of interruptions and the risk of the medications administered *"how easily they (mistakes) can happen, it's quite sort of sobering"* (Participant 03). Another stated that for

medications considered high-risk, they *"prefer to do it* [preparation] *in a really like structured manner to make sure there aren't any mistakes"* (Participant 08). They were also more aware of the frequency of interruptions. This was something they didn't notice beforehand, *"I am much more aware of how much I get interrupted"* (Participant 08).

Empowerment

Barriers to using the blocking strategy identified during the interviews included a lack of confidence and nervousness about the consequences. Participants reported that after the intervention they felt more confident to block interruptions. This was reported as different to what they felt before. Participants reported that previously they felt *"scared*" to block interruptions and considered themselves as *"a bit of a pushover"* (Participant 03). They were now blocking interruptions they would not have blocked previously. By participating in the research study participants felt they had justification to block interruptions, and therefore were less likely to be perceived as rude. One participant recalled an example where they blocked an interruption "*I had the freedom to do it because I am in the research"* (Participant 06). They showed an increased level of understanding 'why' they should manage interruptions appropriately. They stated they had a *"valid reason"* (Participant 07) to block interruptions and were more likely to be firmer if it was a "*particularly dangerous drug" (*Participant 03). The knowledge from the training empowered them to act in an appropriate manner when dealing with a medication interruption. One participant found the *"training gave me an encouragement"* (Participant 06) to utilise the skills they were taught, and another stated that by *"understanding the risks posed by it"* (Participant 08) they felt more confident to stop interruptions and question them. Most participants reported increased confidence post intervention as the training gave them the skills and knowledge to not only manage interruptions appropriately but to understand why it was important.

Simulation Sessions

A recurring theme throughout the interviews was the benefit of the simulation sessions as part of the educational intervention. All participants recalled the simulation sessions as the most beneficial part of the education which they remembered the most. They felt that the role players and scenarios were realistic and emulated situations they had experienced on PICU. The realistic situations allowed them to imagine themselves in the situation and react as they would on the unit – they *"got a better sense of how they would deal with it"* (Participant 05) in real life. This reportedly gave them confidence to do this in clinical practice. One participant stated that if they *"could handle that"* (Participant 07) it would be *"easier to put it into practice"* (Participant 07). Many of the nurses also associated negative feelings towards the simulation session. Many disclosed feeling *"nervous"* (Participant 02) and *"dreading"* (Participant 08) the session and some stated that they found the session *"traumatic"* (Participant 03). All reported surprise that they enjoyed the session and found it useful. They enjoyed exploring options in different situations in a *"safe space"* (Participant 02). They also enjoyed watching others and their reactions. One participant stated that *"it was good to be able to listen to other people having a go and then comment"* (Participant 07). Multiple participants stated that they learned more in the simulation session than the online learning, they felt it was better at getting the message across. They also stated that conducting the simulation session over zoom did not impact the effectiveness.

Team Cohesion

One reason nurses were unlikely to block interruptions and in particular communications, was the perceived detrimental consequences to their relationships with colleagues, patients and families. One theme that emerged through the interviews, was the nurses' high level of concern to being perceived as rude by their colleagues (as discussed in the empowerment theme). Many nurses felt that to stop one of their colleagues from interrupting them, then

they would get labelled as rude and not a team player. None of the nurses stated that they would find it rude but nearly all the participants said that using the blocking strategies could be *"taken the wrong way"* (Participant 06) or could be seen as *"rude or not caring"* (Participant 11). Participants feared their colleagues seeing them this way and then having to work with them for long shifts. PICU nurses rely on good teamwork and therefore fear any breakdown in team cohesion. One stated that it is easier to block people they are familiar with. They believe the colleagues they are closer to and friendly with outside of work, know them better and are less likely to be considered rude. Therefore, they were more likely to block their acquaintances, than a member of staff they do not know well or whom they view as senior to them. They also stated similar feelings about blocking communications from parents/guardians being worried about upsetting people by blocking their interruptions and coping with their reactions. They worried that blocking could cause their relationship with the family to deteriorate and then the family could *"fly off the handle and kick off"* (Participant 05) and then if they are *"in the bedspace for 12 hours it's difficult"* (Participant 05). They also worry about not supporting their colleagues, especially those more junior than them. They said that that they get many interruptions that are questions and pleas for help from junior members of the PICU team. One participant said that they remember what it is like to be in their shoes and they *"must be terrified of everything"* (Participant 03) and therefore they want to help rather than feeling they are ignoring them.

Embedded in the Culture

Many participants felt the intervention was needed and was useful. They often described that if the intervention was to be successful, the strategies should be embedded in the culture. They all stated that if the learning was rolled out to more staff and wider to multidisciplinary team members then they would find it easier to implement strategies. One participant stated that *"if everyone had a similar education everyone would know what to do"* (Participant 07). They showed a particular eagerness for their colleagues who were new, such as doctors and

new nurses to receive the same education. They wanted it to be part of the standard induction training on the unit. They thought this would be helpful to "*teach people how to deal with it in a PIC environment"* (Participant 03). Although they may have experienced interruptions in previous wards, they felt if they knew what to expect and what was expected from them on this unit, it may change their approach to handling these. They all had similar ideas of implementing the intervention at the beginning of their PICU careers, stating that *"if they learnt it from when they start"* (Participant 07) then they would find it easier to implement the strategies. The overwhelming theme from these interviews was how much the nurses believed it would be easier to implement the strategies and the intervention, if all the staff, patients and families were aware of the teaching. They wanted it embedded in the culture and delivered as standard training and reinforced by senior members of staff, justifying the importance of adopting safe medication practise.

Shared Learning

An interesting theme that emerged from the interviews was the participants desire to discuss the learning with others who had received the same training. They wanted to talk about their experiences of their shared learning and use in clinical practice. They deemed it valuable to understand other people's opinions and if their colleagues had faced any challenges and how they had overcome them. They identified that the opportunity to reflect with others had the potential to increase their confidence in the intervention and would facilitate applying the strategies in clinical practice. One participant stated that it would be

> *"Interesting to hear how people have been able to implement the teaching on the unit . . . if people have found it easy, why have they found it easy or if people have been finding it hard"* (Participant 07).

Some participants implied that this resource would help validate their experiences. They wanted reassurance that others had similar experiences when utilising the strategies or when

choosing not to utilise the strategies. Participants also wanted a chance to *"come up with suggestions of how to overcome it"* (Participant 08)—it implying the barriers they found to blocking interruptions. They felt that once they have been given a chance to put them in practice, they could as a group identify what was going well and what wasn't and look at how they could best proceed in the future to ensure medications are administered safely. During the interviews the participants also stated that they went on to champion the teaching. One participant stated *"one of the consultants interrupted me . . . I explained I've been in the medication interruption study and he was interested in it and wanted to know how we could improve things"*. They explained the benefits of the teaching and using the strategies to help keep patient's safe and to reduce the risk of errors. Showing they did not just want to share the learning with those who had similar experiences but also with those who had not had the benefit of the training.

Discussion

The aim of this study was to understand the experiences of the nurses who received the educational intervention. The interview guide was created to facilitate in-depth discussions with the participants to allow the researcher to understand their perceptions and views. Six themes emerged from the data, 1) Situational awareness, 2) Empowerment, 3) Simulation sessions, 4) Team cohesion, 5) Embedded in the culture and 6) Shared learning.

The six themes identified relate to each other and to improving safety culture (Figure 5.1). The Health Foundation (2011) report that a safety culture in organisations is built on communications based on mutual trust (theme: team cohesion), confidence in the effectiveness of the preventative measures (theme: empowerment) and shared perceptions of the importance of safety (themes: shared learning and embedded in the culture). Deighton et al. (2016) stated that situational awareness benefits safety culture and communication and

teamwork between staff. This highlights the dynamic relationships between these themes and how essential they are to ensuring an organisation's safety culture.

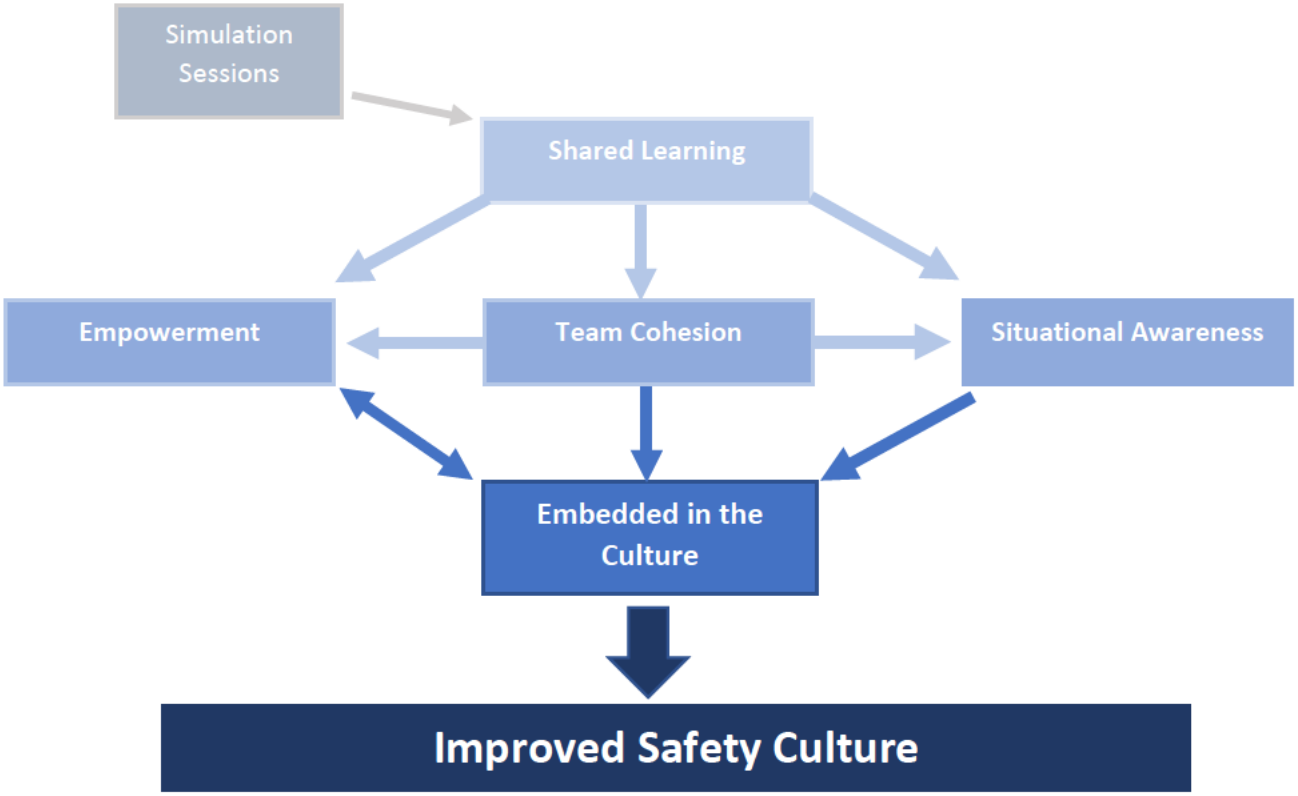

Figure 5.1 Relationship of study themes for improving safety culture

Shared learning allowed the participants the same level of understanding and awareness of the safety issue, and the interventions available to overcome it. The Francis Inquiry of the Mid Staffordshire NHS Foundation Trust emphasised that to create a culture focused on improving patient safety, a culture of learning needs to be embraced by staff (Francis, 2013). Department of Health (2015) also emphasised that this learning should be interdisciplinary and that we should share what we know. In this study, the shared learning, educational intervention, and goals helped promote team cohesion between participants. The objectives

of the education were identified at the start of the session, they were to discuss the epidemiology and consequences of medication interruptions and identify protective behaviours and their appropriateness. The team cohesion theme emphasised how important positive relationships between colleagues are to nurses. During their concept analysis Xyrichis and Ream (2008) found that teamwork is reliant on shared goals. Ladden et al. (2006) found that learning and working together towards an improvement in patient safety, promotes collaboration and allows professionals to understand each other's perceptions and views in pursuit of their shared goal. Providing a common language and understanding it can promote mutual trust between professionals, essential in ensuring effective patient care and continuous improvements in practice (Chambers et al., 2008, Allan et al., 2006). This shows that setting the same patient safety goals (to reduce medication errors), will facilitate the nurses' teamwork and protect their relationships. The shared learning gave nurses the confidence and knowledge to employ the intervention in clinical practice. Singh and White (2008) and Boonyasai et al. (2007) found during systematic reviews that education around healthcare improvement increased participants knowledge and confidence, however, this did not always result in a change of behaviour. This could imply that a change in one of these components alone is not enough to effect behaviour and influence a culture change.

As we know that the participants heavily rely on their relationships at work to determine behaviours, it is safe to assume the increase in team cohesion has a potential to increase the participants confidence in undertaking the intervention. Shared learning also improved the participants situational awareness. The WHO checklist emphasises that shared objectives help increase situational awareness (Green et al., 2017). The WHO checklist was created in response to examples where situational awareness breaks down and has devastating consequences (Green et al., 2017). Green et al. (2017) highlighted that attention is one aspect of situational awareness. Attention is determined by professionals' perception and how important they deem the information to be. By educating the nurse participants they

reported being more aware of interruptions and the consequences they faced and therefore paid more attention to them and showed increased situational awareness. Fore and Sculli (2013) reported that one of the main components in increasing situational awareness is teamwork.

Increasing participants' empowerment to implement the intervention and advocate for patient safety, team cohesion and situational awareness, will help facilitate embedding this learning into the culture. Mannion and Davies (2018) defined organisational culture as shared behaviours, feelings and ways of thinking within an organisation, emphasising how crucial shared goals are to embed the intervention into the culture. Teamwork and cohesion are an essential part of embedding new learning into the culture of an organisation. Shortell et al. (1995) found that teamwork and affiliation have been associated with more successful culture changes in healthcare. Professionals need the knowledge and confidence in a change to ensure it is embedded in the culture. Gill (2002) found that one of the biggest barriers to organisational change is a lack of self-confidence to carry out the change and a lack of confidence of positive results. If these are overcome, the change is more likely to be embedded in the culture. Green et al. (2017) stated that an understanding of the situation and increased situational awareness is crucial in the implementation of any change. Therefore, to facilitate a change and embed it in the culture the organisation needs to demonstrate good situational awareness.

There are reported examples of the devastating consequences when a breakdown in safety culture occurs such as the Bristol Inquiry (Inquiry and Kennedy, 2001), the Morecombe Bay investigation (Kirkup, 2015), Liverpool Community Health Independent Review (Kirkup, 2018) and the Francis Inquiry into the Mid Staffordshire NHS Foundation Trust (Francis, 2013). The events highlighted the detrimental effects for both staff and patients when the culture of an organisation shifts away from making patients and patient safety a priority, and there have been many recommendations and learning points published from these reports. It is essential

that these aspects of improving safety culture are fully developed and encouraged throughout healthcare organisations.

The literature into medication safety shows that a change in culture is needed and the aim of this intervention was for the participants to adopt the behaviours taught. Due to the limited sample size of this feasibility study, a culture change would be an unrealistic aim. However, the nurses wanted to embed this teaching into the culture and for it to become the norm, implying that the intervention may have broken the first barrier of cultural change. Shah et al. (2017) stated that participant's engagement and intent to change are essential for changing the culture of organisations. The organisations readiness to adopt change is also what Khan et al. (2014) identified as necessary to initiate the first step in making a change. The results of these interviews demonstrate the nurses are both eager and ready to adopt this change. The participant's request to embed the behaviours and teaching in the culture, the desire to share their learning, promote the education amongst their peers and increased knowledge from the intervention, could all facilitate a successful cultural change. This highlights that although the study was only a feasibility study and therefore the impact on the culture would be minimal, the participants readiness and desire to adopt this change may imply it is likely to be successful if rolled out to a larger sample size.

Another theme identified was situational awareness. The Page (2004) state that situational awareness is a combination of attention, knowledge and responsiveness. Furthermore, the Organization (2017) defined shared situational awareness as having team cognition, where all team members are aware of what is going on and how to perform better as a team. Situational awareness has been well reported in other high-risk industries such as aviation and the military, it is less reported in healthcare. Fore and Sculli (2013), who conducted a concept analysis on situational awareness, stated there has been a slight rise in nursing studies identifying situational awareness, and in the US the IoM has reported on the importance of situational awareness in patient safety. Kalisch et al. (2009) described

situational awareness as an internal factor when making critical decisions about patient care. Nurses are often the first and last line of defence in medication safety (Fore and Sculli, 2013) and situational awareness increases the chance of protecting patients. The identification of situational awareness as a theme shows the commitment and enthusiasm nurses have for patient safety. It strengthens the implication that the intervention has been successful at increasing medication safety, as we know situational awareness is a key factor in this. Many of the components of successful situational awareness were identified in other themes that arose from the interviews. Fore and Sculli (2013) stated that a main component in increasing situational awareness is teamwork. This goes hand in hand with two of the other themes identified during this study, team cohesion and shared learning. They identified that culture plays a major part in improving situational awareness and nurses' decision making. In the interviews the nurses reported a desire to embed this training in the culture to aid their use of the strategies. The theme empowerment was derived from an increased knowledge post intervention, which is a major component identified in the definition of situational awareness. This increase in situational awareness has changed the way nurses are processing interruptions. Ferner and Aronson (2000) discussed the negative impact of familiarity of conducting a process on medication errors. Similarly, Logan (1988) associated Type 1 errors with familiarity. Type 1 thinking is fast and automatic and therefore increases the risk of errors due to cognitive biases (Norman et al., 2017). These errors occur due to the processing of new information in the same way to a perceived similar experience. By increasing nurses' situational awareness, they are switching from Type 1 thinking to Type 2 thinking, where they consciously assess the situation before determining which strategy they should use. This change was identified by the participants themselves and again strengthens the improvement for patient safety as a result of the educational intervention.

The team cohesion theme emphasised nurses' need to be part of the PICU team and their concern about fragile relationships with their colleagues. Teamwork is essential to deliver

effective patient care (Dietz et al., 2014, Colman et al., 2019). It is evident through these interviews that nurses are aware how essential this element is in their career. Their concern about the demise of their relationship with their colleagues through prioritising their patient safety has also been seen in other studies as discussed in Chapter 5. Research has shown team cohesion and professional relationships are a fundamental factor in nursing job satisfaction (Al-Dossary et al., 2012, Tyler et al., 2012, Varaei et al., 2012). With the current UK nursing crisis and over 47000 vacancies as of September 2022 (Burki, 2023), it is essential that future research focuses on combatting this barrier and ensuring this intervention does not risk the cohesion of the unit.

During the interviews all participants reported that they would recommend the education to their colleagues, and one theme derived from the interviews was that participants wanted to share and champion the learning. Participants wanted a chance to share their newfound knowledge with their colleagues both on and off the unit. One of the main criticisms of previous interruption interventions identified in the scoping review (Chapter 1) was a lack of nurse buy-in (Bower et al., 2015, Hayes et al., 2014, Federwisch et al., 2014). This absence of nurses' approval has been partially blamed for the lack of effect/change of previous interventions. Nurses felt that interventions were adding to their workload and had a negative opinion of them. As the intervention in this study was purely educational with the aim of equipping nurses with the skill set and knowledge required to deal with interruptions appropriately, it did not add to their workload. Negative views of interventions were not seen in this study and many of the nurses stressed the importance of this work. Studies that have sought to gain the understanding and opinions of the nurses found similar results. Shah et al. (2017) found that participants' engagement is a key requirement to change attitudes, beliefs and values. This shows that nurses have the willingness to change but need guidance and support to make this change successful. Johnson et al. (2019) identified that nurses struggled to complete the eLearning due to time and workload. With this intervention, the

education was planned as part of routine teaching to avoid issues with motivation to complete additional tasks. This shows nurses that the education is perceived as a priority by the senior staff on the unit, which reinforces its importance and therefore engagement. Unfortunately, due to the pressures of COVID the offer of study leave to complete the study's education was rescinded. Interviews with participants discussed the difficulty to fit the training around their shifts and to complete the eLearning in their own time. As this is something that has been recognised in multiple studies, overcoming this barrier may be a contributing factor to the success of the intervention.

Limitations

The qualitative research study was changed from focus groups to semi-structured interviews due to the participant's different timetables. Potential information derived from participants sharing and discussing their experiences may have been lost (Rook et al., 2007). However, the findings of several themes that have been reflected in multiple previous studies, imply that the results of this study were not affected by the change in qualitative methods and the qualitative aims were still achieved.

Due to the nature of this feasibility study only a small sample size was used for the semi-structured interviews. This might affect the validity of results and make it harder for themes to emerge. However, the themes that emerged were consistent throughout all the interviews increasing the likelihood of data saturation.

Conclusion

The semi-structured interviews were conducted to explore the results from the observational study and to gain a deeper understanding of the nurses' experience of the education

intervention. The data was consistent with the findings from the observational data, with nurses admitting that they don't always utilise the right strategy and this was reflected in the lack of difference between the intervention and control groups in Chapter 4. However, the interviews showed that the nurses had internalised the teaching and showed increased situational awareness and empowerment to carry out strategies to manage interruptions. One of the barriers to utilising the strategies was that the approach was not embedded in the culture of the PICU. Although, the themes identified showed that the study contains the components needed to embed this teaching into the culture and to help facilitate this it should be delivered to more staff.

Chapter 6 DISCUSSION

This chapter brings together the four components of the study: 1) a scoping review of the literature to inform study design and to find gaps in the literature, 2) a survey to understand the priorities and experience of PICU staff and evaluate a local phrase as an intervention, 3) observational research to identify whether an educational intervention impacted nurses' selection of behaviour management strategies to manage an interruption and 4) interviews to determine nurses' experiences of medication interruption strategies and the educational intervention. It compares and contrasts the findings of each component and uses this to inform understanding around medication interruptions and the impact of an educational intervention on PICU.

Medication Interruption Research

Throughout this study, it is evident that this area of research is needed to reduce potential risks for patients and staff. The scoping review highlighted the economical, physical and emotional cost of medication errors (Hall et al., 2010, Bennett et al., 2014, Colligan and Bass, 2012) and the relationship between medication errors and interruptions (Wakefield et al., 1998, Gladstone, 1995). Although it is difficult to prove this relationship, copious research has discussed the consequences of interruptions to medication safety (Hall et al., 2010, Wakefield et al., 1998, Gladstone, 1995), and this was supported by the interview participants. All bar one of the participants felt that interruptions made the medication process increasingly risky on PICU. They all agreed that they often get interrupted and have experienced, what they perceive to be a risky interruption. This demonstrates staff are aware of the severe consequences that medication interruptions can pose (Hayes et al., 2017), which could help facilitate a much-needed cultural change around medication interruptions. As well as demonstrating understanding of the risks associated with interruptions, staff also demonstrated a strong desire for change and in the survey, many indicated that medication

interruptions need to be prioritised. This desire for change could be driven by the frustration felt by staff around the frequency and consequences of interruptions. This frustration was not identified in the interviews and the scoping review identified a willingness of nurses to engage in interruptions (Colligan and Bass, 2012). Exploring this contradiction in nurses' behaviour and emotional responses will help researchers deliver successful interventions.

Medication Interruption Rates

In the survey, 65% of the participants acknowledged that they have previously interrupted the medication process, evidencing the frequency of medication interruptions on PICU. This was reflected in the observational research where 89% of the medication episodes observed were interrupted at least once, similar to results seen in the medication audit in the same PICU 5 years earlier (Longman, 2017). High interruption rates have been found in several studies (Kliger et al., 2009, Relihan et al., 2010, Anthony et al., 2010). The more than 80% interruption rate reported in this study and the previous audit is much higher than the 25-55% reported in other studies (Kalisch and Aebersold, 2010, Palese et al., 2009, Westbrook et al., 2010). During the interviews participants stated that they were more aware of interruptions, implying they may not have noticed to the same extent pre-intervention. This lack of awareness and surprise at the rate of interruptions during the interviews contradicts the frustrated views of incessant interruptions reported in the survey and the rates observed during the qualitative workstream. This may be due to the fact that many of the survey participants were experienced healthcare professionals, whereas the interviewees were newly qualified or new to PICU and may have had less exposure to interruptions. The lack of consensus around the definition of medication interruptions identified in the survey could cause inconsistent recognition of interruptions. Hopkinson and Jennings (2013) identified this lack of agreement around the definition of a medication interruption and emphasised the need to understand and define this in future research. There has been little research identifying nurses' ability to recognise interruptions. An argument could be made that the

incessant level of interruptions nurses face has desensitised them and therefore they are not able to accurately recognise interruptions, again contributing to the contradiction identified in this study.

Nurse Initiated Interruptions

The observational data identified nursing staff communications as the main cause of interruptions, accounting for over half of observed interruptions. This range included questions about breaks, social conversations, and clinical communication. Other studies have reported similar findings (Kalisch and Aebersold, 2010, Hall et al., 2010, Tomietto et al., 2012, Dante et al., 2016). Anthony et al. (2010) went further stating that self-initiating interruptions accounted for over one quarter of the interruptions they observed. Interestingly this finding did not emerge from the interviews. In fact, nurses tended to identify doctors, surgeons, patients and parents/guardians as sources of interruptions instead. Only two of the nurses interviewed identified other nurses as a source of interruptions. Observations showed that nursing interruptions far outweighed all the total of other interruptions. This suggests that nurses are better at recognising interruptions from other sources and perhaps perceive nurse interruptions as normal. The high volume of nursing interruptions justifies the design of this study to initially focus the education intervention on nurses rather than other healthcare professionals or visitors. This approach is supported by Colligan and Bass (2012) who stated that education and cultural change should be centred around nurses due to their frequent involvement in interruptions. Information about how many interruptions were self-initiated may be needed to help nurses understand and appreciate when they are interrupting and therefore increasing the risk of errors.

Multitasking

During the scoping review, Johnson et al (2018 & 2019) education around management strategies was identified as a useful tool in overcoming medication interruptions. Many elements of the educational intervention were informed by their work. They stated that multi-tasking is never appropriate when interrupted during the medication process. The observation data found that multitasking was the most common strategy utilised by nurses when interrupted. Although the interview did not specifically explore nurses' perceptions around multitasking, the results from the interviews identified that the educational intervention gave nurses the confidence to use the appropriate strategies when interrupted, in particular blocking. Hayes et al. (2017) had similarly found that simulation and role play had increased nurses' confidence around medication safety. This improved confidence did not materialise in use of the blocking strategies. During interviews, the nurses admitted that they often used inappropriate strategies, believing they were taking a calculated risk when deciding upon that inappropriate strategy. Previous research highlighted that multitasking is not unnatural for nurses, often being required to multitask throughout their shift (Kalisch and Aebersold, 2010). This consistent use of multitasking throughout their work may desensitise them to the risks this strategy poses. This could mean that when they weigh up risks associated with the interruption, compared with risks associated with multitasking, they do not afford multitasking the appropriate consequences. This could explain the high levels of multitasking observed in this study, even with an increased knowledge about the risks and consequences of medication interruptions reported from the interviews.

Teamwork

One theme that emerged during the interviews, was team cohesion and the participant's need to maintain it. Participants were concerned that the blocking strategy may derail their team cohesion as they may be seen as rude. Bower et al. (2015) experienced similar reports during their qualitative interviews with staff about decision-making during the medication process. This was supported by the lack of use of the blocking strategy observed in Chapter

4. The blocking strategy was the strategy least likely to be used by both the intervention and the control group. The concern about being rude by blocking interruptions was not identified by participants in the survey. During the free-text comments, participants showed anger at those who caused the interruption, one participant even reported it showed a lack of respect. The results from the survey also showed an agreement by participants that interruptions are a problem that needs to be stopped. The locally developed phrase to block interruptions was deemed appropriate by the majority of participants. The acceptance of the phrase from the survey participants was shared with the intervention participants during the education aiming to increase their confidence in using it. This did not seem to have the desired effect as participant's concern of being rude was prominent throughout the study. The survey findings emphasise the concern reported by the interview participants were not shared by the survey participants. This may again come down to experience and being new to the unit/culture. The interview participants being new, may be less likely to want to 'rock the boat', however, the experienced survey participants may have more confidence to prioritise patient safety. They may also be less likely to fear being shunned by their team as their position is more secure.

Culture Change

There was no significant difference found between the intervention and control group data in relation to how interruptions were managed by nurses. Raban and Westbrook (2014) found many studies showed a similar lack of difference between intervention and control groups. Although there was no significant difference, the intervention group reported a change in behaviour themselves. They acknowledged that they don't always do the right thing, however, they are now more aware of the risks and consequences. It is difficult to determine whether the lack of difference between the groups is a true reflection of the intervention or whether it reflects the sample size and lack of education for every healthcare professional on the unit. During the interviews the participants stated that they would find it easier to implement the training if the training was delivered to all their colleagues as well. The themes

that emerged from the interviews identified all the components needed to facilitate a cultural change. This was also reflected in the results of the survey. The results of the survey showed that it is not only the intervention participants willing to make a behaviour change around medication interruptions. Leadership, organisation's readiness to change and engagement of staff are often reported as facilitators of culture change (Bokhour et al., 2018). Shah et al. (2017) found that employee's engagement is a key requirement to change attitudes, beliefs and values. The survey participants potentially represent a more experienced group with consultants, senior nurses and pharmacists. The willingness to change and engagement demonstrated by this population, who may be in more leadership roles, may help facilitate a cultural change on the unit. Although there was no statistical difference between the groups, the themes from this study imply that the intervention could help facilitate a behavioural change for the unit. Exposing other healthcare staff to the educational intervention may change the results seen in this study.

Intervention Design

The intervention was informed by the scoping review and survey to try to overcome challenges faced by previous interventions, such as lack of nurse buy in, lack of randomisation and a focus solely on education. During the study, several unexpected challenges due to the COVID-19 pandemic emerged and altered the design of the intervention. Many were managed and participants reported no change in the effect. For example, participants reported many benefits from the online simulation sessions, similar to that seen in previous research where the simulation session was conducted face-to-face (Westbrook et al., 2010). During the interviews all participants said they would recommend the education to their colleagues, and one of the themes that emerged was participants' desire to share and champion the learning. Studies that have sought to gain the understanding and opinions of the nurses found similar results (Johnson et al., 2019, Hayes et al., 2017). These results show that online learning is deemed both acceptable and

beneficial to participants and can be a useful intervention for studies. Not only does this reduce the cost of delivering the intervention, but it also facilitates the delivery to greater numbers of participants. The acceptance of the intervention and the increase in knowledge identified in the interviews, was not reflected in the participants behaviour in the observations. Reflecting on this, during this feasibility study we have learnt that the small sample size and lack of longitudinal observations may have affected the result. It is known that culture change is not imminent and can take time. The lack of longitudinal observations due to the COVID-19 pandemic, could explain the difference between the participant's observed behaviour and reported change in the interviews. The scoping review identified that the long-term effects of previous interventions had been scantily investigated. The observations took place during the first two months post intervention, at which point many of the participants had not completed the eLearning module. When interviewed several months later the participants reported a change in their behaviour. To understand the true effect of the intervention and whether the reported change resulted in an actual change in behaviour, observations around the time of the interviews would be needed.

During the scoping review, one study identified that nurses struggled to complete the eLlearning due to time and workload. With this intervention needing time put aside by either the education or research team to facilitate the learning, it firstly emphasises that the unit and their senior leaders believe this education to be important, but secondly, it allows nurses to have time set aside to complete this training away from the unit. Unfortunately, due to COVID the offer of study leave to complete the study's education was rescinded. When discussed with participants the difficulty to fit the training around shifts and completing the eLearning in their own time was highlighted. As this is something that has been recognised in multiple studies, overcoming this barrier may be a contributing factor to the success of the intervention.

Limitations

The limitations of the individual studies have been summarised in Chapters 1–5. In summary, a small sample was used in this feasibility study to ascertain whether this educational intervention could be disseminated to multiple sites with a larger sample size. Despite the small sample size, the data from the survey, focus group and observation in the most part aligned. The small sample size indicates a potential lack of power in the data and could also explain the lack of difference observed between the control and intervention groups.

During the observations, a quarter of participants could not be observed due to lack of availability. Some were allocated to roles with no medication responsibilities such as the resource role, where the nurse does not have their own allocated patient and therefore no medicines to prepare and administer. However, 75% of the participants were still represented and an even number of observations were seen between the control and intervention group.

A second round of observations were planned to be conducted to investigate whether the learning had a more sustained impact on behaviour. Due to the pandemic, students were not allowed on the unit at the time of the second observation, and therefore could not facilitate. Due to the time limitations, we were not able to delay the observation period as the qualitative phase of the study needed to commence. Although the second round of observations did not take place, the interviews happened between 2–8 months post-intervention. The interviews did encourage nurses to reflect on and remember the intervention and sought their current experiences of the behaviours.

Owing to staff availability, the qualitative phase of the study was changed from focus groups to semi-structured interviews. This meant that data derived from participants sharing and discussing their experiences was not captured (Rook et al., 2007). However, similar results and recurrent themes were seen throughout all interviews.

Implications for Future Research

To truly understand whether this intervention can lead to an improved safety culture towards medication interruptions, the intervention needs to be rolled out to a larger sample of participants. Ensuring whole units are recruited to aid cultural change is essential. Learning should be captured from successful campaigns such as those around sepsis (Choy et al., 2022), where interventions were employed hospital or ward/unit wide to ensure consistency in protocol management. This facilitated the participants to employ the learning. Active learning strategies that involved teamwork were deemed contributing factors to the success of the intervention. Although, there is justification to focus on nurses as they are the source of the majority of interruptions, the learning from the success of the sepsis pathway provides an argument for including individuals from the multidisciplinary team who may be involved with the medication process or maybe a source of interruptions. This may also help to overcome participants fear of being rude as everyone will have had the same teaching.

The study identified a lack of agreement between healthcare professionals as to what constitutes an appropriate interruption and a lack of recognition from nurses of interruptions initiated by themselves or colleagues. This is an important area on which to focus future research as this lack of awareness and agreement may hinder any intervention and appropriate management of these interruptions.

Conclusion

This study highlighted the high rate of interruptions that occur in PICU –a high-risk and high-pressure environment. Interruptions were largely made by nurses, but there was a perceived lack of awareness that this was the main cause. Strategies to adopt management of interruptions were not found to be adopted appropriately, although awareness of the need to manage interruptions more effectively did emerge. Although there was no statistical difference between the intervention and control group, this could in-part be explained by the

need for a wider cultural change. A need for a consistent approach among all professionals emerged from the interviews, so that behaviours such as choosing to block an intervention could be understood in the moment and accepted.

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APPENDICES

Appendix 1 – Medication Interruption Questionnaire for Healthcare Staff

Medication Interruptions

Medication Interruption Questionnaire for Healthcare Staff

Background

This questionnaire study is being conducted as part of a Birmingham Health Partners Starter Fellowship research: *Interruptions and Medication Errors: A mixed methods study.*
We are currently seeking thoughts and beliefs of the multi-disciplinary team around the medication process and medication interruptions. We are hoping to use this information to help teach new PICU nurses about the medication process. The questionnaire will take approximately 10 minutes to fill in. Thank you very much for you help with this questionnaire.

Page 2: Consent

Although consent is implied through the completion and submission of the questionnaire, it is important that participants understand how we will use the data. In view of this, we have provided four consent statements below that require acknowledgment prior to the questionnaire commencing.

1. I understand that my participation is voluntary and that I am free to withdraw at anytime, without giving any reason. *Required*

- Yes
- No

2. I understand that relevant sections of data collected during the study may be looked at by appropriate individuals from the University of Birmingham and Birmingham Children's Hospital. I give permission for these individuals to have access to the data collected in the study. *Required*

○ Yes ○ No

3. I understand that the anonymised data may be used in talks about this research for professional audiences of researchers, health and social care staff and trainees.

Required

○ Yes ○ No

Page 3: Medication Interruption Healthcare Staff Questionnaire

4. What is your role within the

☐ Nurse ☐ HCA ☐ Tech team
☐ Doctor ☐ Consultant ☐ Physio
☐ Pharmacist ☐ Housekeeper ☐ Other

5. How long have you worked in this

☐ < 1 ☐ 1 - ☐ 4 -
☐ > 5

6. Which aspect of the medication process are you involved in? You can select more

	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree

than one)

Please select no more than 5 answer(s).

- ☐ Prescribing
- ☐ Supply
- ☐ Clinical checking accuracy
- ☐ Preparation
- ☐ Administration
- ☐ None

7. Medication safety research is important for patient safety

Please don't select more than 1 answer(s) per row.

Please choose an answer	☐	☐	☐	☐	☐

8. Have you ever interrupted a staff member when performing parts of the medication process? (prescribing, supply, preparation, administration)

- ☐ Yes
- ☐ No
- ☐ Not knowingly
- ☐ Unsure

9. Medication interruptions are a problem on PICU.

Please don't select more than 1 answer(s) per row.

	Strongly Agree	Agree	Neither agree or disagree	Disagree	Strongly Disagree
Please choose an answer	☐	☐	☐	☐	☐

10. "I'm sorry I'm preparing medication. Unless it is an emergency, I will speak to you when I have finished."

Do you think this phraseis appropriate for nursesand doctors to use to stop medication interruptions?

☐ Yes ☐ No

10.a. If not, can you provide further information

11. Can you think of a different phrasethat would be more appropriate to use to stop interruptions?

12. Are there certain times where it is appropriate to interrupt nurses/doctors in the medication process?

Please select scenarios where it is appropriate to interrupt, from the answers

Please select no more than 11 answer(s).

- ☐ To update a
- ☐ To update a
- ☐ Answer the
- ☐ Sort out breaks
- ☐ To ask a question
- ☐ To ask a question about the patient
- ☐ Ward round
- ☐ Handover
- ☐ X-ray
- ☐ Physio
- ☐ To tidy the (clear away drugs, mop floors)

13. Any other comments about medication interruptions?

Page 4: Final page

Thank you for taking the time to complete this questionnaire.

For further information or to provide feedback, please do not hesitate to contact us:

- Samantha Owen, PICU Clinical Research nurse/BHP Starter Fellow, E: [redacted]
- Dr Sarah Pontefract, Lecturer in Clinical Pharmacy and Therapeutics, E: [redacted]
- Dr Julie Menzies, PICU Clinical Nurse Researcher, E: [redacted]

Appendix 2 – Simulation Scenarios

LEARNING OBJECTIVES

The key skills that the nurses will have gained by the end of the session are:

- Being able to effectively manage interruptions
- Clear and effective communication
- Confidence in the behaviour management strategy for dealing with interruptions

By the end of the scenario, the nurse will have had the opportunity to practise:

- Using their clinical decision skills to choose an appropriate behaviour management strategy to deal with interruptions
- Be able to block an interruption with clear and effective communication
- Courteously explain to the interrupter that the medication is a priority and unless it is an emergency the interruption will have to wait

With each scenario we ask you to consider:

- Did you feel the nurse was doing something important?

- How did you feel if the nurse asked you to wait until they had finished – did it feel rude or professional?
- Did you feel the nurse was prioritising their patient care?

For your information:

- The management strategies:
    - Blocking – this is where a nurse will completely block the interruption. The nurse will acknowledge the interruption but will explain that they are in the middle of drugs and unless it is an emergency please wait. We encourage this strategy if the nurse is in the middle of complicated drugs.
    - Mediating – this is where the nurse will complete a sub task of the medication process and then engage in the interruption before completing the rest of the medication process. The nurse may have a checklist for an antibiotic, they may make the interruption wait until they have completed one step of the checklist and then they will deal with the interruption. This makes it easier for them to pick the medication process back up, where they left it, reducing the risk of forgetting steps or making mistakes. This strategy is also encouraged.
    - Engaging – this is where the nurse completely stops the medication process no matter where they are in it and engages in the interruption. If the interruption is a patient emergency this may be a completely appropriate strategy to use.
    - Multi-tasking – this is where the nurse tries to engage in both the medication and the interruption at the same time. For e.g., they continue to draw up antibiotics whilst talking to a patient's family/doctor. This strategy is not encouraged as the nurse is at a high risk of making a mistake.
- PICU = Paediatric Intensive Care Unit
- There are 3 sections in PICU, A side, B side and C side. A & B side are classed as the main unit on PICU. A side is for general patients, B side is for cardiac patients and C side is for long term patients (normally over 28 days). Each side has 1 nursing team leader, 2 x registrars and 1 consultant

There is an overall 'nurse in charge' for the whole PICU Most of the children in PICU are intubated (they have a tube down their mouth/nose to help them breathe) on a ventilator. They can be awake or asleep on this breathing tube.

NURSE'S NOTES – Scenario 1

You are a nurse looking after a patient on C-side. The patient is a long-term patient who has had multiple previous admissions. The patient's family have been known to be challenging and have complained several times about the care their daughter has received. The nurse gave a dose of chloral last night as Shelley was very upset and was working hard. The nurse and the doctor had both agreed that chloral was the best action to take. You have not given any chloral today, but Shelley is still very tired from last night. Mum has already rung this morning to say she is not happy with the drugs given overnight and the fact that the nurse looking after them was doubled up (looking after a second patient). The majority of the time on PICU it will be one nurse to one patient, but every now and then due to staffing levels, 2 patients who are deemed to have a lower acuity level may be given to 1 nurse) She has already asked to speak to the nurse in charge when they get in.

N Sometimes it is felt that nurses use sedation (such as chloral) to put the patients to sleep very quickly. This can often be due to safety - whether it is to keep the tube nice and secure or because the patient is fighting the ventilator which then makes it very difficult for them to breathe

It is 13:45 you have antibiotics due at 14:00. You have printed the guide for the antibiotics and started preparing the medication. Please start talking through the preparation of the medication.

ACTOR NOTES – Scenario 1

Cheryl, aged 32, mum of 3.

Your child (Shelley) has been in and out of hospital and PICU their whole life. They are 2 ½ years old and have a complex medical condition – SMA type 2 This is a life limiting condition, that means they have problems with breathing, feeding, mobility and swallowing. They need a wheelchair to help them get around and are fed through a PEG (a feeding tube in their stomach). They have had several respiratory infections which have caused many previous admissions to PICU. Doctors and nurse often try to treat them with NIV (non-invasive ventilation). This uses a ventilator but with a mask (rather than a breathing tube) to help your child breathe. This is what your child is currently on. It makes it hard for your child to play and communicate as the mask covers the majority of their face. You have 3 other children (aged 6, 9 and 12 years old, they are all at school during the day) and are unable to stay at the hospital full time when Shelley is in as you must look after them and take them to school. Work (you work in a supermarket on the checkout tills) are also being difficult with you having time off again, making you feel very anxious and stressed. Your partner (Steve, aged 36) often works away and is currently away for two weeks on a building site in London and unable to help. You feel nurses often give chloral (a sedative) when they don't need to, meaning your daughter is often asleep and unable to play or interact. You think this tends to happen more when the nurse is doubled up as they don't have time to calm your daughter down or play with her so they just 'shut her up'! You often get different nurses who don't know how to look after her and don't know what she likes or dislikes. You have often asked for the same nurse to care for Shelley, so her routine can be kept but you feel it falls on deaf ears. You have come in for the first time today and are angry after last night. When you spoke to the nurse this morning you found out your daughter had been upset last night and needed chloral, but no one rang you to let you know. You asked the team leader not to double up the nurse looking after Shelley as Shelley hadn't been quite right in the day and needed someone to keep an eye on her closely, but you couldn't stay as you needed to catch up on work and get the kids ready for bed.

You come on to the ward to Shelley's bed and you have never had this nurse before. Shelley's bed is on a row of 4 patients on c-side. You want an update immediately as Shelley looks sleepy and you want to know what happened last night.

WHAT WE ARE LOOKING FOR:

We have chosen this scenario as it may be a scenario in which nurses are afraid to ask the parents to wait whilst they finish their medication. We want to see how both the nurses handle the interruption but also how the parents handle the nurses asking them to wait.

The nurses will be given a drug chart to look at and the antibiotic guidelines. We will ask them to speak out loud each step of the antibiotic preparation and administration. You will come and interrupt the preparation after a couple of seconds. We want you to be visibly annoyed but not overly aggressive. You are adamant you need to speak to someone straight away, but you are not abusive. You may come in and say, "Can you explain to me why Shelley received chloral last night and why the nurse was doubled up after I specifically said not to and can you go and get the nurse in charge for me now".

We are looking for the nurses to use the mediating strategy. They should finish a section of the medication process and switch their attention to you. We expect them to be able to communicate the importance of finishing the job they are doing appropriately. They should then be able to switch their attention to you and deal with the problem in hand effectively and professionally.

If you feel the nurse has got over the importance of the medication, then you will calm down and potentially passive aggressively allow them to finish before speaking to you. If the nurse engages with you straight away without finishing a step in the medication, you can become more involved in the conversation potentially getting angrier. We will stop the scenario after a few minutes of this and ask the nurse how easy they would find it to restart the medication now and ask them to repeat the scenario by asking you to wait while they finish steps in the medication process. If the nurse finishes part of the medication but you don't feel like they have made it clear to you why they need to finish it before speaking to you, you can continue to try and engage with them. Again, we will stop the scenario after a few minutes and reflect on how they could have made it clearer to you that this medication is important.

Although as part of this scenario the nurses will get a chance to practice difficult communication with families, this is not the main aim of the session. We do not want the scenario to become all about the communication with families about the medication that was given.

NURSE'S NOTES – Scenario 2

Baby Smith, 27+3, DoB 26.08.2021, admitted from the women's at 06:05 this morning. You are a nurse working on a busy PICU. You have a very busy patient who is very poorly. They have come in overnight ?NEC and are currently ventilated with high pressures (SIMV, PRVC & PS, peak pressures of 32), on triple inotropes (adrenaline, noradrenaline and vasopressin) and are very unstable. It is the start of your shift, and you are trying to catch up with jobs as this patient was only admitted a few hours ago. You have been told that you are aiming for a MAP above 30 but the MAP is currently drifting at 27. Parents have gone to get a cup of tea and some breakfast but will be back very soon. You have been asked to give a gelo bolus and draw up a calcium infusion (continuous). You are aware that they will be

needing surgery soon, you also need to get everything ready for surgery, such as the paperwork, the equipment and making sure the infusions have enough time left on them. You are currently drawing up your gelo bolus and need to start your calcium infusion asap.

ACTOR NOTES – Scenario 2

You are a surgeon just coming on for your day shift. You have just found out there is a baby on PIC (paediatric intensive care) who is very poorly and needs a surgical review. They have been admitted overnight for ?NEC (necrotising enterocolitis). This is a common condition in premature neonates, which can potentially be life-threatening. It can cause parts of the bowel to die, and when a baby is this sick, they need a laparotomy – an operation in which surgeons remove the part of the bowel that has died and re-join the ends together. The longer the surgery is delayed the more bowel will potentially need to be removed, which reduces the babies' chance of surviving. You will not know how much bowel you need to remove until you do the surgery. Your reg (registrar) didn't assess this baby overnight when they first came in – there was a miscommunication between the reg and PIC as to when the baby arrived and the reg was unaware the patient had been on PIC for the last couple of hours. You are annoyed that this delay has caused the baby to deteriorate, and you need to assess this baby asap.

You arrive on PICU (the paediatric intensive care unit) and want an update from the nurse looking after the patient. You want to know patient's name, date of birth, gestation, what ventilator settings they are on (breathing support), what inotropes if any they are on (blood pressure support), if an x-ray has been done, if a cross match has been sent and bloods are ready for theatre and if anyone has talked to the parents.

- You are annoyed and impatient as you are worried about the consequences for the patient if you are delayed
- You need an update instantly to be able to make a decision as to when this patient should have surgery
- You will also need to speak to parents about the possibility of surgery and consent if needed

WHAT WE ARE LOOKING FOR:

We are looking for the nurse to prioritise the medication preparation over the interruption. Although, the surgeon does need information there are other members of the team they would be able to get that information from (e.g., the Dr looking after the patient, the team leader, the consultant, the nurse in charge). All of these people will be present on the unit and if not in the room they will be around and available to talk. The patient is currently deteriorating, and it is imperative the nurse gets the medication on.
You should come up to the nurse and ask them if they are looking after Baby Smith, who has just been admitted from the women's for ?NEC. And then proceed to ask the nurse for information regarding surgery.
The nurse should be able to clearly explain that they need to focus on the interruption and ask you to speak to someone else about the patient or wait until they have finished.
Again, we are looking at the nurses' management of the situation but also how the surgeon reacts to the nurse blocking the interruption. The nurse should explain that the patient is deteriorating, and they are trying to stabilise the patient's blood pressure before they are able

to talk. If the nurse blocks this interruption and explains the severity of the situation clearly then you can try to ask them who you can speak to, in order to get this information, but allow the nurse to prioritise the medication.
If the nurse does not make it clear how severe the situation is, you can push forward to try and get information out of them. This patient is sick and will probably not get better without surgery. Unless the nurse makes it absolutely clear that their blood pressure is currently dropping and they need to give a bolus and start a new infusion to stabilise them straightaway you can argue that they will not get better without your help, which they are now delaying and continue to interrupt the nurse.

The below scenarios are slightly smaller with a focus on potential scenarios nurses may face regularly on PICU. The emphasis is on the nurse being able to effectively deal with the interruption whilst maintaining a good professional relationship with the person who interrupted. The scenarios will be very short, as they will finish when the nurse has dealt with the interruption. We will then review both how the nurse and the actor felt during the scenario.
N.B. if you feel that your character would push the nurse to engage in the interruption rather than block you, feel free to continue to try and get the nurse to engage. We would hope the nurse would be able to deal with this effectively, whilst still prioritising the medication process.

Small scenarios:

NURSE'S NOTES – Scenario 3

You are a nurse looking after a stable post cardiac patient – Jacob Wright. Jacob has had a good night, his ventilator settings have remained unchanged overnight, his gases are good, he had a good response to furosemide and urine output has been >2mls/kg/hr and has had <1mls/kg/hr out of his drains. He has started to wake up but has slept most of the night. You are currently in the middle of your 06:00 drug round; ranitidine, co-amoxiclav, paracetamol, omeprazole and flucloxacillin.

ACTOR NOTES – Scenario 3

You are a cardiac reg (registrar). Each morning you have to visit each of your patients on PIC and get an update to present the patients at the 09:00 cardiac ward round with your superiors. You only have a short amount of time to get this update. You need a handover form the nurse of Jacob Wright. You will confirm that you have the right patient with the nurse and continue to ask them how their ventilator settings have been overnight, how their gasses look, have they passed urine, how much they have had out of their drains and if they have woken up. The nurse should ask you to come back in 10 minutes or look at the chart and wait whilst they draw up their medication. You do have other patients to get an update from so can go and visit them and come back.
If the nurse makes it clear they are busy, and it is important then you can back down and say you will get the information yourself/later. However, if the nurse starts to engage or doesn't make it clear then you can push them for this information.

NURSE'S NOTES – Scenario 4

You are a nurse looking after a TBI patient – 14-year-old Oswaldo Osborne. They are due in MRI at 12:00, it is currently 11:30 and you are drawing up the new infusions for the MRI scan. The patient's parents have not yet been in and haven't rung for an update. The night nurse had let them know about the MRI, so they had decided to have a lie in and breakfast before they came in. The tech team have just been around and said they will be looking at transferring in the next 10 minutes. You need to get the new infusions drawn up and administered.

ACTOR NOTES – Scenario 4

Your child (Oswaldo – 14 years old) was admitted to PICU a week ago after being hit by a car. They have suffered a Traumatic Brain Injury (TBI) and you have been told they are stable enough to go for a scan to see how bad the injury is – this will hopefully give the doctors more information about how damaged the brain is and what sort of recovery he may have. You have just come in to say hello before the scan. You have questions for the nurse about the MRI; how long will it take, when will the results be available, are you allowed to go down with him? Will the doctors be able to tell how damaged his brain is straight away? Will it hurt him? Did he have a good night? Has he shown any signs of waking up?
You are anxious about the scan and the results and what it means to Oswaldo. Due to this you have lots of questions and need some reassurance.
Again, if the nurse can explain the importance, they finish their jobs to make sure they don't miss their MRI time and have to rearrange it, then you will completely understand as this scan is very important to him. However, if they don't portray this to you, you can keep asking them questions.

NURSE'S NOTES – Scenario 5

You are looking after a patient on PICU (Oswaldo from the previous scenario). It has been a really busy day as the patient went to scan and was longer than expected. You have lots of jobs to catch up on and your antibiotic was due at 14:00 and it is currently 14:45. You are just starting to draw up your antibiotics – please use the antibiotic example from earlier.

ACTOR NOTES – Scenario 5

You are the nursing team leader on a busy side of PICU – the day has been nonstop, you have been required in many bedspaces as patient's have deteriorated and there isn't anyone else around to help the nurses. You have had 1 patient go for emergency surgery and 2 patients deteriorate with a very junior workforce. You have just had a patient come back from scan and need to get an update/handover before your other patient comes back from theatre. You need to know how they coped in scan, if anything has changed, are they still on inotropes, have the gases been good, do they have any outstanding jobs.
You feel very stressed and have been pulled in many directions today. This is the first time you are really getting a chance to catch up with this patient and you are very aware that someone has called down to say your patient from theatre will be coming back soon. When a patient comes back from theatre you have to be there for handover from the theatre staff to know what is going on.
Again, if the nurse clearly explains their time constraint for the antibiotic as it is nearly an hour late (it is an error if not admitted within an hour of prescription time) and portrays the

importance of continuing with this, then you can say you will get the information from the doctor.
If the nurse says they need to finish a step of their antibiotic and then update you this is also appropriate.
However, if the nurse does not get clearly explain the importance or tries to speak to you without finishing their step, then you can keep asking them questions. If you run out of questions, you can start complaining about the day that you have had. After a while we will stop and try and ask the nurse to remember exactly what step they were out and to continue the process to see how difficult they find it. We will then ask them to stop and reflect on what they could do differently.

Appendix 3 – Medication Interruptions and Errors: A Mixed Methods Study Participant Information Leaflet

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Medication Interruptions and Errors: A Mixed Methods Study

Participant Information Leaflet

Study summary

- All participants receive education as part of the foundation course.
- Some participants will be randomised to receive an 'extra' training session which will include simulation training (face to face) and an e-learning module at 1 month.

- Both groups will be observed twice in clinical practice preparing and administering medicines (at 2 and 4 months after).
- Those randomised to receive the 'extra' education will be invited to participate in a focus group to discuss their experience.

Background Information

Preventable harm from medicines is a global problem creating huge economic and social burden. Interruptions and distractions are one of the key causes of medication errors. This research aims to determine nurses' thoughts and feelings toward medication interruptions and investigate if an education programme can reduce interruptions on PICU. The University of Birmingham is the sponsor for this study.

Who is being invited to take part?

Due to the limited time of the study, only those currently enrolled on the foundation course will be eligible to be included in the study. Within these cohorts, any band 5 nurses who are new to joining PICU at Birmingham Children's Hospital with no previous PICU experience will be invited to take part.

What does the education session involve?

Participants will be randomised to either receive additional teaching along with the standard education sessions on the Foundation course (intervention group), or to just receive the standard education sessions on the Foundation course (control group).

Those that are randomised to the intervention group will be invited to attend an online education session about the incidence and consequences of medication interruptions and strategies to manage interruptions. During this session participants will practice managing interruptions in a role play scenario. Finally, the participants will be invited to complete an e-learning module about medication interruptions up to a month after the education session. In total, the online education session and the e-learning module, should approximately take 1 day to complete.

What do the observations involve?

Upon completion of the educational session, researchers will observe all the nurses during medicines administration on PICU. This will take place at 2 and 4 months after the education session. Observers will be collecting information on how many times the participant is interrupted and how they manage these interruptions – techniques and ability to draw up the medication or calculations are not being looked at.

Participants are expected to be observed at least 3 times at both 2 and 4 months, however, the dates in which participants need to be observed can be flexible if needed. If a participant does not wish to be observed one day or the bedspace is not appropriate, the participant does not need to withdraw. The researcher will organise another day to observe them. Patients and other staff members will also be made aware that these observations will take place. If an observer is asked to leave at any point in the study, they will leave immediately.

All data taken will be anonymous – observers will be told which staff to observe but staff names and personal information will not be recorded. No patient details will be taken, and no recordings will be made of the observations.

What do the focus groups involve?

Participants who were involved in the intervention group will also be invited to participate in a focus group after the observation period has finished. A new consent form will be provided for those who wish to take part in the focus group.

The focus group will be used to discuss how nurses found the education sessions and if they feel it had an impact on their ability to manage medication interruptions afterwards. Focus groups will be recorded to allow the researcher to transcribe the discussion verbatim in to analyse the data. All data will be anonymous and any identifying names or reference to specific wards during the focus groups or observations will be altered when a transcript is made. Quotes from participants may be used but will be anonymised. Each focus group will last for no longer than 1 hour.

Are there any benefits or risks to taking part?

There is potential that taking part may help increase your confidence in dealing with interruptions, communication and medication administration.

There are no major risks to taking part. People can often feel discomfort when being observed but the researcher will work with the participant to make sure they feel as comfortable as possible. The observer is only looking at medication interruptions and not assessing the participants skills or practice.

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage."

Do I have to take part?

No, you don't have to take part. If nurses decline consent it will not affect their standard education on their foundation course. If you agree to take part and change your mind, you can withdraw from the study up until the end of the last observation period. However, we will ask to use your data (anonymously) up until the point of withdrawal.

Data Management

All data will be kept for 10 years, on a secure server, according to the University standards for keeping research data. Results from this study will be shared in an anonymous format in conferences and publications. Research and Development monitors and inspectors may also access the data to verify or cross-check it. Only those qualified and with an appropriate professional background will be given access to the data.

Your data

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
At the end of the study we will save some of the data in case we need to check it.
We will make sure no-one can work out who you are from the reports we write.
The information pack tells you more about this.

How will we use your information?

The information will include your; initials, name and job details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using personal data must follow UK laws and rules.

Universities, NHS organisations and companies may use personal data to do research to make health and care better. When companies do research to develop new treatments, they need to be able to prove that they need to use personal data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using personal data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use personal data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using personal data, they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking Samantha Owen or one of the research team
- by sending an email to [redacted]
- by contacting the Data Protection Officer;

The Data Protection Officer
Legal Services
The University of Birmingham
Edgbaston
Birmingham
B15 2TT
Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916

Thank you for taking the time to read this information leaflet

If you would like to know more about the study, please contact

Samantha Owen or Dr Sarah Pontefract:

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Appendix 4 – Medication Interruptions and Errors: A Mixed Methods Study Participant Information Leaflet Interviews

UNIVERSITY OF BIRMINGHAM

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Medication Interruptions and Errors: A Mixed Methods Study

Interview - Participant Information Leaflet

Background Information

Preventable harm from medicines is a global problem creating huge economic and social burden. Interruptions and distractions are one of the key causes of medication errors. This research aims to determine nurses' thoughts and feelings toward medication interruptions and investigate if an education programme can reduce interruptions on PICU. The University of Birmingham is the sponsor for this study.

Who is being invited to take part?

Participants who have consented to the Medication Interruptions and Errors: A Mixed Methods Study and were randomised to receive the education programme will be invited to attend an interview. The interview will take place after the observation period has finished. A new consent form will be provided for those who wish to take part in an interview.

What does the interview involve?

The interview will be used to discuss how nurses found the education sessions and if they feel it had an impact on their ability to manage medication interruptions afterwards. The interview will be conducted over zoom and audio-recorded to allow the researcher to transcribe the discussion verbatim to analyse the data. All data will be anonymised and any identifying names or reference to specific wards during the interview or observations will be altered or removed on transcribing. Quotes from participants may be used but will be anonymised. Each interview will last for no longer than 1 hour. Once the researcher has transcribed the data from the interviews, the recordings will be deleted.

Are there any benefits or risks to taking part?

There is potential that taking part may help increase your confidence in dealing with interruptions, communication and medication administration. There are no major risks to taking part.

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage."

Do I have to take part?

No, you don't have to take part and declining will not affect the standard of education you will receive. Participants are free to withdraw up to 14 days after the interview, if participants do withdraw their data will be destroyed.

Data Management

All data will be kept for 10 years on a secure server, according to the University of Birmingham standards for keeping research data. Results from this study will be shared in an anonymous format in conferences and publications. Research and Development monitors and inspectors may also access the data to verify or cross-check it. Only those qualified and with an appropriate professional background will be given access to the data.

Your data

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
At the end of the study we will save some of the data in case we need to check it.
We will make sure no-one can work out who you are from the reports we write.
The information pack tells you more about this.

How will we use your information?

The information will include your; initials, name and job details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using personal data must follow UK laws and rules.

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If they could do the research without using personal data, they would not be allowed to get your data.

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- by sending an email to [redacted]
- by contacting the Data Protection Officer;

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Legal Services
The University of Birmingham
Edgbaston
Birmingham
B15 2TT
Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916

Thank you for taking the time to read this information leaflet

If you would like to know more about the study, please contact

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Appendix 5 – Intervention and Observation Consent Form

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Intervention and Observation Consent Form

Interruptions and Medication Errors: A mixed methods study

Please initial in the box to indicate consent

1. I confirm that I have read and understand the participant information leaflet (version 1.6) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I agree to being observed during medication administration episodes at 2 and 4 months post the education intervention.	
3. I understand that I am free to withdraw at any time without my legal rights being affected. If I do withdraw, I understand that my (anonymised) data up to the point of withdrawal will continue to be used.	
4. I understand that data collected during the study, may be looked at by individuals from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data.	
5. I understand that the data collected will be kept for up to 10 years after publications arising from the study, subsequent to being destroyed. I consent to my data being used during that time.	
6. I agree to take part in the above study.	

_____	_____	_____
Name of researcher	Date	Signature
_____	_____	_____
Name of participant	Date	Signature

When completed, one for participant, one for researcher file

Appendix 6 – Interview Consent Form

UNIVERSITY OF BIRMINGHAM

Birmingham Health Partners
Collaboration. Innovation. Application.

NHS
Birmingham Women's and Children's
NHS Foundation Trust

Consent Form – Interview

Interruptions and Medication Errors: A mixed methods study

	Please initial in the box to indicate consent
1. I confirm that I have read and understand the participant information leaflet (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
2. I agree to participating in an Interview.	
3. I agree to the interview being audio taped.	
4. I agree to anonymised quotations being used in reports produced from this study.	
5. I understand that the data collected will be kept for up to 10 years after publications arising from the study, subsequent to being destroyed. I consent to my data being used during that time.	
6. I understand that data collected during the study, may be looked at by individuals from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data	
7. I understand that my participation in the one-to-one interview is voluntary, and I understand that I am free to withdraw at any time without justification up to 14 days after the interview has taken place, and if I withdraw my data will be destroyed.	
8. I agree to take part in the above study.	

_____	_____	_____
Name of researcher	Date	Signature
_____	_____	_____
Name of participant	Date	Signature

When completed, one for participant, one for researcher file

Appendix 7 – Organisation Information Document (Protocol)

Organisation Information Document – Non-Commercially Sponsored Studies

(Template version: 1.6)

Guidance on using this document:

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS Form. In most instances the Organisation Information Document should be localised before sharing with participating NHS / HSC organisations.

Questions/items marked with an asterisk * (Questions 1-3, 5, 8 and 12-15 and 18, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS Form in all cases. Only if the localised Organisation Information Document is to be used as the Agreement between the parties should the Sponsor or authorised delegate check the relevant check boxes at the top of each subsequent appendix and complete the authorisation section.

Items marked with a caret ^ are completed by the participating NHS / HSC organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the participating NHS / HSC organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the document, click in a box with the grey text (click here to enter text), or choose the relevant option if presented with a drop-down list.

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

We welcome your feedback on the use of the UK Local Information Pack using our online feedback form.

Study Information

1.* IRAS Project ID	292511
2.* Full Title of the Study	Interruptions and Medication Errors: A mixed methods study
3.* Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors	University of Birmingham
4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.	
Name	Samantha Owen

Telephone Number	Enter telephone number
Email Address	
5. * Are all participating NHS / HSC organisations undertaking the same protocol activities?	
Yes	
If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.	
If no, give details	

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement.
Birmingham Women's and Children's Hospital Trust
7. Location/s*:* Please provide detail below where it is planned to undertake the research only at specified locations with the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s))**.** It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation.

Location (enter text below)	**Activity** (enter text below)
Location (enter text below)	**Activity** (enter text below)
PICU - Birmingham Children's Hospital	PPI Survey
PICU - Birmingham Children's Hospital	Identifying eligible participants
PICU - Birmingham Children's Hospital	Approaching and consenting eligible participants
PICU - Birmingham Children's Hospital	Randomising participants
PICU - Birmingham Children's Hospital	Delivering Education Intervention
PICU - Birmingham Children's Hospital	Observations
PICU - Birmingham Children's Hospital	Focus Group
PICU - Birmingham Children's Hospital	Dissemination of study results to participants

8*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?

- Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, local collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, select Chief Investigator.

Principal Investigator

9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.

Name	Dr Julie Menzies
Post / Job Title	PICU Nurse Researcher, NIHR 70@70 Senior Nurse Research Leader
Name of Employing Organisation	Birmingham Women's and Children's NHS Foundation Trust
Email Address	
Telephone number	

Timescales

10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation
The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this participating NHS / HSC organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation.

Predicted Start Date (activities at this organisation)	05/04/2021
Predicted End Date (activities at this organisation)	01/11/2021

For many types of study the following dates are not applicable and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and participating NHS / HSC organisation after sharing the pack.

Predicted Site Initiation Visit Date	N/A
Predicted Start Date for participant recruitment	22/03/2021
Predicted End Date for participants recruitment (i.e. when the study moves into "follow up" activities.)	05/04/2021
Predicted End Date for all study activities (i.e. "last patient visit" completed and study is ready to be archived.)	01/11/2021

Participant Numbers

11. How many research participants are expected at this participating NHS / HSC organisation?

For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained.

Please state if number of participants is per month, per year, overall, etc.

Max 24 participants overall

Study set up and delivery arrangements at Participating NHS / HSC Organisations

12*. The following are needed at the participating NHS / HSC organisation to deliver the study:

e.g. specific equipment, patient/participant groups, service support, nursing time, etc**.** Please detail any specific requirements for participating NHS / HSC organisations to deliver this study, including by clarifying any requirements on participating NHS / HSC organisations relating to monitoring / self-monitoring, e.g. requirements for staff signature and delegation logs to be returned to the Sponsor and/or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the participating NHS / HSC organisation, likelihood of staff not employed at the participating NHS / HSC organisation coming on site, etc.

Increased allocated training time for nurses to allow for consent, e-learning and presentation (no more than half a day). PPI group time for online survey (no more than 5 minutes). PICU Staff time to complete a short survey (no more than 5 minutes). Consented staff to participate in a focus group (no more than 1 hour).
13* . The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified.
Briefing of any additional staff observers if necessary (e.g. use of data collection tool).
14* . The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities. It would not be usual for the Sponsor to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect **training in Good Clinical Practice** for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the **Transcelerate mutual recognition scheme**, etc.
Up to date GCP.
15* . The following funding/resources/equipment, etc. is to be provided to this participating NHS / HSC organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the
participating NHS / HSC organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2.
N/A

16^ The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the UK Policy Framework for Research and Social Care..	Confirmed
17^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.	Not applicable
If yes, please detail conflict of interest	

Sponsor Authorisation

18* Authorised on behalf of Sponsor by:	
Name	Dr Birgit Whitman

Job Title	Head of Research Governance and Integrity
Organisation Name	University of Birmingham
Date	19 April 2021

Appendices

(Contents)

The sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement ("Agreement") between itself and the participating NHS / HSC organisation, the questions that appear at the top of each subsequent appendix.

Appendix 1: General Provisions

***Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the participating NHS / HSC Organisation, or has a separate site agreement been provided?** It is recommended that the Organisation Informati Sponsor and participating NHS trials or investigatic investigations. Where the Organisation Informati Sponsor where this document is the Agreement Additionally, the Sponsor or authorised delegate subsequent appendix to indicate whether or not th Text highlighted in yellow clause may be used. The applicable option should submission. No changes should be mad does not a	Organisation Information Document Agreement HSC organisation for studies that are not clinical Commercial Agreement (mNCA) should be used for on Document is to be used as the Agreement between the eafter singly "Party" or collectively the tract between the Parties. In all cases between the Parties, Appendix 1 applies in full. should use the questions at the top of each g where alternative versions of the same /s should be selected and text not to be used e to any text that

1. OBLIGATIONS OF THE PARTIES

1.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:

1.1.1. the Protocol, including appropriately made amendments thereto (which is/are hereby incorporated into this Agreement by reference);

1.1.2. the terms of all relevant permissions and approvals. These may include, but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee, where applicable.

1.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

1.3. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants and study personnel.

1.4. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating NHS / HSC Organisation's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.

1.5. The Participating NHS / HSC Organisation shall;

1.5.1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study;

1.5.2. allow the Sponsor to support the preparations for such inspection; and

1.5.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the funder if required.

1.6. In accordance with participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to clause 6 of this appendix. The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the study.

2. LIABILITIES AND INDEMNITY

2.1. Nothing in this clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the data protection legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

2.2. Where a Party is a non-NHS/HSC organisation, or an NHS/HSC organisation that is not a member of an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a participant. Where the Party is an NHS/HSC organisation and is a member of an NHS indemnity scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against

claims arising as a result of clinical negligence by the Party and/or its agents brought by or on behalf of the participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS/HSC organisation is a member of one of the NHS indemnity schemes.

2.3. **[SINGLE SPONSOR]** Subject to clauses 2.4, 2.5, 2.6, 2.7 and 2.8, the Sponsor shall indemnify the Participating NHS / HSC Organisation and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands ("Claims") to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Sponsor, and/or contracted third party, in its performance of this Agreement or in connection with the study.

2.4. Subject to clauses 2.3, 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the Sponsor and its agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its agents, in its performance of this Agreement or in connection with the study.

2.5. An indemnity under clauses 2.3 or 2.4 shall only apply if the indemnified Party:

2.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;

2.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and

2.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.

2.6. Any indemnity under clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.

2.7. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:

2.7.1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or

2.7.2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance

2.7.2.1. with the protocol; or

2.7.2.2. with written instructions of the manufacturer; or

2.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.

2.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

2.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

2.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland)
Order 1991: which established Trusts in Northern Ireland as appropriate; or

2.9.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

2.9.3. All Parties are NHS Foundation Trusts; Then
clauses 2.10, 2.11 and 2.12 shall apply.

2.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same indemnity scheme (being one of the NHS Resolution's clinical negligence schemes or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the indemnity schemes, then such Party shall rely on the cover provided by the indemnity scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant indemnity scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

2.11. If:

2.11.1. The Parties are members of the same indemnity scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its indemnity schemes; or

2.11.2. All Parties are NHS bodies in Scotland; or

2.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

2.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. **[SINGLE SPONSOR]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement

or any act or omission of either Party in connection with the performance of the study should be the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

2.14. Notwithstanding clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the study, the Participating NHS / HSC Organisation's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

2.15. **[OPTION FOR NON-NHS SPONSORS ONLY]** The Sponsor/co-Sponsors/joint-Sponsors agree/s that in respect of any personal injury or death of any participant as a result of participation in the study, it/they will provide no-fault compensation and will be insured to pay out on any such claims.

3. PUBLICITY

3.1. [Neither Party] shall use the name, logo or registered image of the other [Party] / or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

3.2. The content and timing of any publicity, advertising or press release shall be agreed by [both] Parties, such agreement not to be unreasonably withheld.

4. PUBLICATION

4.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full study and that the Participating NHS / HSC Organisation shall not publish any study data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

5. FREEDOM OF INFORMATION

5.1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.

5.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.

5.3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days' notice of its intended disclosure.

6. CONFIDENTIALITY

6.1. Subject to clause 5 above, the Participating NHS / HSC Organisation agrees to treat the results, excluding any clinical data of the study, as confidential information of the Sponsor and the Sponsor agrees to treat personal data and confidential patient information as confidential information.

6.2. The receiving Party agrees:

6.2.1. To take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this Agreement

6.2.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 6.2.

6.2.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal

basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.2.4. Not to disclose confidential information in whole or in part to any person without the disclosing Party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.3. The provision of clause 6.2 shall not apply to the whole or any part of the confidential information that is:

6.3.1. lawfully obtained by the receiving Party free of any duty of confidentiality;

6.3.2. already in the possession of the receiving Party and which the receiving Party can show from written records was already in its possession (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.3. in the public domain (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.4. independently discovered by employees of the receiving Party without access to or use of confidential information;

6.3.5. necessarily disclosed by the receiving Party pursuant to a statutory obligation;

6.3.6. disclosed with prior written consent of the disclosing Party;

6.3.7. necessarily disclosed by the receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

6.3.8. published in accordance with the provisions of clause 4.

6.4. The restrictions contained in clause 6.2 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 2: Finance Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? If no, this appendix should be left blank. If yes, this finance appendix forms part of the Agreement between the participating NHS / HSC organisation and the Sponsor.	No

A. Financial Arrangements

The overall, study-wide recruitment for this study is competitive with a maximum figure of [X] Participants. Once this target has been reached, the Sponsor will notify the Participating NHS / HSC Organisation. No additional per participant payments will be made by the Sponsor to the Participating NHS / HSC Organisation for participants consented after such notification becomes effective.

	* **Area of Cost**	* **Payment (£ Sterling)**
1 *	Click here to enter text	Click here to enter text
2 *	Click here to enter text	Click here to enter text
3 *	Click here to enter text	Click here to enter text
4 *	Click here to enter text	Click here to enter text

5*	Click here to enter text	Click here to enter text

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation's VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements [Insert FREQUENCY OR INTERVAL e.g. quarterly

*Invoices to be submitted] to:

[Insert JOB TITLE, NAME OF BODY & ADDRESS]

^Payment to be made by cheque payable to:

[Insert NAME OF PARTICIPATING NHS / HSC ORGANISATION]

^and remitted to:

[Insert JOB TITLE/POSITION] [Insert ADDRESS]

^Or arrange BACS Transfer to: [Insert BANK NAME].

^Sort code: [Insert SORT CODE]

^Account: [Insert ACCOUNT NUMBER]

^And send the relevant paper work to [Insert ADDRESSEE FOR PAPERWORK] at the above address

Invoices must be paid promptly [within xx days of receipt]. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the funder as a result of such delay or inadequacy.

B. Supplies Arrangements

Any equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the participating organisation for use in the study shall be specified below.

Note 1: Parties should complete the table below. If the Participating NHS / HSC Organisation is to procure any items and is to be reimbursed by the Sponsor this should be specified in this appendix. Similarly if the Participating NHS / HSC Organisation is to pay the Sponsor for

any items provided to the Participating NHS / HSC Organisation by or on behalf of the Sponsor this should be specified in this appendix.

Note 2: Parties should specify in this appendix, as appropriate, arrangements for:

- Ownership of items
- Insurance
- Storage instructions
- Instructions for use, return and/or destruction
- Any training to be provided - Maintenance of equipment

Item	**Quantity**	**Frequency of supply**	**Responsibility to supply/procure (either Sponsor or Participating NHS / HSC Organisation only)**
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text

Appendix 3: Material Transfer Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve the transfer of human biological material from this participating NHS / HSC organisation to the Sponsor or its agents? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

Material, as used in this appendix, means any clinical biological sample or portion thereof, derived from participants, including any information related to such Material, supplied by the Participating NHS / HSC Organisation to the Sponsor/Joint Sponsors/either of the CoSponsors or [its] / [their] nominee.

1. In accordance with the protocol, the Participating NHS / HSC Organisation shall send Material to the Sponsor/joint Sponsors/a co-Sponsor or, in accordance with provision 7 below, to a third party nominated by the Sponsor/joint Sponsor s/either of the coSponsors.

2. The Participating NHS / HSC Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.

3. Subject to provision 2 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.

4. The Sponsor/joint Sponsors/one of the co-Sponsors shall ensure, or procure through an agreement with the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above that:

   4.1. the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study;

   4.2. the Material is handled and stored in accordance with applicable law;

   4.3. the Material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent.

5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

6. The Participating NHS / HSC Organisation and the Sponsor/joint Sponsors/a co-Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this appendix.

7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor/joint Sponsors/co-Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor/joint Sponsors/co-Sponsor subsequently provides the Material or the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.

8. The Sponsor/joint Sponsors/co-Sponsor undertake(s) that, in the event that Material is provided to a third party in accordance with provision 2 above, [it] / [they] shall require that such third party shall undertake to handle any Material related to the study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this appendix.

9. Any surplus Material that is not returned to the Participating NHS / HSC Organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

**These provisions do not remove the need for the Sponsor to clearly lay out in their protocol (and to potential participants in the participant information) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: www.hra.nhs.uk*

Appendix 4: Data Processing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve any processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation. For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3).	No

1. For the purposes of the data protection legislation, the Sponsor is the controller and the Participating NHS / HSC Organisation is the Sponsor's processor in relation to all processing of personal data that is processed for the purpose of this study and for any future research use under the controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that processing takes place.
2. The Parties acknowledge that whereas the Sponsor is the controller in accordance with Clause 1 of this appendix, the Participating NHS / HSC Organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants. This personal data may be the same personal data, collected transparently and processed for research and for care purposes under the separate controllerships of the Sponsor and Participating NHS / HSC Organisation.
3. Where the Participating NHS / HSC Organisation is the Sponsor's processor and thus where the processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the study, Clauses 5.a. to 5.j below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is processing the participant personal data as a controller.
4. The Participating NHS / HSC Organisation agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the study and to ensure the Sponsor's compliance with the data protection legislation;
5. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:

a. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

b. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2)) [DELETE IF THE STUDY DOES NOT INVOLVE PICS, such authorisation for engaging Participant Identification Centres (PICs) being hereby given. The Participating NHS / HSC Organisation will notify the Sponsor of any new PIC engaged in advance of that PIC's commencement of PIC activities and the Sponsor will notify the Participating NHS / HSC Organisation of any objections in a timely manner];

c. to process the personal data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).;

d. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

f. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

g. to, taking into account the nature of the processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

h. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f));

i. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Participating NHS / HSC Organisation as controller for the purpose of clinical care or other legal purposes; and

j. to maintain a record of processing activities as required by Article 30(2) GDPR.

6. The Participating NHS / HSC Organisation shall ensure that:

a. its agents do not process personal data except in accordance with this Agreement (and in particular the protocol);

b. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

i. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause;

ii. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

iii. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

7. The Participating NHS / HSC Organisation agrees to:

   a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation's compliance with the obligations described by this Appendix, data protection legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the participating site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

   b. obtain prior agreement of the Sponsor to store or process personal data outside the European Economic Area.

8. Where the Participating NHS / HSC Organisation stores or otherwise processes personal data outside of the European Economic Area as the Sponsor's processor, it warrants that it does so in compliance with the Data Protection Legislation.

Appendix 5: Data Sharing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS/HSC organisation, please select an option below.	
* Does this study involve the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, or transfer of confidential information between the Parties? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

1. Personal data shall not be disclosed to the Sponsor by the participating NHS / HSC organisation, save where this is required directly or indirectly to satisfy the requirements of the protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
2. The Sponsor agrees to use personal data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
   2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.

3. The Sponsor agrees to comply with the obligations placed on a controller by the data protection legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The Sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
    4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating NHS / HSC organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
    4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
    5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
    5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.
    5.3. To identify, review and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
    5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
    5.5. To take action immediately following a data breach or near miss.
6. The Sponsor agrees to ensure personal data are processed using secure and up to date technology. In particular,
    6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
    6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
    6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they Process and for meetings all relevant information governance requirements.

Appendix 6: Intellectual Property Rights

Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC organisation, please select an option below.	
* Does this study require the protection of background intellectual property rights, or is there potential for the generation of new intellectual property? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

1. All background intellectual property rights (including licences) and know how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
2. All intellectual property rights and know how in the Protocol, and in the study data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such intellectual property rights, and undertakes to disclose all such know how, to the Sponsor.
3. Subject to clauses 1 and 2, all intellectual property rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the intellectual property rights in the Sponsor. To give effect to this clause 4, the Participating NHS / HSC Organisation shall ensure that its agents involved in the Study assign such intellectual property rights falling within clauses 2 and 3 and disclose such know how to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own know how or clinical data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor, or their funder. This clause 5 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results. Any study data not so published remains the confidential information of the Sponsor, or their funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use study data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor or their funder. This clause 6 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the Study.

Authorisation When Using This Organisation Information Document as An Agreement

(when used as an Agreement, the Participating NHS Organisation is a "Party" to the Agreement and the Sponsor is a "Party" to the Agreement – collectively the "Parties").

Authorisation on behalf of Participating NHS / HSC Organisation It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).	
^ Authorised on behalf of Participating NHS / HSC Organisation by:	
Name	e.adey
Job Title	Head of R&D
Organisation Name	BWC
Date	12 July 2021

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Appendix 8 – HRA Approval

Samantha Owen, BHP Starter Fellow/PICU Clinical Research Nurse, Email: approvals@hra.nhs.uk
University of Birmingham, HCRW.approvals@wales.nhs.uk
Edgbaston, B15 2TT

04 June 2021

Dear Samantha

HRA and Health and Care

Study title:	**Interruptions and Medication Errors: A mixed methods study**
IRAS project ID:	**292511**
Protocol number:	**ERN_20-1646**
REC reference:	**21/HRA/1923**
Sponsor	**University of Birmingham**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **292511**. Please quote this on all correspondence.

Yours sincerely,

Matt Rogerson

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Birgit Whitman* **List of Documents**

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Interruptions and Medication Errors: A mixed methods study Poster V1.1 19.04.2021]	1.1	19 April 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Interruptions and Medication Error: A mixed method study Insurance Letter]	1.0	26 April 2021
Interview schedules or topic guides for participants [Interruptions and Medication Errors: A mixed method study Focus Group Topic Guide 1.2 19.04.2021]	1.2	19 April 2021
IRAS Application Form [IRAS_Form_28042021]		28 April 2021
IRAS Application Form XML file [IRAS_Form_28042021]		28 April 2021
Letter from sponsor [Interruptions and Medication Errors: A mixed method study Sponsor Letter]	1.0	26 April 2021
Non-validated questionnaire [Interruptions and Medication Errors: A mixed method study Audit Form V1.2 19.04.2021]	1.2	19 April 2021
Organisation Information Document [Interruptions and Medication Errors: A mixed method study OID V1.1 19.04.2021]	1.1	19 April 2021
Participant consent form [Interruptions and Medication Errors: A mixed methods study Consent Form V1.4 19.04.2021]	1.4	19 April 2021
Participant consent form [Interruptions and Medication Errors: A mixed method study Focus Group Consent Form V1.1 29.03.2021]	1.1	29 March 2021
Participant information sheet (PIS) [Interruptions and Medication Errors: A mixed method study PIS V1.6 26.03.2021]	1.6	26 March 2021
Participant information sheet (PIS) [IInterruptions and Medication Errors: A mixed method study Focus Group PIS V1.3 19.04.2021]	1.3	19 April 2021
Research protocol or project proposal [Interruptions and Medication Errors: A mixed method study protocol V1.0 20.04.2021]	1.0	20 April 2021
Summary CV for Chief Investigator (CI) [Sarah Pontefract CV]	1.0	06 January 2021
Summary CV for student [Samantha Owen CV]	1.0	06 January 2021
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [University of Birmingham Liability Document]	1.0	26 April 2021
Summary of any applicable exclusions to sponsor insurance (nonNHS sponsors only) [University of Birmingham CT Coverage]	1.0	26 April 2021

IRAS project ID	292511

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pac expectations

There is only one participating NHS organisation therefore there is only one site type.	Organisations will not be required to formally confirm capacity and capability, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met. You have contacted participating NHS organisations (see below for details)HRA and HCRW Approval has been issuedThe NHS organisation has not provided a reason as to why they cannot participateThe NHS organisation has not requested additional time to confirm.	An Organization information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No study funding will be provided to sites as per the Organization information Document	A Principal Investigator should be appointed at study sites.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertakin any of the research activities listed in the research application would be expected to hold Letters of Access if focus groups/interviews were held in clinical areas. Letters of Access would not be expected if they were held in nonclinical/administrative buildings.

	You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1.				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 9 – Sponsor Approval

FINANCE OFFICE

UNIVERSITY OF BIRMINGHAM

Dr Sarah Pontefract
School of Pharmacy and Therapeutics

University of Birmingham

Thursday, 22 April 2021

Dear Dr Pontefract

Project Title: **Interruptions and Medication Errors: A mixed methods study**
IRAS ID: **292511**
Sponsor Reference: **RG_20-166**
UoB Ethics Reference: **ERN_20-1646**

Under the requirements of UK Policy Framework for Health and Social Care Research, the University of Birmingham agrees to act as Sponsor for this project. Sponsorship is subject to you obtaining a favourable ethical opinion, HRA approval and NHS R&D management approval where appropriate.

As Chief Investigator, you must ensure that local study recruitment does not commence until all applicable approvals have been obtained. Where a study is or becomes multi-site you are responsible for ensuring that recruitment at external sites does not commence until local approvals have been obtained.

Following receipt of all relevant approvals, you should ensure that any subsequent amendments are notified to the Sponsor, REC, HRA and relevant NHS R&D Office(s), and that an annual progress report is submitted to the Sponsor, REC and NHS R&D departments where requested.

Please ensure you are familiar with the University of Birmingham Code of Practice for Research (http://www.birmingham.ac.uk/Documents/university/legal/research.pdf) and any appropriate College or School guidelines.

Finally please contact researchgovernance@contacts.bham.ac.uk should you have any queries.

You may show this letter to external organisations.

Yours sincerely

[redacted]

Dr Birgit Whitman

Head of Research Governance and Integrity

cc: Samantha Owen (Medical and Dental Sciences)

Appendix 10 – Insurance Confirmation

UNIVERSITY OF BIRMINGHAM

FINANCE OFFICE

To Whom It May Concern,

Thursday, 22 April 2021

Dear Sir / Madam,

Project Title: **Interruptions and Medication Errors: A mixed methods study**

Sponsor Reference: **RG_20-166**

The University currently arranges Clinical Research Insurance through membership of UMAL, this cover is renewable annually on 1st August and the University ensures that there are no gaps in cover.

We confirm that the University will arrange insurance for the above research for the duration of the research project involving human participants including legal liability cover. This will be subject to the terms, conditions and exceptions of the relevant liability insurance policies as detailed in the current trial documentation.

The University will provide notification if there are any changes to the provider in a particular year or if the indemnity limits change. Copies of the trial specific annual confirmatory letters will be available upon request.

Yours faithfully,

Dr Birgit Whitman Head of Research Governance and Integrity

Appendix 11 – R&D Approval

Birmingham Women's and Children's NHS Foundation Trust

BIRMINGHAM CHILDREN'S HOSPITAL DETAILS: Research and Development
Birmingham Women's and Children's NHS Foundation Trust
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
B4 6NH
Tel: 0121 333 8751
BWC.research@nhs.net

12/07/2021

Julie Menzies/Sam Owen

PICU
Birmingham Women's and Children's NHS Foundation Trust

Dear Julie and Sam,

Re: Birmingham Women's and Children's Hospital NHS Foundation Trust R&D Confirmation of Capacity & Capability

Project Title: Interruptions and Medication Errors: A mixed methods study
IRAS Ref: 292511
REC Ref: 21/HRA/1923
R&D No: 21/BC/COR/NO/546
Protocol: ERN_20-1646

Thank you for informing Birmingham Women's and Children's NHS Foundation Trust's R&D office of the above project.

I can confirm that Birmingham Women's & Children's NHS Foundation Trust has the capacity and capability to deliver the above referenced study and therefore is issuing R&D Confirmation of Capacity & Capability for this project.

Please find attached our agreed Organisational Information Document as confirmation.

R&D Confirmation of Capacity and Capability of the study is subject to the following conditions:

- If you have not already done so you must ensure that you and other members of the research team complete Good Clinical Practice ('GCP') training and a copy of your certificate is forwarded to the R&D Department before conducting your research.

- The research is conducted in line with the guidance given within the UK Policy Framework for Health and Social Care Research and where appropriate the Medicines for Human Use (Clinical Trial) Regulations 2004. You must also apply the principles of ICH Good Clinical Practice in conduct of your research.

- The research will be conducted in compliance with Trust Policies and carried out in accordance with the General Data Protection Regulation (2018), Human Tissue Act 2004, Health & Safety at Work Act and the Caldicott principles and NHS Code of Confidentiality.

- Any proposed changes or amendments to the protocol will be notified to the ethics committee, the research sponsor and the R&D Manager/R&D Facilitator.

- The UK Policy Framework for Health and Social Care Research published by the Health Research Authority (HRA) and the UK Health Departments make clear that appropriate allocation of responsibility, and clear understanding of responsibility is fundamental to good overall governance of research. You must ensure that all researchers not employed by the Trust follow the standardised procedures for issuing Honorary Research Contracts (HRC) or Letters of Access (LOA) as laid down in the Research in the HR Good Practice Resource

  Pack http://www.nihr.ac.uk/policy-and-standards/research-passports.htm

- Procedures are in place to ensure collection of high quality, accurate data and the integrity and conditionality of data during processing and storage.

- Upon completion of the research you must complete an End of Study report and submit this to
  Ethics and copy in the R&D Manager/R&D Facilitator at Birmingham Women's and Children's NHS Foundation Trust. http://www.hra.nhs.uk/research-community/end-of-study-andbeyond/notifying-the-end-of-study/

- If your project has been adopted by the National Institute for Health Research (NIHR) portfolio you will be required to provide monthly recruitment figures to the R&D Office (or manually update the R&D Database with this (EDGE) and address any issues affecting recruitment.

- That the Chief/Principal Investigator and the research team should be familiar with BWC trial Standard Operating Procedures. These SOPS can be found at the following location on the trust intranet. https://intranet.bwc.nhs.uk/departments/r/research/research-anddevelopment/research-documents/

- The study will be run as outlined in roles and responsibilities section of the CI/PI Agreement which has been duly signed and returned to R & D

NIHR funding to providers of NHS services is conditional on meeting the 60-day benchmark (noncommercial research) to recruit first patient following submission of a complete local package. The date for receipt of a complete local package for this study was 07/06/2021. This therefore equates to a 60 day target date of 6/08/2021

In order for the Trust to collate the data on meeting this condition, please inform R&D when you recruit your first patient. Please can you also inform R&D of any circumstances outside your control that may affect your ability to achieve this target, such as sponsor delays with Site Initiation. The information on both of the above aspects can be e-mailed to bwc.research@nhs.net.

Please see attached HRA approval letter dated 4/6/2021. All approved documents can be accessed via EDGE using the local project reference.

May I also draw your attention to the UK Policy Framework for Health and Social Care Research which can be found on the internet https://www.hra.nhs.uk/planning-and-improving-research/policiesstandards-legislation/uk-policy-framework-health-social-care-research/ and remind you that all research within the Trust should be run to the standards as outlined in this document. Guidance and advice is always available from the Department of Research and Development should you require it at any stage of your project.

Your research activity is now covered by NHS indemnity as set out in HSG (96) 48, and your trial has been entered into the Trusts' database.

The Trust conducts regular audits to monitor 10% of all projects on an annual basis. You must comply with the requests as they have the authority to audit your site files at any time.

If you have any queries relating to R&D, please do not hesitate to contact me. The Trust wishes you success with your research.

Yours sincerely

Head of R & D

Appendix 12 – Online Learning Module

Module Development Template

Module Title:

The user will click on each section to reveal the text you write in the templates below.

Session Information	Module Group: PICU Nurses (Medication Interruption Study Participants) Module Title: Medication Interruptions Module Short Code:
Brief Module Description Displayed on page 1 of your session entitled 'Module overview' (50-75 words)	A short paragraph (a couple of sentences) describing the session. In this module, we will discuss the epidemiology of medication interruptions, both in the UK and internationally. The consequences of medication interruptions will be discussed, and the protective behaviours you can engage in to reduce medication interruptions. To help consolidate your learning this eLearning module should be completed around 2 weeks after the zoom education session.
Learning Objectives These will appear on page 2 of your session entitled 'Module introduction'. (maximum five bullet points)	By the end of this session you should be able to: • Discuss the epidemiology of medication interruptions • Describe the consequences of medication interruptions • Discuss protective behaviours that can be adopted to manage medication interruptions • Recognise appropriate protective behaviour for different scenarios • Understand how being aware of the risks of medication interruptions and taking measures to reduce these risks, aligns with the NMC Code

Prerequisites Prerequisites will appear on page 2 of your session under the Learning Objectives	Prior to commencing this learning, you may want to reflect on your own experience on interruptions in clinical practice. • *What was the interruption for?* • *What were you doing at the time?* • *How did you / your colleague deal with the interruption?* • *What impact did the interruption have?* This eLearning module has been developed as part of a study to investigate the impact of an educational intervention on managing interruptions during the medication process. The module has been made freely available to all learners engaging with the Nursing Portfolio. However, you may notice that aspects of the content refer specifically to the study site. Your engagement with the learning is not part of the study unless you have specifically consented to this in discussion with the research team. Click here for more information if you are part of the study >> reveal below>> Before commencing this module, you have consented to participate in the 'Interruptions and Medication Errors: A mixed methods study'. As part of this study, you will have completed the education session for the study.
Introduction Seen on page 3 of your session (maximum 250 words)	

	Interruptions are common on the Paediatric Intensive Care Unit (PICU). The nature of PICU means that there are lots of different sources of interruptions, including; patient alarms, patients, family members, emergencies, phones, and staff members, to name a few. Not all interruptions are necessarily bad. Some interruptions alert you to new information and potentially life-threatening situations, which could have severe consequences if ignored. On the other hand, interruptions can also distract nurses from tasks, increase stress levels and contribute to mistakes. To reduce the risk of medication errors, it is important we can identify interruptions that need to be dealt with quickly and those that can wait. *Footnote – Understanding the risk of medication interruptions and taking measures to reduce them aligns with **Preserving Safety** area of the NMC Code. In particular, standards 19.1 & 19.2*
Session Key Points This list will appear on the penultimate page of your session (maximum 7 bullet points)	• Medication errors are the number one reported error on PICU at Birmingham Children's Hospital • Medication interruptions can increase the risk of medication errors • As a PICU nurse, you are at higher risk of being interrupted • It is important you apply your clinical knowledge and understanding to assess the risks of being interrupted • Clinical decision-making skills should be used to determine the most appropriate strategy for handling interruptions • Multi-tasking during medication episodes is not advised. • Engaging, mediating or blocking are useful strategies to manage interruptions.

STEP 2: Setting the scene

Page Title - Major heading (max 5-7 words long)	**Subtitle** (max 5-7 words long)
Module Title	Module Description (Mandatory)
Module Title	Learning Objectives and Session Prerequisites (Mandatory)
Module Title	Introduction (Mandatory)
Module Title	Session Key Points (Mandatory)
Module Title	In-module assessment: Introductory Case Vignette
Module Title - Epidemiology of medication interruptions	Medication Interruptions in PICU
Module Title - Consequences of Medication interruptions and errors	Consequences of Medication Errors
Module Title - Consequences of Medication interruptions and errors	Medication Errors
Module Title - Protective behaviours to manage interruptions	Introduction
Module Title - Protective behaviours to manage interruptions	Engaging
Module Title - Protective behaviours to manage interruptions	Multi-tasking
Module Title - Protective behaviours to manage interruptions	Mediating
Module Title - Protective behaviours to manage interruptions	Blocking
Module Title	End of module assessment

STEP 3: The Core Content

Page Title *(Major Heading)* Max 5-7 words	Epidemiology of Medication Interruptions
Page Sub-title Max 5-7 words	Medication Interruptions on PICU
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	 There has been lots of research into medication interruptions on PICU. Results have shown that the majority of medication episodes on PICU are interrupted. Critically ill children on PICU often need round the clock medications requiring complex medication procedures (Bower, 2018). Furthermore, due to the severity of the special patient group, medication preparation often takes place at the bedspace, meaning you are exposed to more interruptions (Bower, 2018). An audit of the medicines administration rounds on PICU at Birmingham Children's Hospital (2016) found that 81% of episodes observed were interrupted. Communications accounted for the

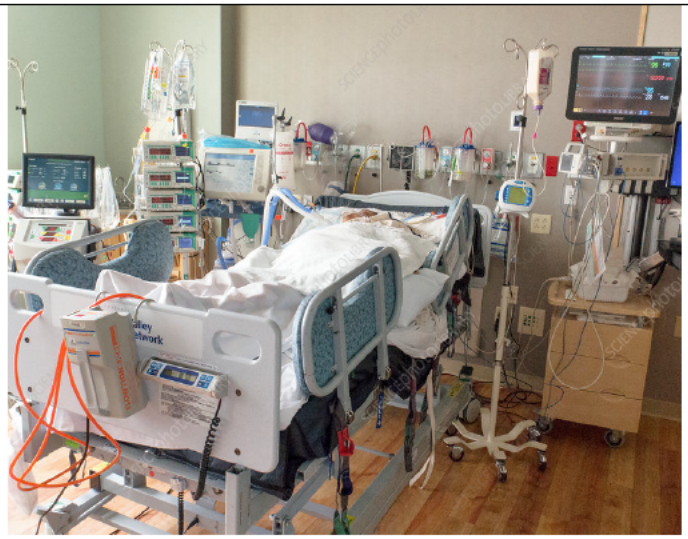
	majority of interruptions, with nursing communication causing 40% of the interruptions. The interruptions caused (on average) a 22 minute delay to the medication process – the length of a nurses break!
Image Content *Detail of images, graphics or animations that support the text*	Hospital Stock Illustration - Download Image Now - iStock (istockphoto.com) Paediatric ward - Stock Image - C035/3320 - Science Photo Library
Page Title *(Major Heading)* Max 5-7 words	Consequences of medication interruptions and errors
Page Sub-title Max 5-7 words	Medication Errors
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	 Interruptions and distractions are one of the leading causes of medication errors (Gladstone, 1995; Wakefield et al, 1998). Research

	suggests there is a cognitive cost of interruptions; diverting attention leading to omissions and affecting the quality of decision-making (McGills Hall et al, 2010). Preventable harm from medicines is a global problem (Dickinson et al, 2012) creating huge economic and social burdens. According to Elliot et al (2018), medication errors are preventable events that may lead to inappropriate medication use or patient harm. In the UK, the National Health Service (NHS) spends more than £750 million on the consequences of medication errors (NPSA, 2007). Approximately 237 million medication errors occur each year, and 66 million of these are potentially clinically significant. Furthermore, high profile reports have highlighted the need for further research into strategies to minimize the number of medication errors that occur (Francis, 2013; Patients First and Foremost, 2013). Adverse Drug Reactions (ADRs), are defined as "an unwanted or harmful reaction which occurs after administration of a drug or drugs and is suspected or known to be due to the drug(s)" (NICE, 2017). The estimated costs of definitely avoidable ADRs are £98.5 million per year, consuming 181,626 bed days in the NHS, causing 712 deaths, and contributing to 1,708 deaths (Elliot et al, 2018). Furthermore, errors often have consequences for staff. Staff can experience psychological trauma after making a medication error (Dumo, 2012), worrying about the consequences for their patient and if they will make another mistake. They can also lose confidence in their clinical abilities, potentially leading to increased stress in the workplace.

Image Content *Detail of images, graphics or animations that support the text*	Syringe Pill Capsule - Free image on Pixabay Hands On Face Depression Mistakes Text Drawing Stock Illustration - Download Image Now - iStock (istockphoto.com) Staff nurses checking intravenous antibiotic drugs - Stock Image - C046/4838 - Science Photo Library
Page Title *(Major Heading)* Max 5-7 words	Major Title (As in your contents table) Consequences of medication interruptions and errors
Page Sub-title Max 5-7 words	Subtitle (As in your contents table) Medication Errors
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	 Children and infants have been identified as a patient group who are particularly vulnerable to medication errors. This is often due to the complex nature of medication doses and administration in this population. Medication doses are calculated on an individual child basis, based on individual parameters such as; age group, development stage and weight.

	Medication errors account for the majority of incident reports at PICU BCH. Below are just a few examples of medication errors from PICU: • Recognised on the evening ward round patient received 2 x 10 fold overdose of captopril. Intent had been to give test dose of 0.1mg/kg and second dose 6 hours later of 0.2mg/kg. The patient was prescribed and received 1mg/kg and then 2mg/kg. The patient was not compromised by the overdose. • Heparin started as per cardiac surgical protocol. Patient's clotting checked routinely. PT 25, PTT >180. Heparin infusion and pump checked. Infusion was correct, however, the pump was programmed incorrectly (2,500 units in 50ml rather than 25,000 units in 50ml). Heparin noted to be charted as 10 units/kg/hr at 3ml/hr, it should have been 0.3ml/hr. The patient was reported to be 'oozy' and have blood stained secretions and coffee ground aspirates. Nurse believes pump was independently double checked.
Image Content *Detail of images, graphics or animations that support the text*	Hospital Stock Illustration - Download Image Now - iStock (istockphoto.com) Paediatric ward - Stock Image - C035/3320 - Science Photo Library

age Title *(Major Heading)* Max 5-7 words	Interruption Handling Strategies
Page Sub-title Max 5-7 words	Introduction
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	We know that not all interruptions are bad, and therefore we need different management strategies depending on the type of interruption. There are many different factors that need to be considered to ensure the right management strategy is chosen. Previously nurses have suggested they conduct both risk and efficiency assessments to determine how they proceed in a medication task (Colligan and Bass, 2012). They identify how 'risky' the medication is based on the likelihood and severity of medication errors. They also determine how easy it would be to pick the medication back up and the cost of delaying the primary task. Colligan and Bass (2012) have identified five task-related factors nurses consider during medication interruptions: 1. **Urgency of Task** – Medications that addresses an urgent need (e.g. adrenaline) are prioritised. Similarly, interruptions that address an urgent need (e.g. desaturation) are prioritised. 2. **Dynamics of Task** – Some interruptions can wait, however some interruptions can only be addressed for a short period of time 3. **Medication-specific Factors** – Some drugs are more familiar than others due to the frequency of use (e.g. furosemide, paracetamol etc.). These are less likely to lead to a dosing errors. However, if a drug is new or has a greater potential to cause harm (ciclosporin, potassium etc) they are more likely to block interruptions to be able to concentrate. What we should also remember though, is that the more familiar we are with certain drugs, the more likely we are to be complacent when drawing them up. This should also be considered when identifying how 'risky' a medication is. 4. **Patient-specific Factors** – paediatric nurses often have a family-centred focus when delivering care, and therefore, may be more likely to prioritise interruptions from parents/guardians/family members. Also, patients who are very sick or have challenging families maybe prioritized due to the consequences of potential drug errors. 5. **Task-specific Factors** – some tasks have sub tasks that can be suspended with reasonable support for task resumption. Allowing nurses to be interrupted but easily resume the task. *Footnote – Understanding your level of competence and familiarity with the drug is also part of the code that focuses on **Preserving Safety** (13)*

Image Content *Detail of images, graphics or animations that support the text*	Can the page be split into two?
Page Title *(Major Heading)* Max 5-7 words	Major Title (As in your contents table) Interruption Handling Strategies
Page Sub-title Max 5-7 words	Subtitle (As in your contents table) Engaging
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	 Now we have identified factors that need to be considered when interrupted, we need to know what strategies we can use to handle interruptions. Colligan and Bass (2012) explain that there is an 'interruption lag' between when a nurse is interrupted and the start of the secondary task. This lag occurs whilst the nurse prepares to stop the medication episode (the primary task). The interruption lag allows the nurse to use their decision-making skills to decide which interruption handling strategy is required. We are going to be looking at the interruption handling strategies identified by Colligan and Bass (2012) and Johnson et al (2018). **Engaging**

	If the interruption is due to a high priority secondary task – such as a patient emergency, the medication episode needs to be suspended and the secondary task engaged in immediately. We call this interruption handling strategy - engaging. It is important to use your experience and knowledge to determine which interruptions require this strategy. For example, if the monitor alarms interrupt a nurse due to their patient desaturating, it is entirely appropriate to use this strategy. However, if a doctor interrupts the medication episode to ask a question about the patient's status (non-emergency), engaging in the interruption increases the risks of errors being made.
Image Content *Detail of images, graphics or animations that support the text*	Renal patient on ventilator support - Stock Image - C029/8877 - Science Photo Library
Page Title *(Major Heading)* Max 5-7 words	Interruption Handling Strategies
Page Sub-title Max 5-7 words	Multi-tasking
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	 **Multi-tasking**

	Multi-tasking, along with engaging, is often the chosen strategy nurses use to deal with interruptions. However, multi-tasking is the strategy that poses the highest risk to medication safety. During multi-tasking the nurse deems both tasks to be of similar priority and therefore tries to undertake them simultaneously by dividing attention between the two tasks. For example, the nurse is currently drawing up intravenous paracetamol for a patient, during this medication episode the patient's parents ring for an update. The nurse continues to draw up the paracetamol whilst on the phone updating the parents. By trying to multi-task the nurse accidentally draws up 10 times the dose. It is essential you apply your knowledge of medication safety and the consequences of medication errors, to prioritise medication episodes. Multi-tasking is not a recommended strategy.
Image Content *Detail of images, graphics or animations that support the text*	Nurses checking medication - Stock Image - C015/3326 - Science Photo Library

Page Title *(Major Heading)* Max 5-7 words	Interruption Handling Strategies
Page Sub-title Max 5-7 words	Mediating
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	Sometimes nurses need to partake in the secondary task even if it is not an emergency. For example, the amber alarm is sounding but no action is needed. However, the alarm itself is an interruption and to leave the alarm continuing to sound will be a constant distraction. Here the nurse may find it easier to use the mediation interruption handling strategy. This strategy allows the nurse to stop the medication episode and tend to the secondary task. However, this differs from the engaging strategy, as when the nurse stops the medication episode, they take measures to support prospective memory (memory we need to make actions in the future). They do this by marking the state of the task or completing a subtask before moving onto the secondary task (Colligan & Bass, 2012). For example, they may have a mental checklist for the preparation and administration of a drug. Before they switch to the new task they may compete certain sub-tasks to make it easier to recommence the drug episode.
Image Content *Detail of images, graphics or animations that support the text*	Document And Clipboard List Icon Vector Stock Illustration - Download Image Now - iStock (istockphoto.com)

Page Title *(Major Heading)* Max 5-7 words	**Interruption Handling Strategies**
Page Sub-title Max 5-7 words	**Blocking**
Knowledge Content (Text) Text that will appear on the page. (maximum 200 words)	Blocking should be used when participating in a high priority task, for example, resuscitation drugs, high risk medicine, critical medicines or unfamiliar medicines. Due to the high priority of the primary task, any secondary task or interruptions will be blocked and the nurses will not engage in them. When adopting the blocking strategy, it is useful to apply a consistent approach, for example, with the use of a signal or phrase that is known to other staff. A phrase that can be used to block medication interruptions is *"I am currently preparing medication. Unless it is an emergency, I will speak to you when I have finished".* This phrase has been deemed appropriate during a survey with BCH staff members, patients and families. *Footnote – Being able to communicate clearly with colleagues and work with them to preserve the safety of those receiving care is part of the* ***Practicing Effectively*** *section of the code (7, 8 & 8.5)*
Image Content *Detail of images, graphics or animations that support the text*	No Trespass Sign Stock Illustration - Download Image Now - iStock (istockphoto.com)

Page Title **(Major Heading)** **Max 5-7 words**	Reflection
Page Sub-title **Max 5-7 words**	
Knowledge Content (Text) **Text that will appear on the page.** **(maximum 200 words)**	You should now be aware of the causes of medication errors, the task-related factors to consider and the protective behaviours you can use to manage the interruption. You may now want to think back to your personal examples of interruptions you recalled at the start of the module. • *With the information you now have, would you have done anything differently?* • *Would you have used a specific protective behaviour to manage the situation?* • *Do you think it would have made a difference to the outcome?*
Image Content **Detail of images, graphics or animations that support the text**	No Trespass Sign Stock Illustration - Download Image Now - iStock (istockphoto.com)

Session Key Points This list will appear on the penultimate page of your session (maximum 7 bullet points)	• Medication errors are the number one reported error on PICU at Birmingham Children's Hospital • Medication interruptions can increase the risk of medication errors • As a PICU nurse, you are at higher risk of being interrupted • It is important you apply your clinical knowledge and understanding to assess the risks of being interrupted • Clinical decision-making skills should be used to determine the most appropriate strategy for handling interruptions • Multi-tasking during medication episodes is not advised. • Engaging, mediating or blocking are useful strategies to manage interruptions.

Page Title (Major Heading) Max 5-7 words	Further Reading
Page Sub-title Max 5-7 words	
Knowledge Content (Text) **Text that will appear on the page.** **(maximum 200 words)**	• Colligan L, Bass EJ (2012) Interruption handling strategies during paediatric medication administration. Available at: https://www.researchgate.net • Johnson M et al (2018) A qualitative study of nurses' perceptions of a behavioural strategies e-learning program to reduce interruptions during medication administration. Available at: https://www.sciencedirect.com • Dickinson C et al (2012) A Systematic Approach to Improving Medication Safety in a Pediatric Intensive Care Unit. Available at: https://journals.lww.com • NSPA (2007) Safety in doses: Medication safety incident in the NHS: The fourth report from the Patient Safety Observatory. London: NSPA • Francis R (2013) Report of the Mid Staffordshire NHS Foundation Trust public inquiry: executive summary (Vol. 947) The Stationery Office • Department of Health (2013) Patients First and Foremost: The Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (Vol. 8576) The Stationery Office • Bower R (2018) A qualitative, exploratory study of nurses' decision-making when interrupted during medication administration within the Paediatric Intensive Care Unit. Available at: https://www.sciencedirect.com

	• Gladstone J (1995) Drug administration errors: a study into the factors underlying the occurrence and reporting of drug errors in and district general hospital. Journal of Advanced Nursing; 22(4): 628-637 • Wakefield B et al (1998) Nurses' perceptions of why medication administration errors occur. Medsurg Nursing; 7(1): 39-44 • McGillis Hall L et al (2010) Interruptions and pediatric patient safety. Available at: https://www.sciencedirect.com • Elliot R et al (2018) Prevalence and economic burden of medication errors in the NHS in England. Available at : https://dispensingdoctor.org/wp-content/uploads/2018/03/medication-error-report-revised-final.2-22022018.pdf • NICE (2017) Advanced drug reactions: Summary. Available at: https://cks.nice.org.uk/topics/adverse-drug-reactions/ • Dumo A (2012) Factors affecting medication errors among staff nurses: basis in the formulation of medication guide. Available at: https://www.researchgate.net
Image Content **Detail of images, graphics or animations that support the text**	

Step 6: Summative Assessment

Summative Assessment	Pre and Post Module Questions Question 1 During a medication episode a cardiac surgeon asks you for an update on your patient. Which ONE of the following is the best strategy for you to use in this case? • Blocking CORRECT • Engaging • Mediating • Multi-tasking • Negotiating >> Feedback In this scenario blocking would be the best strategy to adopt as the interruption is not high risk. Mediating and multi-tasking increases the risk of error, and as the update is not urgent it is not worth the risk. Engaging is not an appropriate strategy in this scenario as the cognitive cost of the interruption could lead to an error. Question 2 How many medication errors occur each year in the NHS (approximately)? • 137 million • 237 million CORRECT • 178 million • 278 million • 312 million >> Feedback Approximately, 237 million medication errors occur each year, and 66 million of these are potentially clinically significant. Question 3 You are drawing up your patient's flucloxacillin dose. You have printed the instructions and have just drawn up your water for injection when your IV pump starts alarming for occlusion. What protective behaviour should you utilise? • Blocking • Engaging

	• Mediating CORRECT • Multi-tasking • Negotiating >> Feedback In this scenario mediating would be the best strategy to adopt. The nurse can engage in measures to help support their prospective memory. The steps within the instructions will allow the nurse to leave the medication preparation to engage with the interruption, but help facilitate the nurse to recommence the task. Blocking the interruption is not needed as the instructions and step by step guide help reduce the risk of error. It is important to complete a sub-task of the medication episode, rather than just engaging in the interruption. The engaging strategy would not help support/facilitate the recommencing of the task and the risk of error would remain high. Multi-tasking is not an appropriate strategy as trying to complete both the medication episode and deal with the interruption simultaneously, increases the risk of errors being made Question 4 The familiarity of a drug is a part of which task-related factor, that nurses should consider during medication interruptions? • Urgency of Task • Dynamics of Task • Medication-Specific Factors CORRECT • Patient-Specific Factors • Task-Specific Factors >> Feedback Medication-Specific Factors consist of the familiarity of the drug, the severity of the drug and the complexity of the drug, It is important to recognise that complacency may effect how 'risky' we determine a drug is. Question 5 During a medication episode the emergency alarm goes off in PICU, you realise that the patient in the bedspace next to you has desaturated and requires help. What protective behaviour is the most appropriate strategy in this scenario? • Blocking • Engaging CORRECT

- Mediating
- Multi-tasking
- Negotiating

>> Feedback
In this scenario engaging would be the best strategy to adopt as the interruption is a high priority task and requires immediate attention. Blocking would not be appropriate as it puts the patient's safety at risk.
Mediating and multi-tasking would also not be appropriate, due to the urgency of the interruption and the high risk to the patient's health.

Question 6

You are trying to draw up an adrenaline infusion for your patient who has become hypotensive. The team leader asks about an interpreter for the patient's MDT later today. What strategy do you use to manage this situation?

- Blocking CORRECT
- Engaging
- Mediating
- Multi-tasking
- Negotiating

>> Feedback
In this scenario blocking would be the best strategy to adopt. Dealing with the patient's hypotension must be the priority and every effort should be made to reduce the risk of error when drawing up this drug.
Mediating and multi-tasking would be too risky when the patient's health is currently deteriorating.
And engaging in the interruption would be completely inappropriate and put the patient's health at risk.

Question 7

In the recent audit of medication episodes on PICU, what was the percentage of episodes that were interrupted?

- 81% CORRECT
- 75%
- 61%
- 85%
- 71%

>> Feedback
The audit found that 81% of episodes observed were interrupted.

Question 8

What was the most frequent type of interruption?

- Patient Emergency
- X-Ray
- Communication CORRECT
- Physio
- Patient care need

>> Feedback
The audit found that communication contributed to 40% of the overall interruptions and nurses were the main cause of these types of interruptions.

Question 9

You have drawn up a heparin infusion and had it checked by your neighbour. You are just about to programme the pump, when the nurse next to you wants to handover their patient so they can go on break. Which medication strategy do you use?

- Blocking CORRECT
- Engaging
- Mediating
- Multi-tasking
- Negotiating

>> Feedback
Blocking is the most appropriate strategy for this scenario. We know heparin is a high-risk drug and has the potential for errors. It is important you stay focused on this task and block out the interruption.
Engaging, multi-tasking and mediation could all increase the risk of medication errors which could cause severe harm to the patient.

Question 10

What are the consequences of interruptions?

- Reduces the quality of decision-making CORRECT
- Increases the time needed to complete a medication episode CORRECT

	• Increases the risk of omissions CORRECT • Increase levels of frustration for nurses CORRECT • Increases the risk of errors CORRECT >> Feedback All of the above are potential consequences of medication interruptions and the reason we are tying to reduce the risk of medication interruptions.

Author Name, Title and Affiliations *(First Author)* Appears at end of session	Full Name: Samantha Owen Author's title: Birmingham Health Partner's Starter Fellow/PICU Clinical Research Nurse University of Birmingham/Birmingham Children's Hosptital Academic, NHS or other affiliation here together with city and country.
Author Biography A link to your biography will be displayed with your name on the title page of the module.	I have been working in the Paediatric Intensive Care Unit at Birmingham Children's Hospital since 2016. I first became interested in medication interruptions during my final year as a student when I helped with a medication audit on PICU at Birmingham Children's Hospital. During this audit we observed over 380 medication episodes to determine how many interruptions and delays nurses faced during this process. Since starting at PICU, I have secured a junior sister post with the research team and have gone onto complete a Clinical Academic Internship Programme with the Birmingham Health Partners. I am currently studying for my Masters in research through my appointment as a Birmingham Health Partner's Starter Fellow. Both the Clinical Academic Internship Programme and the Starter Fellowship have allowed me to continue my research into Medication interruptions and the identification of strategies to combat this problem. Description of the author in 2-4 short paragraphs. Include information on background, professional interests and, in particular, give reference to your expertise in the area that you are writing about.

Peer Reviewer	Full Name: Dr Sarah Pontefract Lecturer in Clinical Pharmacy and Therapeutics, SCRIPT Programme Director University of Birmingham, Birmingham, UK

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Medication Interruptions and Errors: A Mixed Methods Study

Interview Topic Guide

- Introduction
  - Researcher introduces themselves
  - Check the consent form signed, are you happy with recording the interview and to continue in the study?
  - Introduces the aim of the study and the interview
  - Participant give a brief introduction of themself; how long they have been on PICU, previous experience, what stage they are in the foundation course now
- Medication Processes on PICU
  - What is it about the medication process on PICU that makes it high risk for example; task/environment?
  - Do you think interruptions during the medication process are risky? Have you ever experienced an interruption that you felt was risky? Would the learning have changed your approach to this?
- Intervention
  - The learning was delivered at the beginning of this study (date) and then you were observed in (date), do you feel that you remembered the learning throughout the whole of the study?
  - You have participated in an intervention study, what aspects of this intervention study (the education session, the simulation and the e-learning programme) did you find useful/not useful? *Is there any part you would change (e.g. would you add something, take something out etc)*
  - Do you think you changed your practice as a result of the learning?
  - Do you think you will continue to change your practice as a result of the learning?
  - Looking at the data, blocking is the strategy used the least, can you think as to why that might be – what are the barriers to blocking? What can help you (e.g. training) use and improve that approach?
  - Looking at the data, nurses struggled to appropriately handle interruptions from parents or colleagues the most, any ideas as to why? What could be done to improve this?
- Conclusion
  - Anything you found difficult about being a part of the research study?
  - Anything else you would like to say?
  - Thanks for participation.

- Prompts if needed:
    - What causes interruptions?
    - Did it help you to manage interruptions?
    - Is there anything else that could help you manage interruptions?
    - Do you have any perception of how many times and how long they add up to

Appendix 14 – Data Collection Tool

Participant _____

Bedspace _____

Medication Interruptions

Audit Form V.2.2 04.11.2021 IRAS ID: 292511

[redacted]

Drug Episode	Type of Interruption (use code)		Time duration for Interruption (mins: secs:ms)	Protective Behaviours Observed (use code)	
	Code	Description		Code	Description

	Type of Interruption (use code)		Time duration for Interruption (mins: secs:ms)	Protective Behaviours Observed (use code)	
	Code	Description		Code	Description
e.g. 1					

Medication Interruption Codes:

Interruption Codes:

A – Patient care Need
B – Own patient emergency
C – Silencing alarms
D – Neighbouring bed emergency
E – Telephone/Vocera call
F – Parental communication
G – Nursing staff interruption
H – Consultant/registrar interruption
I – Senior PICU staff interruption
J – Pharmacy staff interruption
K – Other Staff Interruption

Protective Behaviour Codes:

A – Engaging – medication episode is suspended and the focus is completely on the interruption
B – Multitasking – simultaneously trying to deal with the interruption and the medication episode
C – Mediating – stops the medication episode after completing a sub task to deal with the interruption, then picks the medication episode back up
D – Blocking – the interruption is blocked, and the focus remains on the medication episode