Safety Measures to Reduce Medication Administration Errors in Paediatric Intensive Care Unit

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Submitted to the University of Hertfordshire in partial fulfilment of the requirements of the degree of Doctor of Philosophy

February 2015

Acknowledgement

I would like to express my deepest appreciation to all those who have provided me with the support to take advantage of this life-changing opportunity. A very special thanks to Dr Maisoon Ghaleb and Professor Soraya Dhillon who have supervised this project and mentored my development. I am extremely grateful for all the unforgettable and stimulating discussions that helped to shape this research. I am sincerely much obliged to you for giving me the freedom to lead and take on this research.

This research would not have been possible without the support I received from staff and patients at Great Ormond Street Hospital. I witnessed the excellent world-class level of care provided by everyone at the PICU in particular. I thank Professor Mark Peters, Alison Taberner-Stokes, Rachelle Booth, Venetia Simchowitz and Ghislaine Stephenson for facilitating and welcoming this research. I cannot thank enough the unsung heroes that allowed me to observe them and exchanged thoughts on all circles of life and healthcare practice.

I highly appreciate the research committees of UK Paediatric Intensive Care Unit as well as the Neonatal and Paediatric Pharmacist Group for sending out questionnaires to their members. Their input in this study is of key importance. Also, all those doctors, nurses and pharmacists across the UK who took part in this study. I thank you all very much.

Furthermore, I am grateful for all the support I received from my colleagues at NHS England; Patient Safety Domain. Especially the Safer Medicines and Devices Team: Dr David Gerrett, Dr David Cousins, Steve Williams, Isobel O'Grady and Dagmar Luettel. The insightful and inspirational discussions I received on medication safety have been tremendous. I am thankful for all the learning opportunities you have given me. Also, I thank Windwood Chemist for their immense support: Mahendra Amin, Kirtida Mehta, Sarah Talia, Sandrine Hamzoie and Safoora Khatibzada.

I am also so thankful for the financial support by the University of Hertfordshire in funding this PhD Programme. It would have been extremely

difficult to undertake this programme without this help. Moreover, the support by Department of Pharmacy staff and clinical pharmacy practice research students was absolutely priceless. I have shared with them all the hardship of PhD and research. I thank them for their patience with me and I thank them for their infinite thought provoking questions. I have made many friends who, I am sure will be around in the coming years. I will always come back for advice and support from everyone in UH Pharmacy.

I have been blessed with friends that have made this journey less difficult. They have always motivated me by asking "when is this finishing?". I will not attempt to name any one of them individually. I sincerely thank you all for the support and knowing how to cheer me up in difficult times.

Lastly but by no means least, I cannot express how thankful I am for the endless encouragement and motivation I receive from my family. Words cannot express the amount of gratitude I have for my biggest role models; my parents. They have been the fuel that powered my development in everything. I will always be indebted to them for their unconditional advice, love and guidance. I would also like to thank my siblings Hayder, Zina and Khalid for their limitless supply of motivation and dealing with PhD induced mood swings. A big thank you to Baby Ali for not failing to put a big smile on my face every time.

Abstract

Objective: Medicine administration is the last process of the medication cycle. However, errors can happen during this process. Children are at an increased risk from these errors. This has been extensively investigated but evidence is lacking on effective interventions. Therefore, the aim of this research is to propose safety measures to reduce medication administration errors (MAE) in the Paediatric Intensive Care Unit (PICU).

Method: The research was carried out over five studies; 1) systematic literature review, 2) national survey of PICU medication error interventions, 3) retrospective analysis of medication error incidents, 4) prospective observation of the administration practice, and 5) survey of PICU healthcare professionals' opinions on MAE contributory factors and safety measures.

Results: Hospital MAE in children found in literature accounted for a mean of 50% of all reported medication error reports (n= 12552). It was also identified in a mean of 29% of doses observed (n= 8894). This study found MAE retrospectively in 43% of all medication incidents (n= 412). Additionally, a total of 269 MAEs were observed (32% per dose observation). The characteristics of the interventions used to reduce MAE are diverse but it illustrated that a single approach is not enough. Also for an intervention to be a success it is fundamental to build a safety culture. This is achieved by developing a culture of collaborative learning from errors without assigning blame. Furthermore, MAE contributing factors were found to include; interruptions, inadequate resources, working conditions and no pre-prepared infusions. The following safety measures were proposed to reduce MAE; 1) dose banding, 2) improved lighting conditions, 3) decision support tool with calculation aid, 4) use of pre-prepared infusions, 5) enhance the double-checking process, 6) medicine administration checklist, and 7) an intolerant culture to interruption.

Conclusion: This is one of the first comprehensive study of to explore MAE in PICU from different perspectives. The aim and objectives of the research were fulfilled. Future research includes the need to implement the proposed safety measures and evaluate them in practice.

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List of Abbreviations

ADE	Adverse Drug Effect
ADR	Adverse Drug Reaction
BCMA	Barcode Medicine Administration
BNF	British National Formulary
CI	Critical Incident
CIVAS	Central Intravenous Additive Service
CPOE	Computerised Physician Order Entry
CQC	Care Quality Commission
DF	Drug Formulation with difficult strength expression
DH	Department of Health
eCalculator	Electronic Calculator
eLearning	Electronic Learning
EMA	European Medicines Agency
FEMA	Failure Effect Mode Analysis
GOSH	Great Ormond Street Hospital
HR	High Risk Medicine
IV	Intravenous
MAE	Medication Administration Error
ME	Medication Error
MHRA	Medicines and Healthcare products Regulatory Agency
MRP	Medicine Related Problem
MSO	Medication Safety Officer

NHS	National Health Service
NICU	Neonatal Intensive Care Unit
NPPG	Neonatal and Paediatric Pharmacists Group
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OPE	Opportunities for Error
PICANet	Paediatric Intensive Care Audit Network
PICU	Paediatric Intensive Care Unit
PRISMA	Preferred Reporting Items for Systematic Review and Meta Analysis
QI	Quality Improvement
R&D	Research and Development
RCA	Root Cause Analysis
RCPCH	Royal College of Paediatrics and Child Health
REC	Research Ethics Committee
STEIS	Strategic Executive Information System
SUI	Serious Untoward Incident
UK	United Kingdom
UKPICS	UK Paediatric Intensive Care Unit
US	United States
WHO	World Health Organization

Chapter 1: Introduction

"If a physician operate on a man for a severe wound with a bronze lancet and cause the man's death, or open an abscess in the eye of a man with a bronze lancet and destroy the man's eye, they shall cut off his fingers."

Hammurabi's Code of Laws (1772 BC)

"Primum Non Nocere
[First Do No Harm]"
Hippocratic Oath (400 BC)

Providing healthcare is associated with threats to patient safety. Many of these threats are the result of latent failures and some are the result of active failures (Reason, 2000). Patient safety has been at the heart of medical practice since the beginning of civilisation as demonstrated by Hammurabi's code of law number 218 (Harper, 1904, p. 77). It was also emphasised by the Hippocratic oath of medicine. The World Health Organization (2006) have defined a patient safety event as "a process or act of omission or commission that resulted in hazardous healthcare conditions and/or unintended harm to the patient".

Ensuring safety in the medical field is becoming ever more complex and challenging. This is due to the rapid development and progression of medicine and medical practice over time. Patient safety concerns are widespread in developed, developing and transitional countries. An epidemiological study across 58 hospitals in five Latin American countries found that 1191 out of 11379 patients (10.5%) had had at least one adverse event related to medical care. In all, 60% of these adverse events were considered to be preventable (Aranaz-Andrés et al., 2011). Fortunately, Hammurabi's code is no longer practised, however, it is important to enforce legislations, monitoring and guidance amongst all healthcare professionals to ensure the

safety of patients is maintained at all times. It is also important to make changes to the system to minimise mishaps (Department of Health, 2000; Kohn, Corrigan, & Donaldson, 2000).

1.1 Children & Young People: Special Population

Children and young people are a large, vulnerable group. They are estimated by the census of 2011 to number around 15 million persons in the UK, representing around 23% of the total UK population (Office for National Statistics, 2012). This large group is broken down into:

- Infants (0–1 year of age)
- Toddlers (1–3 years of age)
- Pre-schoolers (3–5 years of age)
- Middle Childhood (6–11 years of age)
- Young Teens (11–14 years of age)
- Teenagers (15–18 years of age)

They undergo a rapid growth and development process from the very first day of life. This process of development will build up their strength physically and cognitively. Therefore, they face many challenges in this process. Some may require healthcare professionals' advice and a stay in hospital for treatment. It is estimated that 2.4 million children (aged 0 to 18 years) were hospitalised in 2012/2013 across England (Health & Social Care Information Centre, 2013).

The majority of these hospital admissions receive safe care but some encounter a patient safety incident. Most of these patient safety incidents are harmless and could be prevented. However, it is still unacceptable and lessons must be learnt to prevent these incidents happening again. Every now and then patient safety incident attracts wide media attention, one of the most recent incidents that attracted a public response related to a 10 year old girl who was injected with a glue in her brain instead of a surgical dye (Campbell, 2014). This has led to unfortunate permanent brain damage. This incident was found to have been avoidable if a simple safety measure had

been taken, such as marking the glue injection with a colour code. This case is so far the largest medical negligence case that has been settled at a London based high court. The hospital responsible was ordered to pay at least £24.2 million in compensation for life-long care.

Therefore, there is no room for error when providing care for this group of patients, since preventable incidents can have a major impact on their quality of life. High standards of care are always expected for this population regardless of pressures. It has been nearly 14 years since the recognition of the challenges of providing safe medication care by the Department of Health (2001) in their report on building a safer healthcare system.

The issue of safety and specifically safe use of medications is an international worry. Many agencies and departments formed to tackle this issue. However, the key developments for improving hospital patient safety in the United Kingdom, including children, are as follows:

- **An organisation with memory** report (Department of Health, 2000) recommendations included to develop:
    - Safety cultures within the organisation instead of blame cultures.
    - Error reporting to encourage learning and improvement to the system.
    - Clinical governance to support continuous improvement of care quality.
- **Building a safer NHS for patients: Implementing 'an organisation with a memory'** (Department of Health, 2001)
    - Introduced the National Patient Safety Agency (NPSA), an independent body to support adverse events and error reporting.
- **A spoonful of sugar** (Audit Commission, 2001)
    - Review of medicine management policies in hospitals against the recommendations of an organisation with a memory report.

  - Recognised the need for more pharmacist involvement in the management of medicines to ensure safe and effective use.

- **High quality care for all** report by Lord Darzi (2008)
  - Set out a future vision for NHS organisations of quality of care.
  - Underlined the importance of maintaining patient safety as top priority across the different settings.
  - Addressed Patient Safety First initiative by the NPSA.
- **Report of the children and young people's health outcomes forum** by Lewis and Lenehan (2012)
  - Putting children, young people and their families at the heart of things.
  - Mandatory reporting of medication errors to NRLS.
  - Ensure safe and sustainable services; development of bundle of interventions in order to eliminate or reduce medication errors.
- **A promise to learn – a commitment to act: improving the safety of patients in England** by Berwick (2013)
  - Need of systematic changes to improve leadership and transparency of patient safety incidents.
  - Remove blame culture and encourage development of modern quality improvement programmes.
  - Support NHS staff to learn and improve on patient safety matters.
- **Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry** by Francis (2013)
  - Duty of openness, transparency and candour throughout the healthcare system.

    - Improved support for compassionate, caring and committed care and stronger leadership.

- **National Medication Safety Network** by NHS England (2014b)

    - Collaborating to increase the number of medication incident reports, improve quality of reporting and support local and national learning from incidents.

it is noticeable that all major reviews, reports and initiatives by the various governmental organisations highlight the need to improve patient safety in children by: 1) being open and transparent, 2) continuously reviewing services to improve quality, 3) supporting changes to the system to prevent unintentional harm, 4) taking accountability of actions and learning from mishaps, and 5) maintaining high standards.

1.2 Hospital Care: Risky Environment

Hospitals are meant to be the places where people are least likely to be harmed. But they are now considered one of the most dangerous areas, compared to other industries such as aviation and nuclear power plants. These industries were traditionally associated with a high risk of harm if preventable errors occurred. However, these two industries were able to transform their safety records by the extensive use of checklists, automation of practice and sharing lessons. Children and young people in hospital are facing avoidable incidents (Sandars & Cook, 2009, pp. 1–2) such as:

- Diagnostic errors
- Infection control incidents
- Medical equipment failures
- Medication errors
- Patient access, admission, transfer or discharge incidents
- Surgical/Treatment mishaps

These incidents could be a result of the complex interaction of human factors and the healthcare system. In a report by the former National Patient Safety

Agency (2009, NPSA) that reviewed the incidents submitted to the National Reporting and Learning System (NRLS) for the period of one year (between 2007 and 2008). It was found that most incidents relate to use of medication (16%, n= 10041). The majority of these incidents were reported from acute settings (84%). These findings indicate that there is a need to investigate medication use in children's hospitals.

The issue of safety versus usual practice is a major issue in every regulated occupation where innocent lives can be put in risk. Two classic examples are the aviation industry or nuclear power reactors. Both industries are quite young compared to healthcare. However, they have learnt considerably from their mistakes. The introduction of checklists and changing the concept of teamwork played a major part in enhancing safety. The vast financial investments these industries have made into improving safety have to be admired. However, the key safety initiative that is the foundation of safe practice is minimising the differences between teams (Gordon, Mendenhall, Connor, & Sullenberger, 2013). This cultural change is vital since every member of the team can raise a concern without fear (Swartz, 2015).

Healthcare is very much like these high-reliability industries. Since healthcare serves a much wider scale in terms of population size and employs a large number of people with diverse professional backgrounds it is increasingly utilising advancing technology and providing services around the clock. Thus, there is no excuse for not improving safety and learning from others who have mastered it.

1.3 Medication Use & Errors in Children's Hospitals

The medicine use process in children's hospital as demonstrated in Figure 1.1 usually starts with the physician making a clinical diagnosis. Followed by a prescribing process in accordance with national guidelines and local protocols. A pharmacist will then clinically check this prescription/medication chart before dispensing. This process is carried out either in clinical areas such as the intensive care units or in the pharmacy dispensary. The third process is the administration of the medicine. Nurses mostly carry this out in line with administration procedures. The final process is the monitoring of the treatment. This is typically carried out using a multidisciplinary approach. The

aim of the monitoring process is to review patient's responses to treatment against clinical parameters, symptoms and blood levels.

A medication error can occur at any stage of this process. Medication errors (ME) were defined by the European Medicines Agency (2012, EMA) as "unintentional errors in the prescribing, dispensing, administration or monitoring of a medicine while under the control of a healthcare professional, patient or consumer. They are the most common single preventable cause of adverse events in medication practice". In a systematic literature review, Miller, Robinson, Lubomski, Rinke, and Pronovost (2007) found that prescribing errors range between 2 and 30 per 100 children's medication prescriptions. Whereas dispensing errors in children are between 5 and 58 per 100 reported ME. A review by Ghaleb et al. (2006) found that administration errors in children range between 0.6 and 27 per 100 reported ME. So far, limited research has been conducted to investigate monitoring errors in children's hospitals. Only one study is known to have investigated monitoring errors in children and this found it to be 4 per 1000 patients (Kaushal et al., 2001).

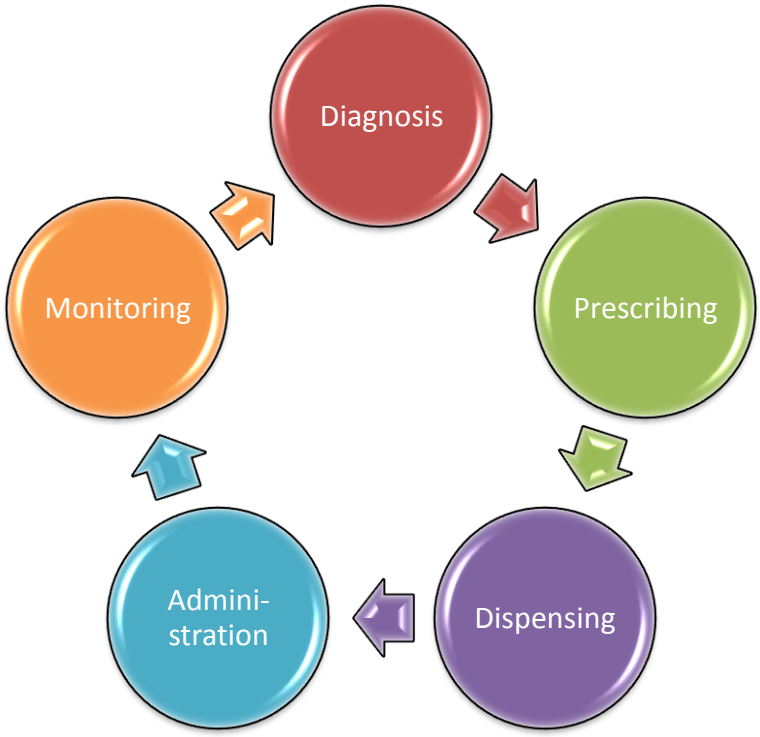

Figure 1.1: Medicine use process in children's hospital

The broad definition of ME evolved from a wide range of research. From this research expert consensus has highlighted two important points. The first point is that these errors are preventable. This could either be by changes to the system or by modification to human factors. The second point is that these errors are related to adverse events which refers to "any occurrence or injury related to management of a disease" (Goedecke, 2013). This also relates to the following concepts:

- Adverse Drug Reactions
- Adverse Drug Events
- Medicine Related Problems

Adverse drug reaction (ADR) is defined by the Directive 2010/84/EU (2010) as "a response to a medicinal product that is noxious and unintended. Effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse, off-label use and abuse of the medicinal product". This definition builds upon the World Health Organization (1972) and other medication safety experts such as Edwards and Aronson (2000). Whereas adverse drug events (ADE) were described by Edwards and Aronson (2000) as "an adverse outcome that occurs while a patient is taking a drug, but is not or not necessarily attributable to it". Therefore, ADE is related to issues such as drug interactions with other drugs, food or disease. But also it indicates that a medication error can lead to ADE that could cause an ADR.

On the other hand, a medicine related problem (MRP) is an "event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes" as defined by Pharmaceutical Care Network Europe Foundation (2010). Therefore, ADR, ADE and ME are considered to be subtypes of MRP. This also relates to patient use of medication. For instance in a paediatric context, many patients will be reliant on others administering their medication. So if that person is not aware of the dose requirement, the child could receive an overdose or an underdose that leads to an MRP.

Figure 1.2 illustrates this relationship and the research evolution of these concepts over time.

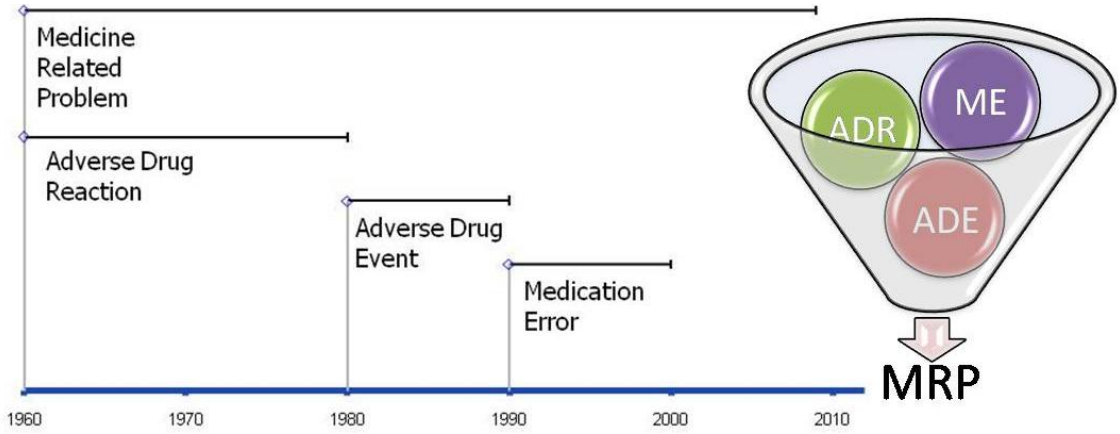

Figure 1.2: Evolution and relationship of medication safety concepts

Referring back to the definition of medication errors by the EMA, it was suggested that medication errors are the single most preventable adverse events. Thus, this is also correct for MRP. Controlling medication errors can have a real impact on both patients and the healthcare system, since medication errors can lead to serious harm that could be irreversible. Reducing patient risk will also reduce risk of readmission to hospital or a prolonged hospital stay. These factors are economically costly since the NPSA (2007b) estimated the cost of preventable harm from medicines in England is more than £750 million each year. This figure is likely to be on the increase due to: 1) more ME incident reports since the published report, 2) increased financial costs of providing healthcare in hospitals, and 3) lack of evidence that supports ME being on the decrease.

The system is designed to place barriers to stop ME from happening, such as pharmacists checking safe prescribing of medicines. However, it is often more complicated when dealing with children's medication. For instance, during prescribing special consideration is required when it comes to deciding a dose, since nearly all children's doses are weight-based. Also the process of dispensing is complicated by the need to adjust formulations to meet requirements for use in children. Moreover, the administration stage is challenged by the small physiology of children. Therefore, children's medication processes are likely to be more error-prone. Kaushal et al. (2001)

concluded in their prospective study that children are at a higher risk of developing potential ADE as a result of ME than adults ($p = 0.001$). The administration process is the last chance for errors to be intercepted, therefore, putting patients at a greater chance of unintentional harm. Hence, it is important to make sure that this process is secure and physical as well as non-physical measures are in place to avoid errors.

1.4 Medication Administration Errors in Children's Hospitals

The process of medication administration in children's hospital is complex. It is composed of two main procedures: the first is the preparation of the medication and the second is the administration of the dose to the child. Often a registered nurse carries this out, but occasionally doctors and trainee nurses take part in this process too. The process can be lengthy in time depending on the number of medicines to be administered and the preparation of the dosage form. For example a parenteral dose will take longer to prepare than an oral dose. Therefore, the risk of errors in this process is high. In a systematic literature review by Ghaleb et al. (2006) it was found that the rate of medication administration errors in children's hospitals is between 0.6 and 27 per 100 dose administrations.

There are different ways to complete this stage of the medicine cycle but the key components involve the following:

- Prescription for the medicine must be present before the process begins. The prescription will need to be checked against the prescribing protocol of the hospital or recommended resources such as the BNF.
- Assembly of the medicine must be carried out in a safe and clean area. Aseptic preparation may be needed for certain formulations such as intravenous infusions.
- Product collected needs to be checked against the prescription to ensure it is the correct medicine requested.

- The preparation will then be carried out in accordance to manufacturers' recommendations and hospital guidelines. For example, injectable medicines may require use of diluent and to take into consideration factors such as displacement volume and suitability. Similarly, oral doses will need to be measured using labelled/marked oral syringes and not intravenous syringes with ports as highlighted by the NPSA (2007a) alert.

- Administration of the medicine is then performed. Making sure that the correct medicine is given to the correct patient at the correct time with the correct dose via the correct route.

As can be seen from the description above, the process is lengthy, requires concentration and planning ahead. Thus, there are multiple opportunities for errors in this task. Each opportunity can lead to a potential for serious harm. For example, if the incorrect medicine is picked up due to sound alike/look alike cause but were prepared and administered as if it was the correct medicine. If no barriers are in place to prevent this from happening, it can potentially harm the child. Therefore it is important to study this area and develop a better understanding of the factors that could lead to harmful errors. This was reflected in a systematic literature review by Keers, Williams, Cooke, and Ashcroft (2013b) which found administration errors in children between 17.4% and 33.8% per 100 opportunities for error. On the other hand, in adult populations the error rate falls to between 4.7% and 27.8% per 100 opportunities for error as demonstrated by Keers et al. (2013b).

Other factors that can contribute to increased risk of errors in medication administration practice includes the extensive use of unlicensed and/or off-label medicines in children's hospitals (Conroy et al., 2000; Turner, Nunn, & Choonara, 1997). This is common in critical clinical areas such as the intensive care units. Unlicensed medicines are therapeutic agents without marketing authorisation from the medicines regulatory authorities. Whereas, off-label use is when a medicine is used for an indication outside the medicine regulatory authorities licensed indications.

The rate of error in these medicines has been investigated by Conroy (2011) who found an association of ME with unlicensed and off-label medicines. She

found that 42% (n= 34 reported incidents) were incidents in administration involving unlicensed and off-label medicines. Additionally, some medications are only available in a certain formulation. Hence will require extra preparation steps thereby increasing the opportunity for errors to occur (Conroy, Appleby, Rostock, Unsworth, & Cousins, 2007a; Gonzales, 2010). Also, many of these specially prepared formulations would have a shorter expiration date and require special storage conditions. Therefore, this further increases the risk of errors by mistakenly administering out-of-date medicines or forgetting to store the medicine appropriately in the fridge.

Also, not to forget that children's doses are relatively smaller than their equal adult doses. As is known, nearly all doses are based either on weight or body surface area. Thus, resulting in a challenge for the nursing team when preparing the doses since many formulations are not friendly for child dosing. Therefore, there is a potential for 10-times or more overdose far more easily than in adults (Gonzales, 2010). This issue can also lead to wrong infusion rate of parenteral medicines. Under dosing is also a potential risk and it could be harmful since the patient will be receiving a sub-therapeutic treatment.

An example of an overdose error was reported in an organisation with a memory report (Department of Health, 2000) where a premature baby girl died after being given an overdose of 15mg morphine instead of 0.15mg, this was due to miscalculation of the dosage by the Senior House Officer, which was checked by a nurse and administered by the Senior Registrar. The report documented many other examples where patients were harmed because of either human or systemic factors.

These factors relating to humans or the system can be explored using Reason's (2000) model of error causation. Reason suggests that errors occur as a result of either active failures or latent conditions. Active failures are the direct unsafe acts that led to an error. On the other hand, latent conditions are the factors in the system that provokes an error. A systematic literature review by Keers, Williams, Cooke, and Ashcroft (2013a) explored causes of administration errors in children's hospitals using Reason's model. Keers and his colleagues concluded that the main causes of administration errors in

children's hospitals were slips and lapses due to interruptions, workload and staffing levels.

Additionally, violations of tasks and knowledge-based errors are also a leading cause. Failure to interpret prescriptions correctly was also an associated cause along with mismatching patients. These contributory factors can lead to errors relating to delay or omission of the dose without a clinical justification. Bear in mind that administration of medicine is a skill, which requires training and experience.

Thus, healthcare professionals that are involved in giving medicine may encounter errors relating to their administration technique or failure. Moreover, normally administration of medicines to children involves use of medical devices such as infusion pumps that are subjected to errors in setting up and running the infusions.

1.5 Paediatric Intensive Care Unit

The Paediatric Intensive Care Audit Network (PICANet) reports a total of 60343 paediatric intensive care admissions (up to age 16 years old) for the period between 2011 and 2013 across the UK. This represents a 4% increase in admissions (PICANet, 2014). The mortality rate in PICU is very low since 96% of children were discharged alive in 2011 and 2013. The reports also document that only 15% (n= 5) of Paediatric Intensive Care Units (PICU) met the national standard for level of nursing (7.01 whole time equivalent per critical care bed) in 2013. This data is worrying since it is reflecting an increase in demand for critical care that is not being met with adequate staffing levels.

Children that are in critical clinical areas such as PICU are at a higher risk of being subjected to medication administration errors. This is due to the fact that these children are bound to be receiving more frequent administrations of medications compared to other acute wards. More likely to be required narrow therapeutic window medicines and intravenous infusions (Campino, Lopez-Herrera, Lopez-de-Heredia, & Valls-i-Soler, 2009; Suresh et al., 2004). Also there is a need for continuous dose calculations due to children specific pharmacokinetic considerations.

Moreover, medicine administration in the PICU is not allocated to specific time slots. Hence, administration could be frequent at any time. This is an important issue since there is a potential for administering medicines without clinical checks by a pharmacist. This also increases the chance of giving medicines at the wrong time due to prioritising other clinical duties or due to interruptions by other members of the healthcare team and the patient's companions. Also, due to the compromised health status of this cohort, they will be more prone to harm and deterioration in the event of an error. This will also affect the rate of drug metabolism and excretion (Wilson et al., 1998). Additionally, PICUs are increasingly employing agency/bank staff to address the issue of shortages. This is a huge risk since agency/bank staff will not necessary have the knowledge or skills needed for critical care. Furthermore, there is a risk of bringing in uncommon practices that are not

routinely performed in certain PICUs or not part of the local procedures/protocols.

Despite all these factors, there has been limited research carried out to understand fully the true nature of medication administration errors in PICU. As will be demonstrated in chapter 3 of this thesis, the majority of research is carried out in general wards. Nevertheless, Wilson et al. (1998) found that over two years of continuous monitoring of adverse incidents, medication errors are seven times higher in PICU compared to other wards. This is extremely distressing since it is similar to the findings of the early research by Bates et al. (1995). Although both studies are 20 years old, the trend of risk is still the same as demonstrated by Agarwal et al. (2010) and Ghaleb, Barber, Franklin, and Wong (2010). Children who are in PICU are much sicker and require error free care in order to speed up recovery. Additionally, in the PICU there is a 1.5:1 nursing ratio, therefore errors must be limited. Moreover, the research that is carried out in PICU is restricted to investigation of these errors but not finding out evidence-based solutions to reduce them.

1.6 Research Aim & Objectives

The aim of this research is to propose safety measures to reduce medication administration errors (MAE) in paediatric intensive care units.

The objectives of this research are:

1. To review literature on MAE in children's hospitals.
2. To investigate the nature of MAE in PICU.
3. To characterise existing MAE interventions used nationally in PICU.
4. To identify MAE contributory factors in PICU.
5. To outline the nature of MAE interventions recommended by healthcare professionals in PICU.
6. To propose safety measures to reduce MAE in PICU.

Chapter 2: Methodology

2.1 Introduction

Research is defined as "the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions" (Oxford Dictionary). The purpose of conducting a research study can be to:

- Explore current knowledge in a particular field and recognise a new phenomenon.
- Inspect existing known problems or identify a problem.
- Suggest a solution to a problem.
- Hypothesise or develop new procedures or systems.
- Add new knowledge to current practice/knowledge.
- Or a combination of any of the above.

(Blaxter, Hughes & Tight, 2010)

Therefore the purpose of research can be themed as: exploratory, descriptive, analytical, or predictive. Undergoing research will eventually lead to a conclusion. Researchers will need to be aware of the two models of reasoning:

- **Deductive reasoning** is the approach of narrowing what is generally known (rules/principles/hypothesis/definition) to the particular knowledge needed to reach a logical conclusion with assertiveness. Usually known as the "top-down" approach.
- **Inductive reasoning** is the claiming of a conclusion to be likely/probable to given evidence. Induction makes specific knowledge into broader general knowledge. Usually known as the "bottom-up" approach.

This chapter will discuss the different types of research philosophies used to reach a conclusion. The overall research questions in this research and the research methodological approach taken will also be explored in this chapter.

2.2 Research Philosophies

Research philosophy is an important part of research methodology development since it will help researchers to develop new knowledge. It is based on a set of assumptions, values, concepts and practices. The following is a brief summary of key research philosophies (Blaxter et al., 2010; Bowling, 2009; Holloway, 2005; Knox, 2004; Saunders, Lewis, & Thornhill, 2007):

- **EPISTEMOLOGY**– Concerns knowledge and how to acquire it
    - ***Positivism*** – Deductive approach
        - Structured observation of phenomena that will lead to a synthesis of convincing data and uses current theories to produce hypotheses. These hypotheses will undergo testing and analysis, this will lead to future research and replication of methodology. Researchers use natural sciences as a model of investigation, to conclude with objective knowledge.
        - *Example: Use of direct observation of medication administration practice to identify MAE.*
    - ***Realism*** – Deductive approach
        - Employs scientific approach to collect data similar to the positivism approach. However, realism philosophy takes into account the independence of reality to the researcher and that there is an autonomous external reality. Requires triangulation of data from many sources to identify knowledge.
        - *Example: Implementation of an intervention to reduce MAE.*
    - ***Interpretivism / Constructivism*** – Inductive approach

        - Supports the requirement for the researcher to recognise diversity between humans unlike fixed objects. Involves critical thinking of positivism philosophy. Interpretive philosophy would suggest different versions of facts to build a theory. Researcher concludes with subjective knowledge.
        - *Example: Interviewing healthcare professionals involved in MAE to identify causes or factors that led to the error.*

- **ONTOLOGY**– Concerns reality and how to view it
    - ***Objectivism***
        - Existence of a single reality to build theory cumulatively independently of the researcher. Measurable either directly or indirectly.
        - *Example: Survey of healthcare professionals' perception of MAE.*
    - ***Subjectivism***
        - Perception and consequent actions of humans with regard to study of interest to construct a theory dependent on the researcher. Process of continual interaction to view a phenomenon.
        - *Example: Focus group to determine severity of harm as result of MAE.*

- **PRAGMATISM**– Concerns achieving positive research outcomes
    - ***Research Questions***
        - Allows utilising of both epistemological and ontological philosophies in order to study what is of specific value to the problem of concern. This will overcome the dilemma of justifying choosing one research philosophy over

another. Furthermore, the approach allows the use of both philosophies simultaneously.

- *Example: Investigation of MAE in practice to develop an intervention.*

- **AXIOLOGY** – Concerns ethical judgement
    - Values ethical principles and practice of research. Values the researcher-researched interaction.

The above brief summary is an overview of research philosophies. It demonstrates the different approaches that can be used when conducting a research study. It is decided that this research project will be adapting a pragmatic approach. The reason for this is to make the investigation of MAE the central focus of the research. Therefore, the researcher is not restricting the methodological approach to a single philosophy. Pragmatic thinking provides the flexibility of carrying out research from different perspectives using a series of specific research questions.

2.3 Research Questions

The following is a list of research questions of this project:

1. What is current evidence around MAEs in children's hospitals?
2. What is the nature of MAEs in paediatric intensive care units?
3. What interventions are used to reduce MAEs in paediatric intensive care units nationally?
4. What contributing factors to MAEs are perceived by healthcare professionals in PICU?
5. What do healthcare professionals recommend to reduce MAEs in PICU?
6. What safety measures are needed to reduce MAEs in paediatric intensive care units?

2.4 Research Methods

According to the Oxford Dictionary, methodology is "a system of methods used in a particular area of study or activity" (Oxford Dictionary). Methods are typically qualitative or quantitative in nature. Qualitative methods are used to explore and to understand social interactions. Whereas, quantitative methods are used to test a hypothesis, identify correlations/trends and generate predictions, and measure specific variables such as the number of interruptions during a medicine administration round (Blaxter et al., 2010; Bowling, 2009). However, the methods, when used, are similar in nature.

The various methods that are used in healthcare research are shown in Table 2.1. Every method has its advantages as well as disadvantages. These need to be taken into consideration when designing the overall methodology. Additionally, there are issues of data accuracy, validity and generalisability.

Table 2.1: Features of common research methods used in healthcare practice

Features	**Healthcare Practice Research Methods**				
	Focus Group	**Interview**	**Literature Review**	**Observation**	**Questionnaire**
Deductive Reasoning			✓	✓	
Inductive Reasoning	✓	✓			✓
Subjective	✓	✓			✓
Objective			✓	✓	
Low Cost					✓
Large Sample		✓	✓	✓	✓
Quick Reach			✓		✓
Flexible			✓		✓
Standardised		✓	✓		✓
Reliable		✓	✓	✓	
Validity Limitation	✓	✓	✓		✓
Rapid Data Collection	✓				✓
Complex Ethical Issues	✓			✓	

Qualitative Methods have been widely used in healthcare practice research (Pope & Mays, 2008). Qualitative methods are generally interested in the description of an individual's experience rather than the cause-effect relationship (Green & Thorogood, 2002, pp. 5–10). Therefore, qualitative methods are often described as epistemological approaches to research, hence the data collected will be used to build a theory. On the other hand, quantitative methods are more ontological. The theory is built using a hypothesis and data collected is represented empirically (Fisher & Stenner, 2011, p. 89).

In healthcare practice research, qualitative methods can contribute vital evidence to knowledge since they provide an account of 'real' situations and experiences and do not just rely on numbers or frequency to assess the situation or experience. This is important in healthcare due to the complexity of the system and the multifaceted nature of the problems it encounters (Green & Thorogood, 2002, pp. 22–25). Additionally, qualitative methods can provide answers to questions that cannot be objectively measured.

The interview method is the most common qualitative approach used in healthcare setting research (Pope & Mays, 2008, p. 12). Interviews are essentially a series of conversations between the researcher and the subject being studied. There are three types of interview methods: structured, semi-structured, and the in-depth interview (Pope & Mays, 2008, pp. 13–15).

Structured interviews typically consist of questions with a fixed choice of responses in a form of questionnaire administered by the researcher. This yields a standardised approach to conducting the research and eases data analysis. However, findings from this method are controlled by the researcher's development of the questions and the choices of responses available. Moreover, findings will only be expressed descriptively. On the other hand, semi-structured interviews are more flexible and less formal in nature since the researcher would be asking open-ended questions as well as close-ended questions. Hence it allows the interviewee to freely express their thoughts and opinions. In-depth interview methods are precisely focused on one or two issues. However, the interviewer would be developing the questions depending on the interviewee response. Therefore, the role of the

interviewee is more dominant in controlling the interviewer (Pope & Mays, 2008, pp. 13–15).

However, there are issues that need to be taken into consideration when conducting interview methods:

- Questions need to be developed in a non-misleading structure.
- Clear wording to enable the interviewee to provide the information required accurately.
- The interviewer must have a good level of experience of asking questions that are sensitive in nature. Be able to adapt the tone when required. This illustrates that conducting interviews is a skill and hence it requires practice
- The interviewer must use equipment to record, transcribe and analyse the interview
- Sampling should be purposive in accordance with the research aim and should be statistically representative.

Another method is the use of focus groups. This is similar to the interview methods but the researcher is communicating with a group of participants to generate responses. The data generated in this method is a result of a group discussion in response to the questions asked. This type of interaction will help to explore the issue by the extensive use of open-ended questions. However, the presence of other participants can hinder confidentiality of responses and may alter the individual's answers due to peer pressure. Focus groups also encounter similar issues to those faced in interview methods.

Alternatively, the survey method can also be in the form of self-completed questionnaires. This method is able to collect data using both open-ended and close-ended questions. There are different types of questionnaire dissemination methods in healthcare research: paper-based distribution of the questionnaire either by post or by hand, and web-based questionnaires that can be distributed electronically via email client.

So far the methods mentioned above will report the beliefs and attitudes towards the area of study. However, it cannot be assured that this is reflected in their practice or work environment (Green & Thorogood, 2002, p. 131). Hence, the observation method can gather information and evidence of what actually happens in real practice. The observation method can be utilised to gather qualitative data relating to behaviour or causal factors using ethnography research techniques (Green & Thorogood, 2002, p. 135; Pope & Mays, 2008, p. 33). It can also be used to collect quantitative data by measuring the incidence of a certain phenomenon occurring in practice or by developing a correlation to a measured variable. The observation method can be carried out in disguise and undisguised. However, researchers will be faced with a number of challenges when conducting the observational method, such as:

- Hawthorne effect, meaning the presence of the researcher will change how the individual or group being observed do things in practice.
- Researcher access to the setting of the study will often be in an opportunistic manner, therefore the observations may not be representative of actual practice.
- The individual or group being observed may be hostile towards the observer due to their belief that the observer is judging their performance in doing their job.
- Observation is a skill, hence to carry out this method a good level of experience is required to ensure accuracy of the observation.
- Ethical issues need to be considered carefully especially with disguised observations.

The research method for this research was developed in accordance with the research questions. A mixed method was developed pragmatically. It involves the use of both qualitative and quantitative approaches. A detailed description of the methods used in this research is presented in each study chapter in this thesis, but an overview is given in section 2.7 in this chapter.

2.5 Research Generalisation

Generalisation of research findings is the expression of the outcomes to the overall area of interest. This is a complex issue, however generalisation of conclusion reached by research is of importance since the purpose of research is to contribute new knowledge to existing knowledge. Therefore, this is vital in order to provide evidence-based practice (Polit & Beck, 2010).

Issues of generalisability in quantitative methods are less complex since it can be determined by number of variable measured or observed i.e. a larger sample size will generate more generalisable results. However, Firestone (1993) developed three models of generalisation for both quantitative and qualitative methods in healthcare research:

1. **Statistical Generalisation**

    - Applies to quantitative methods where the researcher identifies a study population and tests a sample that represents the total population. Representative sample is best achieved by the method of random selection that allows each member of the population an equal chance of inclusion into the study

2. **Analytic Generalisation**

    - Applies to both quantitative and qualitative methods through rigorous inductive analysis. Relies on richness and depth of findings. This model requires assessment of results credibility in order to achieve insightful conclusion.

3. **Transferability Generalisation**

    - This model relies on the research to provide a detailed description of method, results and conclusion. This will allow the reader to make a judgement about extrapolation of findings to the general. Therefore, this model makes the reader evaluate the application of findings to another setting. This model applies to both quantitative and qualitative methods.

In order to achieve any of the above models, there are known tactics that can be used to enhance generalisation (Polit & Beck, 2010):

1. Sampling / Study Replication
2. Triangulation / Integration of Findings
3. Conceptual Reflection on Findings
4. In-depth Description

In this research, generalisability of findings will be assessed in each study using one of the above models.

2.6 Theoretical Framework

Medication administration errors in children's hospitals are researched in current literature using three domains. The following is a short description of these domains:

1. MAE Investigational Studies

A number of methods have been used to identify and investigate MAE in hospital settings. These are divided into retrospective review studies and prospective observational studies. Retrospective review studies identified MAE by: review of serious incident reports, analysis of medication errors specific reports and medication charts review. Prospective observation methods are carried out either in disguised or undisguised manner of the administration practice. Another prospective method is using reviews of medical records and drug charts of in-situ patients.

Retrospective review looks at all serious incident reports that have been documented. The reports include all patient safety breaches. This method allows the measuring of the prevalence of medication errors in comparison to other patient safety incidents (Suresh et al., 2004; Thomas & Panchagnula, 2008). Additionally, this method can be used to target specific quality improvement programmes and measure their effect across all patient safety issues. Also data availability is dependent on voluntary reporting by healthcare professionals that judge the incident to be harmful.

Reviewing medication error only reports provides greater understanding of the nature, type and possible causes of MAEs (Doherty & McDonnell, 2012; Ross, Paton, & Wallace, 2000; Stavroudis et al., 2010). Availability of medication error reports can be challenging. Also, the quality of documentation can be poor for learning and effective analysis.

Another approach to identifying MAEs is by reviewing medication charts retrospectively (Franklin, Birch, Schachter, & Barber, 2010), however this method will provide limited MAE insight since little information is available to decide the presence of MAE due to the nature of documentation kept post-administration. However, medication chart review is useful to identify prescribing errors.

Prospective observation of medication administration practice is a method that can identify MAEs that are not reported by healthcare professionals. These include two approaches to direct observation: a disguised approach (Conroy et al., 2007a; Ghaleb et al., 2010; Prot et al., 2005), and undisguised approach (Cousins, Sabatier, Begue, Schmitt, & Hoppe-Tichy, 2005; Feleke & Girma, 2010). Also, prospective review of medical notes and drug charts.

Observation method offers various advantages over retrospective review of incidents, medical notes and drug charts. This method is great at identifying trends and causes of MAEs. Observation is carried out objectively and is not looking to assign blame to individuals but is focused on the system. Additionally, it allows quality improvement to the system with evidence from actual practice. Moreover, individual observations can be reviewed and validated for quality assessment by others. Furthermore, the observation method provides real-time MAE documentation. Another advantage is that variables such as adherence to standards, number of interruptions during medicine administration process and other factors that contribute to a MAE can be collected.

Conducting direct observation will provide great insight into the culture of medication safety within the team greatly. However, this method of investigating MAE can face a number of challenges, including; observer expertise, ethical consideration, and observer effect. Observation involves the

requirement of the observer to have knowledge of medication preparation and administration procedure. The observer's clinical experience is also of importance since a judgment is required. Additionally, observers will face an ethical challenge of when to intervene in stopping an MAE reaching the patient and causing harm. The challenge is to balance research interest and the fact that MAEs would happen regardless of the observer presence. An additional challenge includes the fact that the presence of the observer may cause a change in the behaviour of the individuals being observed. This is known as the "Hawthorne effect" or "observer effect". The Hawthorne effect can be reduced in MAE observation by carrying out the study for longer periods of time so that the participants are used to the observer being around them. Also assuring the participants that the study is system focused and is not aiming to allocate individual blame.

2. MAE Exploration Studies

Research in the MAE field is not only focused on detecting the nature and prevalence of MAEs in practice but the research is also exploring MAEs from the healthcare professionals' perspective. This will identify factors that lead to MAEs, barriers to error reporting and the culture of patient safety within the team (Lin & Ma, 2009; Lisby, Nielsen, & Mainz, 2005; Stratton, Blegen, Pepper, & Vaughn, 2004; Tang, Sheu, Yu, Wei, & Chen, 2007; Wakefield et al., 2001). Distributing questionnaires, conducting interviews and setting up focus groups are often the methods used to explore MAEs.

3. MAE Interventional Studies

There are also studies found which involved testing interventions to reduce MAEs (Bertsche et al., 2010; Fontan, Maneglier, Nguyen, Loirat, & Brion, 2003; Larsen, Parker, Cash, O'Connell, & Grant, 2005). Interventional studies cannot be carried out unless MAEs have been quantified, risk factors identified and causes explored before designing and implementing an intervention. Evaluation of intervention is important and hence re-assessment of MAEs in practice will be necessary after putting the intervention in place for a prolonged period of time. This type of study provides solutions to specific problems during the medication administration process. However, there are

also challenges that could hinder the success of these types of studies, such as the cost of intervention, uptake by healthcare providers and commitment to running of the intervention.

2.7 Methodological Design

In this thesis, the context of the research is to develop evidence based safety measures to reduce MAEs in PICU as demonstrated in Figure 2.1. This evidence is collected using a number of studies: (1) gather current knowledge from mainstream literature databases, (2) retrospectively review incidents of MAEs, (3) observe medication administration practice, (4) find out the current interventions used in different PICU to reduce MAE, (5) characterise MAE contributory factors and interventions as perceived by PICU healthcare professionals, and (6) propose safety measures based on the previous studies.

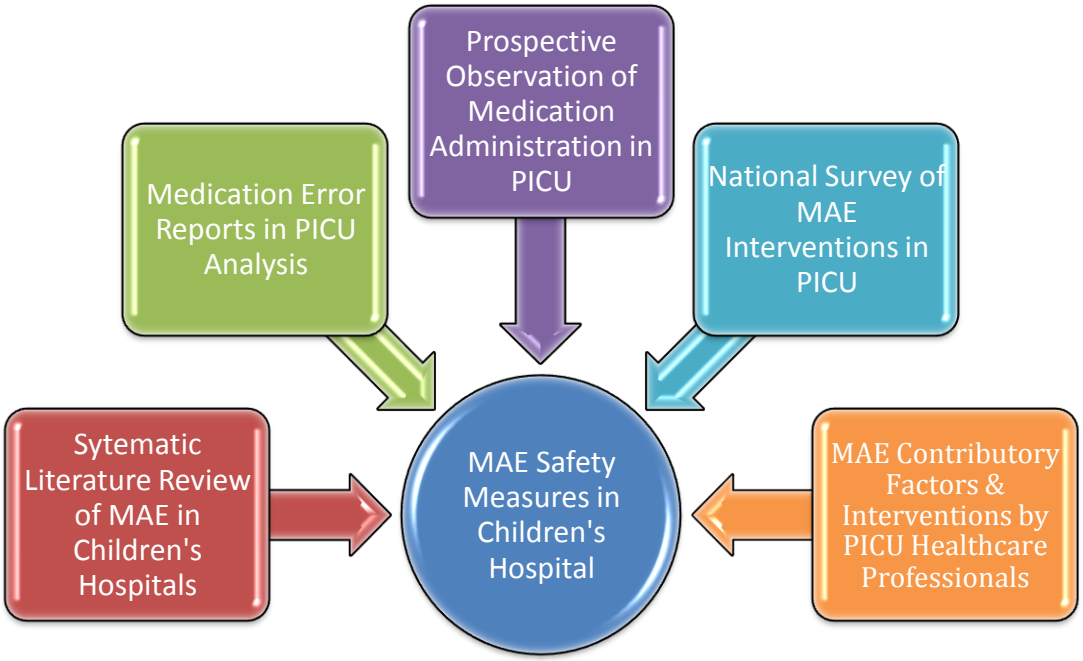

Figure 2.1: Illustration of methodological approach

Objective 1: To review literature on MAEs in a children's hospital

This objective aims to collect the global knowledge regarding MAEs in children's hospital care. Finding out this knowledge will help to understand the reported nature of MAEs and identify the interventions used to reduce this type of error in children's hospitals. There are three methods that can be used to achieve this; narrative literature review, systematic literature review, and meta-analysis literature review.

Narrative literature review is a method of gathering evidence to give an overview of the researched area. This is typically produced without a detailed search protocol or specific article selection criteria. But it relies on the researcher to populate evidence based on the strength and quality of individual articles. Systematic literature review is a process of rigorous appraisal of all evidence available that fits a predetermined protocol. This protocol is used to select studies using specific key search terms from listed literature databases. It will also contain inclusion/exclusion criteria to focus the review process to the aims and objectives of the review.

On the other hand, meta-analysis review is a more extensive form that aims to pool the findings of all studies selected. Meta-analysis selection of studies is carried out using a more focused protocol to ensure the homogeneity of methods. This in turn will allow a statistical analysis of the outcomes across multiple studies to generate evidence. Hence this is ideal to review randomised control trials.

For the purpose of this research, it was found that narrative review is not suitable since it is a weak form of evidence. Narrative review will not capture all the insights of the MAE research field. Whereas, meta-analysis review is a strong form of evidence but will be limited by the fact that there is a wide heterogeneity between MAE studies. Therefore, systematic literature review is chosen for this objective. Thus, a detailed protocol is described in chapter 3 for selection of literature.

Objective 2: To investigate the nature of MAE in PICU

As was discussed earlier, there are two broad types of methods to investigate MAEs. The first approach is to retrospectively review medication charts, medication error reports or serious incident reports to identify MAEs. An alternative approach is a direct prospective observation of the medication administration practice either in disguise or undisguised.

The retrospective method offers the advantage of rapidly reviewing a large dataset to identify MAEs. The dataset can be used to find trends of MAE and find system factors that contribute to MAEs. Additionally, MAEs due to active and latent failures can be explored. Moreover, this method has been proven to be simple, valid, reliable and auditable.

Medication charts have been used to identify MAEs, but provided limited evidence. The nature of MAE identified using medication charts is mostly related to time errors and omitted doses. On the other hand, review of medication error reports will provide evidence of MAE trends and risk factors. Medication error reports will include both serious incidents that resulted in death or severe harm and incidents that did not cause any harm. Therefore, reviewing medication error incidents will address all type of incidents. Serious incidents are the tip of the medication errors iceberg since they only include the incidents that reach the patient and caused serious harm. Hence to achieve this objective, analysis of medication error reports method was chosen. The alternative approach to achieve this objective was to carry out prospective observations. This method of direct prospective observation of medication administration practice will be able to identify MAEs that may not be reported. This method will also document factors that are not reported, such as interruptions. Also, prospective observation methods reduce the limitation of the retrospective analysis of medication error reports method such as:

- Disagreement between staff of what constitute a reportable MAE.
- Concerns of the person involved in the MAE of the response from management and colleagues.

- The quality of reporting and time needed to document the error.
- Reporting of the medication incident depends on whether the reporter acknowledges that an MAE has occurred.

However, there are a number of challenges that need to be taken into consideration when conducting prospective observation of medication administration practice. Observers will need to have experience in the process involved when preparing and administering medicines or observers should receive extensive training before conducting the study. Also in order to collect a good amount of data that is representative, the observation will need to be carried out over a long period of time and this should also include night and weekend duties. There are other challenges such as ethical issues, such as when does an observer intervene to stop an error and the Hawthorne effect.

Therefore, to achieve the optimal findings for this objective, combined methods were used. The retrospective analysis of medication error reports will give trends of MAE over a long period of time. The prospective observation method will provide an insight into the current practice, identifying factors associated with MAEs and exploring areas of improvement within the system of medication administration. A detailed method is discussed in chapter 4 and 5 respectively.

Objective 3: To characterise existing MAE interventions used nationally in PICUs

There are a number of methods that can be used to characterise current interventions used in different PICU settings. These include: site visits / observations, focus groups / interviews, and questionnaires. These methods allow the researcher to use a naturalistic or realistic approach that does not manipulate the studied group to reach a hypothesis. This is an advantage when there is little or no evidence of knowledge, a complex issue and the need to reach a maximum opportunity for exploration (Bowling, 2009, p. 380).

In this study a questionnaire method was chosen in order to meet this objective. This survey method is in the form of an online self-completion questionnaire have a number of advantages over the other methods such as:

1. Minimises risk of Hawthorne effect and bias by researcher compared to focus group, individual interview or site visit/observation. Participants will be able to express their thoughts without interference from the researcher or other participants.
2. Participants will have time to consider their answers.
3. Does not require the presence of the researcher with the participant.
4. Does not distract the participants from their usual duties and responsibilities.
5. Can be delivered to all sites and participants at the same time.
6. Standardised collection of responses that ensures consistency and can be repeated at a later date.
7. Data collection occurs in a shorter period of time and it is an inexpensive way to cover a large geographical area.
8. Online questionnaires are being used increasingly in healthcare practice; therefore participants will be familiar with the format and arrangement of this method.
9. Large number of responses is possible, thus making the findings more representative.
10. Online questionnaires are more cost-effective compared to site visits/observations and focus groups

However, survey methods encounter challenges that could question their validity such as the actual development and construction of the questions asked and the overall content of the questionnaire. This is an important issue that will need to be tackled during the survey development and validation process. Moreover, it is vital to keep the questionnaire concise, specific and not misleading. Therefore, construct validity is required to ensure that the

content of the questionnaire meets the objective and at the same time does not mislead the participants. This is to ensure a generalisable finding is achieved. An additional limitation is that it would be difficult to probe participants to elaborate on their responses.

Online self-completed questionnaire was chosen instead of posted/paper-based questionnaire for the following reasons:

1. An online questionnaire will be sent via recognised professional networks to the correct person. However, with postal questionnaires there is a risk it will not be delivered on time to the correct person or not delivered at all due to an incomplete address.
2. There is minimum cost involved in developing and sending out the online questionnaire, compared to the postal questionnaire which will cost significantly more
3. The speed of response is faster with online questionnaires than postal.
4. There can be a rapid analysis of responses since no transcription is needed and no validation of the transcription is required either.

Objective 4: To identify MAE contributory factors in PICU

In order to identify contributory factors for MAE in PICU that could not be found using the above studies, it is necessary to approach healthcare professionals. This objective can be achieved by the use of focus groups, interviews or questionnaires. However, to garner a large response from healthcare professionals, an online questionnaire is used. Also, participants will be able to express their thoughts without interference from other participants or the interviewer. Moreover, when using an online questionnaire, responses can be captured from multiple sites nationally. Therefore, this increases the generalisability of the findings. These findings will be used to propose safety measures to reduce MAE in PICU.

Objective 5: To outline the nature of MAE interventions recommended by healthcare professionals in PICU

This objective will be achieved alongside objective 4. The same questionnaire will include a question asking participants to describe the nature of an intervention that would reduce MAE in their practice. The findings of this objective will be used to propose the safety measures for MAEs in PICU.

Objective 6: To propose safety measures to reduce MAEs

This objective aims to triangulate the findings from the previous studies in order to propose a set of safety measures to reduce MAE as shown in Figure 2.1. It recognises that MAE is multifaceted and a single intervention will not be able to address all MAEs. Following the agreement of the research team on the proposed safety measures, opinions on the usefulness of the proposed can be sought by: 1) Delphi/Nominal group consensus, 2) focus group/interview, or 3) questionnaire.

Consensus groups are often constituted of key experts in the field of interest and are set to seek agreement or collect information focused on close-ended material. There are two types of consensus groups: Delphi and Nominal. Delphi groups are independent panels of experts that respond to a questionnaire without interference from other members. It is often repeated a number of times until consensus is reached between members. Nominal group experts reached consensus via engagement in open dialogue. The limitation of consensus groups is that participants must demonstrate a good level of experience in the field. Therefore, this causes bias to the study since it does not represent the entire healthcare team who is involved in medicine administration. Also it consumes a lot of time since it is often difficult to reach consensus from the first round of Delphi groups. Hence this method is not ideal for this objective.

Focus groups are aimed at seeking opinions of participants with a diverse range of backgrounds. It is a method of sharing ideas and thoughts on an open-ended topic. One limitation of this method is that participants will need to commit their time to take part. This is difficult for this study since participants are healthcare professionals in a highly demanding clinical area.

Therefore, response to invitation will be low and not representative. Hence the optimal method for this objective is to carry out an online questionnaire to collect opinions of the PICU healthcare professionals.

2.8 Thesis Structure

A pragmatic approach is taken in this research to enable the researcher to get a deeper understanding the problem of MAEs in PICU. Also pragmatic inquiry was the best fit for the supervisors of this project since they come from diverse professional backgrounds and have an enormous level of research experience.

The aim of research is to reach new knowledge that is generalisable and based on evidence. This research is not a service evaluation or practice audit since this research project is not measuring current practice of medication administration against known standards. Therefore, the intent of this research is to find out how to reduce MAEs by investigating the current characteristics of MAEs, exploring the methods used to reduce these errors nationally and proposing evidence-based MAE safety measures for PICU practice.

This thesis used a deductive method of reasoning to drive the outcomes throughout the overall research. Table 2.2 represents the objectives of this research and the different methods that can be used to achieve that objective. This is followed by an indication of which method was selected with a given justification, strength/limitations of the method and the chapter number where a detailed method with discussion of the findings can be found.

As described above, the research method is divided into six studies:

1. Systematic literature review
    - This will explore all published literature on MAEs in children's hospitals to ascertain the current state of knowledge.
    - Results from this study will also help to design the method needed for the other studies and will contribute to proposing the final safety measures.

2. Retrospective review of medication error reports at a London based PICU

    - Reporting of medication errors are carried out by healthcare professionals in the PICUs on a regular basis.

    - The review will indicate the key risk factors that can contribute to causing MAEs and will strengthen the understanding of the researcher of the commonly reported MAEs.

3. Prospective observation of medication administration practice in a London based PICU

    - Direct observation of the medication practice will reveal MAEs that are not usually reported and it will provide vital insight into system factors that lead to MAEs.

    - Outcomes of this study will help to shape the safety measures to improve practice.

4. Survey of current interventions used in PICUs nationwide

    - There are a limited numbers of hospitals in the UK that offer PICU services. The purpose of this study is to explore the nature of interventions used in these units that may not have been reported in literature.

    - This study will enable identification of good practice in the management of PICUs and adaptation of this practice to a local setting.

5. Survey of MAE contributory factors and interventions as viewed by PICU healthcare professionals

    - Many studies explore MAE contributory factors from the perspective of the individuals who made these errors. This approach is not necessarily fit for purpose, since the factors would not be generalised to everyday practice but restricted to that specific event. However, approaching all healthcare professionals in PICU to

identify contributory factors of MAE will result in a more representative view of the true nature of their practice. Also, this would engage healthcare professionals in finding solutions to these problems. Thus, both frontline practitioners and evidence from the other investigational studies will drive the recommendation of the safety measures.

- This study will provide knowledge of how PICU practitioners view the factors that cause MAEs and what is needed to reduce these errors in practice. This knowledge will be of vital importance in proposing the MAE safety measures.

6. Proposing of MAE safety measures based on the findings of the previous studies

    - This study will triangulate the findings from the previous four studies to propose a set of safety measures to reduce MAEs in PICUs. Local PICU healthcare teams and national expert groups will assess the proposal. The assessment will be in the form of collecting opinions on the usefulness of the proposed intervention

Table 2.2: Summary of methods used in this thesis

Research Objective	Possible Methods	Selected Method & Brief Justification	Strength & Limitation	Chapter Number
1. To review literature on MAE in children's hospital	• Narrative Review • Systematic Review • Meta Analysis Review	***Systematic Literature Review*** **–** A standard method using a protocol to explore all research. Meta analysis not carried out due to large heterogeneity.	Comprehensive review of all evidence to identify current knowledge. Limitation of systematic review is the wide heterogeneity between studies and the use of different numerators and denominators to express incidence of MAE.	3
2. To investigate nature of MAE in PICU	• Review of Drug Charts/ Medication Error Reports/ Serious Incident Reports • Prospective Observation/ charts/notes	***Retrospective Review of Medication Error Reports and Prospective Observation of Practice –*** Combined method to investigate the nature of MAE in PICU from all perceptive	Able to establish the complete nature of MAE occurring in PICU. Risk factors can be identified in the medicine administration practice. Review of human factors as well as system factors can be assessed. However, It will encounter ethical difficulties. Observer will need to be trained and develop observation skills. The method will be consuming long time.	4 & 5
3. To characterise existing MAE interventions used nationally in PICUs	• Site Visits / Observation • Questionnaire • Focus Group/ Interview	***Online Self-Completion Questionnaire*** – A rapid method to explore the nature of interventions used.	Automation of data entry and safe storage. Convenient for participants since they can answer at their own time and location. Avoiding bias from other participants and interviewer. Responses to invitations sent via email can low.	6
4. To identify MAE contributory factors in PICU 5. To outline the nature of MAE interventions recommended by healthcare professionals in PICU 6. To propose safety measures to reduce MAE in PICU	• Delphi/ Nominal Group Consensus • Focus Group/ Interview • Questionnaire	***Online Self-Completion Questionnaire –*** Rapid responses from large group will be possible. Opinions on the design/nature of the intervention can be sought from both internal and external representations.	Automation of data entry and safe storage. More convenient for participants since they can answer at their own time and location. Avoiding bias/interference from other participants and interviewer. Responses to invitations sent via email can low.	7

2.9 Ethical Consideration

Every clinical pharmacy practice research study faces ethical situations and this one is no exception. In fact it has faced some a very challenging ethical situations. Examples of these challenges are; firstly, consent to be observed and secondly, when to intervene in the event of identifying a potential MAE. Therefore, this research required a full ethical committee approval. An application was submitted to NHS REC London Bloomsbury and the local NHS R&D (Great Ormond Street Hospital). Following a meeting with the committee and amendments made to the research protocol, NHS REC London Bloomsbury (Appendix 1) and NHS R&D (Appendix 2) granted a favourable decision. Moreover, local approval from the PICU risk manager was obtained (Appendix 3). The detailed ethical consideration for each study will be discussed in its appropriate chapter.

Chapter 3: Systematic Literature Review of Hospital Medication Administration Errors in Children

3.1 Introduction

Over the last 14 years there has been a rapid growth of MAE evidence in children's hospitals. However, a limited number of comprehensive systematic literature reviews were conducted.

One of the earliest reviews in this area was by Ghaleb et al. (2006) that identified incidences of MAE between 0.6 and 27 per 100 administered doses in children's hospitals. This review focused on medication errors in general. It has identified the need to develop validated definitions to help understand the true scale of the problem and to test interventions to reduce these errors. Another systematic review by Miller et al. (2007) found an MAE rate between 72 and 75 in every 100 reported medication errors. This review recommended unifying numerators and denominators when collecting data and a standardisation of definitions. Rinke et al. (2014) reached similar conclusions with their review on interventions used to reduce medication errors.

Keers et al. (2013b) also carried out a systematic literature review on studies that reported MAEs per total opportunities for error. They have found the MAE rate between 17.4 and 33.8 per 100 opportunities for error. Similar concerns regarding standardising definitions and methods were raised. But in another review that was focused on identifying the causes of MAE in children's hospitals using Reason's model of causation, Keers et al. (2013a) highlighted the effectiveness of the double-checking procedure and the impact of interruptions on MAEs. Raban and Westbrook (2013) reviewed the evidence on interventions based on reducing interruptions and found that these interventions have weak evidence that support their use in reducing MAEs.

Despite the various published systematic literature reviews there is still a need for a review that addresses: 1) definitions used to identify MAE in children's hospitals, 2) the different methods used to investigate MAEs and 3) how interventions are used to reduce MAE. Therefore, this systematic review's aim is to investigate all studies of hospital MAEs in children. The review's objectives are:

1. To explore definitions used to identify hospital MAE in children.
2. To report the prevalence of hospital MAE in children.
3. To identify the nature and severity of these errors.
4. To identify the interventions used to reduce hospital MAE in children.

3.2 Method

3.2.1 Data sources and search terms

Studies were obtained from 12 databases that are used to archive healthcare related publications (PubMed, Science Direct, Web of Knowledge, British Nursing Index, Scopus, Global Health, EMBASE, NeLM, CINAHL, International Pharmaceutical Abstracts, PsycInfo and PsycExtra) in July 2014. The following search terms were used; ("Medication Error" OR "Medication mistake" OR "Drug error" OR "Drug mistake" OR "Drug mishap" OR "Adverse drug event" OR "Near Miss" OR "Death") AND ("Administration Error" OR "Medication administration error" OR "Drug administration mistake" OR "Drug administration" OR "preparation error") AND ("Hospital" OR "Secondary care" OR "Tertiary centre") AND ("Paediatric " OR "pediatric" OR "Child" OR "Infant" OR "Adolescent" OR "Toddler" OR "Neonate" OR "Newborn" OR "Under 16" OR "Teen" OR "Teenager" OR "Baby"). Also, a hand search of relevant publications from recent systematic reviews to identify all possible studies was carried out.

3.2.2 Selection criteria

The following inclusion criteria were used to select studies:

1. Publication date between 01/01/2000 to 01/07/2014. This is to avoid repetitiveness of findings since earlier studies have been reviewed by other researchers and build on existing reviewed evidence

2. Presented in English language. Studies that are not available in English require a different set of search terms. These search terms will need to be in different languages to cover all possible languages. Also to avoid bias, non-English literature databases will need to be searched. Moreover, professional interpreters with research background would be required to search, retrieve the studies and extract data for this review. The inclusion of non-English studies would be faced with financial and validation

challenges. Therefore, it was decided to restrict search to studies presented in English only.

3. MAEs in children's hospital settings in children aged between 0 and 18 years old. This is to reflect the population of interest for this research. This will also ensure that the data collected is relating to the children's hospital setting only.

All articles that are not peer reviewed such as; opinions, letters, comments, editorials, reviews studies were excluded. However, they were used to hand search for additional studies from their bibliographies. Studies that did not report child data were also excluded.

3.2.3 Quality Assessment and Extraction process

The researcher retrieved studies for review from the above databases using the search strategy. A rigorous review to assess suitability against the review criteria was carried out. An independent researcher reviewed all the articles that were identified. A high level of agreement was established between reviewers and the studies that were in disagreement (n= 4) were resolved through a discussion and referring back to the criteria set. There was no need for a third opinion.

The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA, 2014) standards were used to extract data and assess the quality of the studies. Citations were imported into a reference manager EndNote X7 (Thomson Reuters, Times Square, New York, US). Microsoft Excel 2010 (Microsoft, Redmond, Washington, US) was used to store data extracted from the selected articles. The following data was recorded: authors, year of publication, country of origin, study type, setting, duration, MAE definitions used, method of identifying MAEs, key findings and recommendations.

3.2.4 Data Analysis

Data extracted from each study was aggregated into three categories: 1) studies that reported a specific definition for hospital MAEs in children, 2) investigational studies that found the nature of hospital MAEs in children without testing an intervention, and 3) studies that evaluated the effectiveness of an intervention.

Basic descriptive analysis of data was conducted for studies that used the same numerator and denominator of MAE.

3.3 Results

3.3.1 Database search results

The search strategy has found 2936 articles. As illustrated in Figure 3.1, 2899 articles were eliminated in compliance with the inclusion/exclusion criteria. This yields 37 studies that were found to be eligible for the purpose of this review. These studies were carried out in:

- US (Herout & Erstad, 2004; Hicks, Becker, Windle, & Krenzischek, 2007; Kaushal et al., 2001; Larsen et al., 2005; Marino, Reinhardt, Eichelberger, & Steingard, 2000; Miller et al., 2010; Morriss et al., 2009; Pauly-O'Neill, 2009; Russell, Murkowski, & Scanlon, 2010; Sowan, Gaffoor, Soeken, Johantgen, & Vaidya, 2010; Stavroudis et al., 2010; Suresh et al., 2004; Yamamoto & Kanemori, 2010)
- UK (Alsulami, Choonara, & Conroy, 2014; Conroy et al., 2007a; Ghaleb et al., 2010; Ross et al., 2000; Simpson, Lynch, Grant, & Alroomi, 2004; Stewart, Purdy, Kennedy, & Burns, 2010; Thomas & Panchagnula, 2008; Warrick et al., 2011)
- Argentina (Otero, Leyton, Mariani, & Ceriani Cernadas, 2008)
- Australia (Manias, Kinney, Cranswick, & Williams, 2014a)
- Canada (Doherty & McDonnell, 2012; Ellis et al., 2011; Trbovich, Pinkney, Cafazzo, & Easty, 2010)
- France (Fontan et al., 2003; Prot et al., 2005)
- Malaysia (Chua, Chua, & Omar, 2010; Raja Lope, Boo, Rohana, & Cheah, 2009)
- Ethiopia (Feleke & Girma, 2010)
- Germany (Bertsche et al., 2010)
- Netherlands (Chedoe, Molendijk, Hospes, Van den Heuvel, & Taxis, 2012)
- Saudi Arabia (Sadat-Ali et al., 2010)

- Switzerland (Frey et al., 2002)
- Turkey (Ozkan, Kocaman, Ozturk, & Seren, 2011)
- Multicentre (Cousins et al., 2005)

Table 3.1 represents a summary of all 37 studies that were reviewed. It contains the core information for each study and an overview of the key findings. As can be seen, the studies were themed into three groups: studies that used a retrospective approach to investigate MAE, prospective observational studies, and studies that investigated the effect and impact of an intervention.

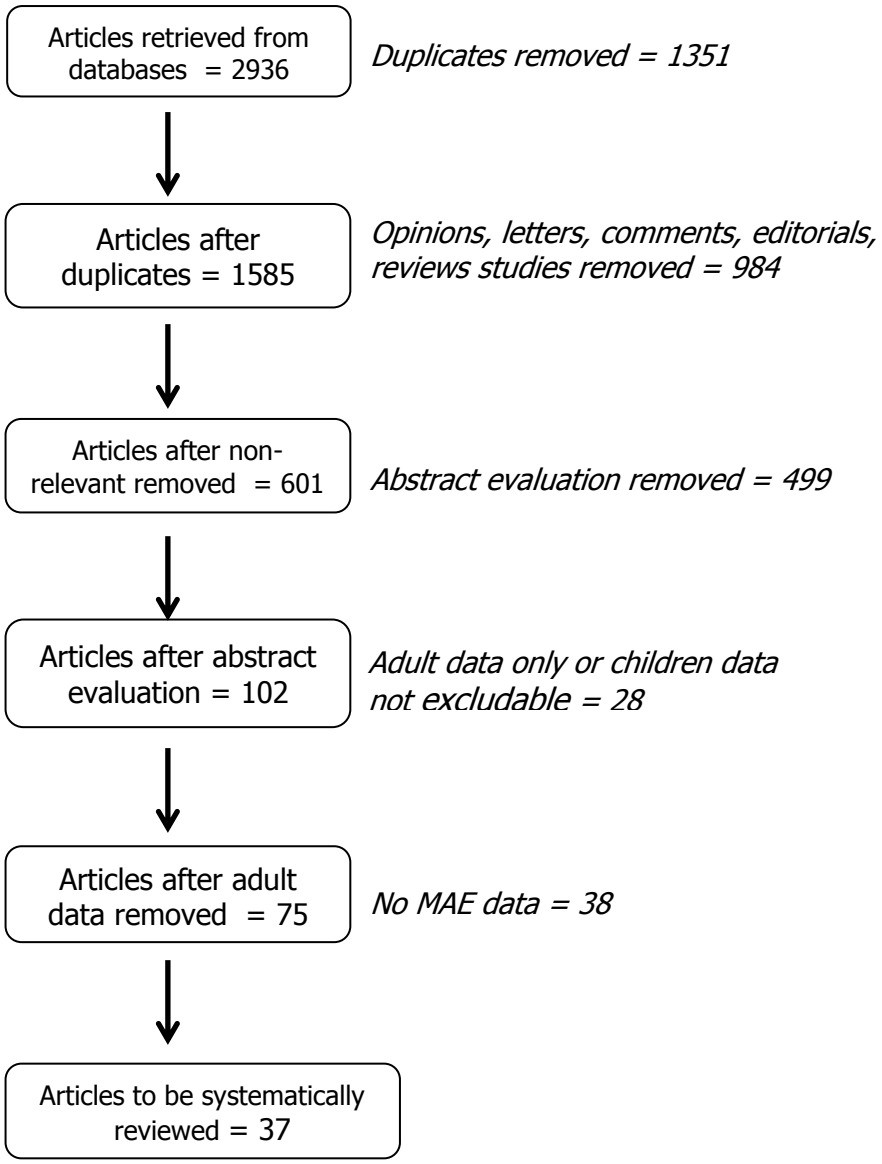

Figure 3.1: Flow diagram of article selection for the systematic literature review

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Retrospective Studies					
Doherty and McDonnell (2012) (Canada)	Retrospective Review	5 years	Hospital (300 Bed)	252 medication error reports	87 MAE (34.5%/ME reports)
Frey et al. (2002) (Switzerland)	Retrospective Review	1 year	Children hospital	275 medication error reports	200 MAE (72.7%/ME reports)

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Hicks et al. (2007) (US)	Retrospective review	4 years	MedMARx reports	645 medication error reports	384 MAE (59.5%/ME reports)
Kaushal et al. (2001) (US)	Retrospective Review	6 weeks	2 Teaching hospitals	616 medication errors identified during chart review	78 MAE (12.7%/ME)
Manias et al. (2014a) (Australia)	Retrospective Review	4 years	Children Hospital (334 bed)	2753 medication error reports	1952 MAE (70.9%/ME report)
Miller et al. (2010**)** (US)	Retrospective Review	1 year	Children hospital	140 medication error reports	79 MAE (56.4%/ME report)
Ross et al. (2000) (UK)	Retrospective Review	5 years	2 Children hospitals	195 medication error reports	149 MAE reports (76.4%/ME report)
Sadat-Ali et al. (2010) (Saudi)	Retrospective Review	2 years	Teaching hospital	38 medication error reports	15 MAE reports (39.5%/ME report)
Simpson et al. (2004) (UK)	Retrospective Review	1 year	NICU	105 medication error reports	30 MAE reports (28.6%/ME report)
Stavroudis et al. (2010) (US)	Retrospective Review	5 years	MedMARx reports	6749 medication error reports	3256 MAE reports (48.2%/ME report)
Suresh et al. (2004) (US)	Retrospective Review	2 years	54 NICU	1230 critical incident reports	181 MAE reports (14.7%/CI report)
Thomas and Panchagnula (2008) (UK)	Retrospective Review	7 months	NPSA database	12084 critical incident reports	181 MAE reports (12.2%/CI report)
Prospective Studies					
Alsulami et al. (2014) (UK)	Prospective Observation (Undisguised**)**	4 months	Medical, Surgical, NICU & PICU wards	2000 Doses Observed	191 MAE identified (9.6%/dose administered)
Chua et al. (2010) (Malaysia)	Prospective Observation (Undisguised**)**	3 months	Children Hospital	857 doses observed	100 MAE identified (11.7%/dose observed)
Conroy et al. (2007a) (UK)	Prospective Observation (Undisguised**)**	6 weeks	Children hospital (92 beds)	752 doses observed	150 MAE identified (20%/dose observed)
Ghaleb et al. (2010) (UK)	Prospective Observation (Undisguised**)**	2 weeks	5 Hospitals	2240 opportunities for error observed	429 MAE identified (19.1%/OPE)

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Herout and Erstad (2004) (US)	Prospective Observation (Undisguised)	1 month	Surgical intensive care unit (16 bed)	206 doses observed	26 MAE identified (12.6%/dose observed)
Marino et al. (2000) (US)	Prospective Observation (Undisguised)	5 days	Teaching hospital	784 medication errors identified during chart review	16 MAE detected (2.1%/ME)
Ozkan et al. (2011) (Turkey)	Prospective Observation (Undisguised)	25 days	Teaching hospital (52 bed)	2344 doses observed	855 MAE identified (36.5%/dose observed)
Feleke and Girma (2010) (Ethiopia)	Prospective Observation (Disguised)	2 weeks	Teaching hospital	218 doses observed	196 MAE identified (89.9%/dose observed)
Cousins et al. (2005) (UK, Germany & France)	Prospective Observation (Disguised in Germany & France)	6 months	6 Hospital units	UK 273 doses observed; Germany 425 doses observed; France 100 doses observed	UK 185 MAE (67.8%/dose observed), Germany 262 MAE (61.6%/dose observed) France 34 MAE (34%/dose observed)
Prot et al. (2005) (France)	Prospective Observation	1 year	Teaching hospital (440 beds)	1719 doses observed	538 MAE identified (31.3%/dose observed)
Intervention Studies					
Stewart et al. (2010) (UK)	Intervention (Workshop)	2 hours	Simulation	48 medical students & 21 nursing students	Improved knowledge and awareness of children medication safety and medication errors
Pauly-O'Neill (2009) (US)	Intervention (Simulation)	5 hours	Simulation	44 students, 3 hours lecture followed by 2 hour tutoring session and a stimulation exam after 1 week	Pre-intervention: 22% of student administered medication correctly Post-intervention: rate improved up to 96%

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Trbovich et al. (2010) (Canada)	Intervention (Simulation)	Not Reported	Simulation	24 nurses, 3 pump type (traditional, smart & barcode), 7 infusion task for each pump type	Participants found 88% of wrong patient errors using barcode pump, smart pump 58% and traditional 46% of the errors. Smart pump remedied wrong dose high limit (75%), 79% bar code and 38% with the traditional pump
Larsen et al. (2005) (US)	Intervention (Standard concentration & smart pump)	2 years	Children's medical centre (242 beds)	Pre-intervention: 12109 medication error reports Post-intervention: 12399 medication error reports	Pre-intervention: 28 infusion errors Post-intervention: 8 infusion errors
Ellis et al. (2011) (Canada)	Intervention (New Guidelines)	22 weeks	Children Hospital	1000 Morphine doses	No child required morphine antidote or respiratory support following morphine administration
Chedoe et al. (2012) (Netherlands)	Intervention (Education)	20 days	NICU (14 Bed)	Pre-intervention: 311 doses observed Post-intervention: 284 doses observed	Pre-intervention: 151 MAE identified (49%/dose observed) Post-interventions: 87 MAE identified (31%/dose observed)
Otero et al. (2008) (Argentina)	Intervention (Education)	2 years	Children unit (110 bed)	Pre-intervention: 1174 administered dose, Post-intervention: 1588 administered dose	Pre-intervention 99 MAE identified (8.4%/administered dose) Post-intervention 94 MAE identified (5.9%/administered dose)
Raja Lope et al. (2009) (Malaysia)	Intervention (Education)	1 month	Teaching Hospital (34 beds)	188 doses administered	Pre-intervention: 188 non-adherence to the six rights rule Post-intervention: non-adherence dropped to 169

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Bertsche et al. (2010) (Germany)	Intervention (Education to staff & parents)	7 weeks	Children neuro ward (19 beds)	Pre-intervention 646 medication administration by nurse & 29 by parents Post-intervention 453 medication administration by nurse & 36 by parents	Pre-intervention: 261 MAE identified (40.4%/administered dose) by nurse & 28 MAE identified (96.6%/administered dose) by parents. Post-intervention: 36 MAE identified (7.9%/administered dose) by nurse & 2 MAE identified (5.6%/administered dose) by parents.
Fontan et al. (2003) (France)	Intervention (CPOE)	1 month	Children hospital	CPOE: 3943 opportunities for error handwritten prescription: 646 opportunities for error	CPOE: 888 MAE identified (22.5%/OPE) Handwritten prescription: 189 MAE identified (29.3%/OPE)
Yamamoto and Kanemori (2010) (US)	Intervention (CPOE)	Not Reported	Emergency department & PICU	38 Nurses	Conventional method had 70 MAE whereas computer assisted dosing had 27 MAE.
Sowan et al. (2010) (US)	Intervention (CPOE simulation)	Not Reported	Simulation	108 Infusions	Nurses were able to identify 53% of MAE in 72 infusions containing MAE. Whereas, nurses were able to identify 40% of MAE in 72 infusions that contains MAE of handwritten prescriptions.
Russell et al. (2010) (US)	Intervention (CPOE & smart pumps)	24 days	Children hospital (30 bed)	296 doses administered	72 infusion discrepancies (24%) between CPOE and setting on smart pump
Warrick et al. (2011) (UK)	Intervention (Clinical information system)	3 weeks	Teaching Hospital	Pre-intervention: 528 scheduled doses Post-intervention: 278 scheduled doses	Pre-intervention: 43 omitted doses (8.1%/scheduled dose), Post-intervention: 4 omitted doses (1.4%/scheduled dose)

Table 3.1 Summary of studies relating to hospital MAE in children

Reference (Country)	Study Type	Study Duration	Study Setting	Sample Size (denominator)	Key Findings
Morriss et al. (2009) (US)	Intervention (BCMA)	9 months	Teaching Hospital (36 bed)	92398 doses, 475 without Bar-code & 483 with Bar-code.	19 MAE found in 39 ME observed with no BCMA. 12 MAE found in 20 ME observed with BCMA

ADE Adverse Drug Event
BCMA Bar Code Medicine Administration
CI Critical Incident
CPOE Computerised Physician Order Entry
MAE Medication Administration Error
ME Medication Error
NICU Neonatal Intensive Care Unit
NPSA National Patient Safety Agency
OPE Opportunities for Error
PICU Paediatrics Intensive Care Unit

3.3.2 Definitions of Hospital MAE in Children

There were eight studies that reported a specific definition for hospital MAE in children (Chua et al., 2010; Cousins et al., 2005; Feleke & Girma, 2010; Fontan et al., 2003; Ghaleb et al., 2010; Herout & Erstad, 2004; Prot et al., 2005; Raja Lope et al., 2009). Table 3.2 illustrates the key components of the definitions found. As can be seen, MAE can generally be defined as "variation of the dose given from that originally prescribed". The remaining studies did not report a specific MAE definition. However, they utilised a broad ME definition such as the one by Kaushal et al. (2001) which describes ME as "errors in drug ordering, transcribing, dispensing, administering, or monitoring".

Table 3.2: Key definition's components used to investigate MAE in children's hospitals

Study	Definition Components				
	MAE is variation of dose given from			Preparation Errors	Other
	Prescription	Hospital procedures	Manufacture Procedures		
Chua et al. (2010)	✓	✓			
Cousins et al. (2005)	✓	✓	✓	✓	
Feleke and Girma (2010)					"occurs while administering a medication to a patient"
Fontan et al. (2003)	✓				
Ghaleb et al. (2010)	✓	✓		✓	
Herout and Erstad (2004)	✓				Includes omission, dosing errors for weight based infusion were defined as a 5% difference
Prot et al. (2005)	✓				
Raja Lope et al. (2009)					Process of "commission and omission" by nurse

3.3.3 Prevalence of Hospital MAE in Children

Studies that investigated the prevalence of hospital MAE in children have used two methodological approaches. The first was a retrospective method that included: critical incident review (Suresh et al., 2004; Thomas & Panchagnula, 2008), analysis of ME specific incident reports (Doherty & McDonnell, 2012; Frey et al., 2002; Hicks et al., 2007; Manias et al., 2014a; Miller et al., 2010; Ross et al., 2000; Sadat-Ali et al., 2010; Simpson et al., 2004; Stavroudis et al., 2010), and review of medication charts (Kaushal et al., 2001; Marino et al., 2000). The second methodological approach was using a prospective

method. This was in form of either undisguised observation of the medication administration process (Alsulami et al., 2014; Chua et al., 2010; Conroy et al., 2007b; Cousins et al., 2005; Ghaleb et al., 2010; Herout & Erstad, 2004; Ozkan et al., 2011; Prot et al., 2005) or disguised observations (Cousins et al., 2005; Feleke & Girma, 2010).

Retrospective Methods

As can be seen in Table 3.1, retrospective studies are a commonly used method to investigate MAE. This approach was utilised by 12 studies to investigate hospital MAEs in children compared to 10 prospective studies. It involves the review of records kept by healthcare professionals that are in the form of critical incident reports, ME reports or medication charts.

Critical incident reports included MAE as part of all other patient safety incidents. Two studies (Suresh et al., 2004; Thomas & Panchagnula, 2008) using this approach found 362 MAEs in 13314 critical incidents relating to children in hospital care. This is the equivalent of a prevalence rate between 12 and 15 MAE in every 100 critical incident reports.

Whereas, ME reports relate specifically to incidents of medication use. This includes prescribing, dispensing and administration errors. This approach was used in nine studies (Doherty & McDonnell, 2012; Frey et al., 2002; Hicks et al., 2007; Manias et al., 2014a; Miller et al., 2010; Ross et al., 2000; Sadat-Ali et al., 2010; Simpson et al., 2004; Stavroudis, Miller, & Lehmann, 2008). Despite the heterogeneity of data, there were 12552 ME reports in children's hospitals and MAEs accounted for 50% of the reports (n= 6246). This yields a prevalence of between 29 and 76 hospital MAEs in every 100 ME reports in children.

Another method found was to identify MAE from medication charts. Screening medication charts for ME is carried out first. This is then represented in a breakdown of all ME types including MAE. Studies that used this method found a prevalence of MAE between 2 and 13 MAE in every 100 ME identified (Kaushal et al., 2001; Marino et al., 2000). There was no study that has reviewed medical records to identify MAE.

Prospective Methods

The second approach that was found to investigate hospital MAE in children is the use of prospective observation of medication administration practice. This is conducted in disguise or undisguised manner. The prevalence of MAE is dependent on the denominator used. The studies that measured MAE against the number of doses observed have found MAE rate between 9 to 90 MAEs in every 100 doses observed (Alsulami et al., 2014; Chua et al., 2010; Conroy et al., 2007a; Cousins et al., 2005; Feleke & Girma, 2010; Herout & Erstad, 2004; Ozkan et al., 2011; Prot et al., 2005). Despite heterogeneity, cumulatively this represents a total of 2537 children's hospital MAEs (29%) identified in 8894 doses observed.

As presented in Table 3.1, only two studies were conducted in a disguised manner. The first study is multi-centred and was undisguised in the UK but disguised in Germany and France (Cousins et al., 2005). The study found a prevalence of MAE between 34 and 62 MAEs in every 100 doses observed respectively. However, using the same definition and method they found 68 MAEs per 100 doses observed undisguised in the UK. The second study that was carried out in a disguised manner was by Feleke and Girma (2010) in Ethiopia that found at least 90 MAEs in every 100 doses observed.

Another denominator that was used to represent prevalence of MAE is the number of opportunities for error. This was used by the Ghaleb et al. (2010) study that measured MAE in 10 children wards. Ghaleb and colleagues found 19 MAEs in every 100 opportunities for error. This denominator assumes that there are multiple opportunities for error in each dose observed.

3.3.4 MAEs Nature

The following are categories reported to be types of MAE by seven studies in this review (Alsulami et al., 2014; Chua et al., 2010; Cousins et al., 2005; Feleke & Girma, 2010; Ghaleb et al., 2010; Prot et al., 2005; Ross et al., 2000), the remaining 30 studies did not report specific MAE types but categorised MAE with other ME types :

- Preparation, Administration Technique, Medicine Infusion Rate
- Dosage, Extra Dose, Dose Omission, Time of Administration
- Wrong Medicine, Unauthorised Medicine
- Wrong formulation, Wrong route, Wrong Strength

In addition, other incidents, such as failure to follow hospital rules or policy and administration of doses without double-checking were also classified as types of MAE. None of the 37 studies have assessed the severity of the errors found or assessed the potential for harm specific to MAE.

The most reported therapeutic agent that has been associated with hospital MAEs in children are antimicrobials (between 22.9% (Miller et al., 2010) and 50.3% (Feleke & Girma, 2010)). Followed by: anticancer, anticonvulsants, steroids, cardiovascular, opioids and insulin agents.

Only one study (Chedoe et al., 2012) was found to have measured the potential harm of MAE to the patient. A doctor, nurse and a pharmacist carried out this assessment independently where they were asked to rank the potential of harm on a scale of 0 to 10. This was an interventional study that concluded the pre-intervention harm was: 42% minor (n= 67), 57% moderate (n= 91), and 1% severe (n= 1). Whereas post-intervention harm was: 23% minor (n= 24), and 77% moderate (n= 80). This study carried out an observation of 10 days before and after the intervention. The intervention was based on an educational programme, posters for safe preparation and administration, and updated guidelines for the medicine administration process.

3.3.5 MAE Interventions

A review of the literature found five types of interventions evaluated to reduce hospital MAEs in children: bar code medicine administration, computerised physician order entry, education and training, smart pumps and use of standard concentrations.

Bar Code Medicine Administration (BCMA)

BCMA is where patients are wearing a bar coded wristband. The barcode contains patient identification details such as patient's name, date of birth and hospital number. Before each medicine administration, the bar code will need to be scanned against that of the dispensed medicine in order to confirm that the medicine is for the correct patient and is the correct prescribed medicine. Morriss et al. (2009) observed the number of ME using a review of medication charts and records kept by the infusion pump. The number of ME in the pre-intervention phase that did not use BCMA was 39 ME, 19 were MAEs. In the post-intervention phase of using BCMA fewer ME (n= 20) were identified. MAE accounted for 12 incidents. MAE observed with BCMA were relating to omission (n= 1), wrong dose given (n= 1), administration technique (n= 1) and wrong time errors (n= 9).

Computerised Physician Order Entry (CPOE)

CPOE is where a prescription is generated electronically for dispensing and administration. This is also known as electronic prescribing. There have been studies that looked at the use of CPOE and its relation to MAE. The Fontan et al. (2003) retrospective review found that MAEs are lower with the aid of CPOE (22.5%) than with handwritten prescriptions (29.3%).

Additionally, Sowan et al. (2010) found in a simulation study that CPOE increase the probability of detecting a MAE. The simulation involved 144 infusions that are prepared either against a handwritten prescription or CPOE form. The simulation found that nurses were able to identify 53% of MAEs in infusions that were ordered using CPOE. On the other hand, nurses identified 40% of the MAEs in the handwritten infusion prescription. Also, Warrick et al. (2011) evaluated a clinical information system that was integrated with electronic prescribing. This approach has significantly reduced the omitted doses from 8.1% (43 omitted doses in 528 doses) to 1.4% (4 omitted doses in 278 doses).

Yamamoto and Kanemori (2010) carried out a prospective comparison between two medication administration practices. First practice was using a computer-assisted administration that has the prescription integrated and

other resources. The second practice was using a conventional method of medicine administration and dosing without access to a computer programme or electronic resources. They have found that using computer assisted administration practice MAE (n= 27 MAEs) rate is lower than conventional method (n= 70 MAEs) with significant difference ($P < 0.001$). This computer assisted dosing is a combination of an electronic calculator for preparation and administration of children's medicines.

Education and Training

Educational programmes to raise awareness and reduce hospital MAEs in children have been delivered to doctors, nurses and graduating students. Chedoe et al. (2012) was able to reduce MAE by 37% in the Netherlands after implementation of a comprehensive educational programme as well as individual nurse training of preparation and administration procedures. The intervention was able to reduce the potential severity of harm. Notably the wrong administration rates both of minor and moderate harm reduced by 23% and 12% respectively. However, the frequency of MAEs such as medication incompatibilities or intravenous lines not flushed increased by 20% in frequency and severity.

Otero et al. (2008) looked at the effect of comprehensive educational programmes for the nursing team. The intervention designed and implemented a "10 steps to reduce medication errors" checklist. The checklist was also provided in a plastic pocket card for nurses to carry around with them. The study pre-intervention MAE rate was 8.4% and post-intervention rate reduced to 5.9% per 100 administered doses. The intervention has reduced dose omission, incorrect dosing and wrong infusion rate errors.

Another interventional study was by Bertsche et al. (2010) that aimed to provide training on medicine administration to both the healthcare team as well as the parents. This partnership in improving medication delivery via effective training has significantly reduced hospital MAEs in children. MAE rate pre-intervention was 40.4 % by the healthcare team and 96.6% by the parents. The post-intervention MAE rate reduced significantly for the nursing team and parents, 7.9% and 5.6% respectively per 100 doses administered.

There have also been interventions that looked at reducing MAEs in the undergraduate education of nursing (Pauly-O'Neill, 2009; Stewart et al., 2010) and medical (Stewart et al., 2010) students. This is to equip newly graduates with knowledge and understanding of the medication administration process. Another one is training of staff to improve adherence to hospital regulations and policy by Raja Lope et al (2009).

Moreover, Ellis et al. (2011) demonstrated that implementation of new guidelines can prevent harm from MAE. They have managed to prevent the need for the use of morphine antidote or respiratory support in children following administration of a morphine overdose.

Smart Pumps and Standard Concentrations

Smart pumps are devices with in-built algorithm that match the patient's parameters such as weight or body surface area with the correct infusion rate. Thereby decreasing the incidence of MAEs due to the wrong infusion rate and intercepting prescribing errors due to incorrect calculation of dose and infusion rate.

Trbovich et al. (2010) have evaluated three types of infusion pumps: traditional infusion pump, smart infusion pump, and bar code infusion pump. They have found that overall, bar code pumps helped to minimise wrong patient and medicine errors by the nurse scanning a patient wristband against the infusion using a bar code scanner. Whereas smart pumps were more useful in reducing dose MAEs through its in-build library. However with a traditional infusion pump, nurses relied more on their skills and experience. A study by Russell et al. (2010) found that 24% of medicine observed had a discrepancy between the prescribed dose and the actual dose being given to the patient due to the infusion pumps.

Additionally, Larsen et al. (2005) explored using standard concentrations of medication combined with the use of smart pumps. This combination has resulted in decreasing 10-fold MAEs from 0.41 to 0.08 per 1000 dose.

3.4 Discussion

The review was able to explore definitions, methods and interventions used to investigate MAE in children's hospitals. Different definitions for MAEs were identified, reflecting the diversity in understanding of the problem. However, it was possible to recognise key components that constitute a mutual definition of MAEs. These components consist of an agreement that MAE is a deviation of medicine administered from the prescribed instruction. It also includes errors during the preparation process and the failure to follow hospital standard procedures. Nevertheless, there is a need to develop a definition for MAEs agreed by medication safety experts and practitioners that provides a clear and precise statement.

The definition should address issues such as prescribing, dispensing or monitoring errors that were not intercepted before the administration process. Such errors should also be considered as a MAEs since most hospital standard operating procedures for medication administration require staff to conduct adequate clinical checks. The benefit of a standard/agreed MAE definition is that it can reduce heterogeneity of future studies. This will lead to a possibility of meta-analysis and can also be used to conduct randomised control trials of interventions. Also there is a need for clearer defined subcategories of MAE. This will enable a better standardisation of investigations and interpreting of findings. For example, the majority of the studies identify wrong time, but there is no clear indication of what exactly constitutes the wrong time, many state it's the administration of the dose ±1 hour of scheduled time. Others state ±30 minutes. The impact of these differences can be vital since it will affect the number of MAE identified. Therefore, this is a major cause for heterogeneity of the data.

Furthermore, this review found various methods used to investigate hospital MAEs in children. There are indeed strengths and limitations for each method but a triangulation of methodological approaches to study hospital MAEs in children will lead to a better understanding of the true nature, causes and severity of the problem.

There were variations in the denominators of which MAEs were expressed. This could cause confusion, misunderstanding or irregularity in interpreting MAE prevalence. Also, the number of MAEs detected prospectively is dependent on factors like observer clinical experience and knowledge of the medicine administration process. Similar concerns were expressed by the McLeod, Barber, and Franklin (2013) review.

If the heterogeneity between studies due to factors such as: study setting, definitions, size, duration of study and tools used to identify hospital MAE in children were neglected, this review found cumulatively 12552 reported hospital ME incidents. MAEs accounted for 50% (n= 6246). Whereas, using a prospective observation method a total of 2537 MAEs (29%) were detected when 8894 doses were observed. These findings demonstrate the scale of the problem when providing medicine to children in hospital. Yet data is lacking regarding the level of harm this is causing or the potential for harm.

Antimicrobials agents were found to be the medicine most commonly associated with MAE. This finding is expected since antimicrobials are considered the most prescribed agents in this cohort. However, this is also due to difficulties in dose calculations, giving it at the correct time intervals or the preparation of intravenous infusions. Moreover, this could have been as a result of other errors not intercepted in the prescribing or dispensing process. Especially as many medications are used unlicensed and/or off-label in children. The review found only one study that carried out an assessment of MAE potential harm. Another gap in the literature is that no study has been carried out exploring the contributory factors of MAE in PICU. This is important since both knowledge of severity of harm and contributing factors can help to develop interventions and will facilitate the development of interventions that focus on risky practices by both the system and practitioners.

In addition, interventional studies in hospital MAE were explored and categorised as: bar-code medicine administration, electronic prescribing, education and training, use of smart pumps and standard concentration. However, evidence is not strong enough to support their true impact or

effects on reducing MAEs. This is possibly due to the multifaceted nature of MAE.

For example BCMA have shown the advantages of reducing MAEs relating to wrong patient, wrong medicine and time errors. However, other MAEs may not be reduced such as errors in preparation, administration technique or wrong dose. Additionally, implementation of this BCMA system will encounter financial costs and requires staff training to ensure competence.

On the other hand, CPOE allows clearer dosage instructions than handwritten prescriptions, hence minimising the risk of giving the wrong dose and can help detect prescribing errors before administering the medicine. Also use of pharmaceutical calculation aids can provide better personalised clinical decisions. Therefore, this will help to ensuring correct administration of medicines by informing the amount of drug to draw out, diluent volume and the infusion rate. However, this approach may not address issues such as wrong patient, wrong time or wrong medicine and it may introduce new errors, such as discrepancies between what is electronically recorded and what is actually given. Therefore, more evaluation is required of these interventions and a study of the impact of multiple interventions on MAE.

The current evidence suggests that there is a need for more than one intervention to reduce MAE in practice. They should focus on supporting good medication safety practices that have no blame culture, promote learning from errors and involve new technologies. Nevertheless, it is equally important to put in place suitable monitoring methods over long periods of time to assess the suitability of interventions.

However, the review identified a key gap in literature and that is the limited number of interventions in PICUs, although there have been a number of studies carried out in PICUs to quantify the scale of the problem. Additionally, no study was found which investigated the opinions of PICU healthcare professionals about causes of MAE or sought recommendations from them to improve their administration practice. As far as the researcher is aware, there were only two studies carried out in the UK that tried to reduce MAEs (Stewart et al., 2010; Warrick et al., 2011). Both studies did not actually

address MAE fully nor did they reduce MAEs in PICUs. Stewart et al. (2010) investigated the use of education and simulation of the administration process with undergraduate nurse students. The study is of less application in real practice since the study was carried out over a very short period of time. Also they did not follow up the students' performance in real time clinical situations. On the other hand, Warrick et al. (2011) utilised a clinical information system to provide support for doctors and nurses. However, they only measured MAE in means of omitted doses. This is by no means a reflection of the true level of the problem in practice. Also, they carried out the study in an emergency department where patients are only likely to stay for a very short period of time. Hence many of the scheduled doses will be missed because they would have either been discharged to another ward or sent back home. Therefore, there is a serious need for evidence-based MAE safety measures in PICUs.

This review builds upon knowledge found by other researchers. The prevalence of MAE found in this review is similar to that of (Ghaleb et al., 2006; Keers et al., 2013b; McLeod et al., 2013). It also agrees with Raban and Westbrook (2013) that reducing interruption alone is associated with weak evidence of reducing MAE.

This review did not identify research written in non-English language due to time constraints and lack of translators. Inclusion of such research would add vital insight into the type of research and nature of MAE in different parts of the world. However, the databases that were searched did return a number of non-English studies that were judged not to be relevant for this review. A separate search on non-English databases would be required along with a trusted translator that has experience in conducting literature reviews.

Additionally, only interventional studies related to hospital MAE were reviewed, but it would have been beneficial to review overall ME interventions as well since this review shed light on the multifaceted nature of MAE. Also this review has focused only on hospital interventions to MAE in children. A separate review is recommended specifically to identify all the MAE interventions in both adults and children to allow shared learning and adaptation of interventions across different settings.

Moreover, future MAE research involve the need for a validated expert consensus on a clear practical guide to carry out MAE studies. This should include a standard manner to define, classify and reporting of MAE. This will result in a better understanding of the problem and will lead to development of evidence-based interventions.

3.4.1 Conclusion

This review has identified wide variation in the prevalence of hospital MAE in children. This is attributed to the methods and definitions used to investigate these errors as identified in this review. Additionally, the review found weak evidence for one single intervention to reduce hospital MAE in children. This illustrates the complexity and multifaceted nature of this issue. Therefore, there is a need to develop a set of safety measures to tackle these errors.

3.5 Study Contribution to Knowledge

1. The overall contribution of this review is that it provided a deeper understanding of the nature of MAEs in children's hospitals and identified the gap in PICU-based MAE research.
2. This review found that the most agreed definition is that MAE is a deviation from prescriber's instructions and hospital procedures.
3. The most clear and concise definition is by Ghaleb et al. (2010). It states that MAE is "the administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policy and procedures. This includes errors in the preparation, and administration of intravenous medicines on the ward".
4. There is no consensus in defining the subtypes of MAE.
5. No mention of prescribing/dispensing errors that were not intervened in before the administration process.

6. Only one study carried out assessment of potential harm due to MAE.
7. No study explored contributing factors of MAE in PICU.
8. Healthcare professionals' opinions were not investigated to identify the causes or recommendations of MAE prevention methods in PICU. Weak evidence found to support use of a single intervention to reduce MAE.
9. Only two studies carried out an intervention in the UK. Neither investigated MAE fully. One looked at the use of simulation in undergraduate nurse students and the other developed clinical information systems in the emergency department.
10. No study has been carried out in the UK to reduce MAE in PICU.

Chapter 4: Retrospective Analysis of Medication Error Reports of a London PICU

4.1 Introduction

The systematic review of literature in this thesis has identified a number of methods to investigate MAE. This includes the review of patient safety incidents submitted to a reporting system. The NPSA (2010) have defined a patient safety incident as "any unintended or unexpected incident which could have or did lead to harm". The same definition is used by NHS England following NPSA function transfer to NHS England in 2012. The following are categories of patient safety incidents:

- Incidents that caused no harm or minimum harm.
- Near Miss Incidents (NMI). These are incidents that had the potential to cause harm but did not reach the patient.
- Serious Untoward Incidents (SUI) that result in severe harm or death. This also includes incidents where there is police involvement or media interest and never events.

Medication errors are included in all categories of patient safety incidents. There is a requirement to report these incidents to the National Reporting and Learning System (NRLS) within two days of detecting the incident. However, for SUIs there is an additional requirement to notify the Department of Health within two hours and document a report in the Strategic Executive Information System (STEIS) within two days. Moreover, a thorough investigation should be carried out by root cause analysis. This will lead to identifying areas for improvements and lessons learnt.

The NRLS received a total of 42029 incidents relating to the care of children between 1st October 2007 and 30th September 2008 (NPSA, 2009). This represents 4.2% of the total incidents reported to the NRLS (n= 910089). Incidents relating to medication use were found in 17% (n= 7145). It was found that administration of incorrect dose or strength of medication was the highest reported medication incident type (23%).

In order to investigate MAEs occurring in PICUs regardless of the level of harm caused, reviewing all reported incidents is ideal rather than simply review of one specific type of incidents. This will ensure that all reported incidents are captured whether they have reached the patient or not. An additional advantage is that trends and correlation of risk can be measured regardless of harm caused.

The aim of this study is to identify retrospectively the baseline characteristics of MAEs reported in a PICU of a children's hospital. The study objectives include:

1. To characterise occurrences of patient safety incidents in PICU.
2. To determine the nature of incidents related to medicine use in PICUs.
3. To report the documented severity of harm caused by the medicine incidents in PICUs.
4. To identify prevalence of MEs and MAEs reported in PICUs.
5. To investigate factors associated with MAEs in PICUs.
6. To assess the quality of medication incident reports in PICUs.

4.2 Method

4.2.1 Setting

The study was carried out at Great Ormond Street Hospital (London, UK) PICU. It hosts 13 beds, with approximately 1200 patients admitted annually.

4.2.2 Study Definitions

The hospital's classifications of patient safety incidents were used to categorise the incidents not relating to medication use. The NPSA definition of ME was used in this study to classify errors relating to medicines. It states that ME incidents are "patient safety incidents involving medicines in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred" (National Patient Safety Agency, 2007b, p. 9).

A more specific definition for MAE was also used to explore the incidents relating to administration. In this study MAE has been defined as "the administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policies and procedures. This includes errors in the preparation, and administration of intravenous medicines on the ward" (Ghaleb et al., 2010).

Another definition used to categorise medication incidents is near miss. A near miss is "where the error was discovered before the medicine was supplied to the patient" (NPSA, 2007b, p. 11).

4.2.3 Selection Criteria

All patient safety incidents reported to the PICU risk management system between 1st January 2007 and 30th September 2012 will be analysed. The study excluded any errors related to blood related products and blood transfusion. Detailed analysis was carried out only on medication incidents that relate to prescribing and administration errors.

4.2.4 Data Collection

All patient safety incident reports from 1st January 2007 to 30th September 2012 submitted, whether as paper-based reports or to the electronic risk management system (Datix), were collected. The following data will be recorded:

- Date and time of incident or when it was reported.
- Name of medication involved.
- Patient age at the time of the incident.
- Detailed account of the incident.
- Nature of incident.
- Subtype of incident (i.e. wrong dose, wrong time, dose omission).
- Reported severity of harm by the incident.

Paper based patient safety incident reports were recorded manually by the researcher. The data was transcribed into a Microsoft Excel 2007 Worksheet (Microsoft, Redmond, Washington, US) for analysis. Patient safety incident reports that were submitted electronically were extracted into a Microsoft Excel file format from Datix. All patient identifiable information or details of staff involved were removed. The risk management assessment of severity of harm data was used in this study.

4.2.5 Data Analysis

A single dataset was created in Microsoft Excel combining both paper-based critical incident reports and the Datix dataset. Thematic analysis was carried out on all medication related incidents to identify the subtypes of MEs. Moreover, NHS England (2014c) Medication Optimisation Dashboard was used to calculate the level of medication safety. This measurement is carried out as a percentage ratio of number of medication incidents resulting in harm over the total number of medication incidents.

4.2.6 Data Validation

The researcher asked a PICU nurse to select a random sample of 20 patient safety incident reports. The nurse compared the documented incident to that recorded by the researcher electronically into Microsoft Excel. The nurse

found all 20 reports to match the associated transcribed reports. Also, the nurse noted that the researcher complied with all information governance requirements. Moreover, an independent fellow PhD candidate validated a further random sample of 50 patient safety incident reports that were thematically analysed by the researcher. The independent researcher was given all definitions and was briefed on the aim and purpose of this study. There was agreement in 48 reports (96%) and the remaining two reports were agreed after discussion, there was no need for a third opinion.

4.2.7 Calculation of medication error prevalence

The Paediatric Intensive Care Audit Network (2014, PICANet) provided various data such as number of admissions. This data is available to the public to view individual PICUs' annual activities. Therefore, the number of admissions and number of patient bed days were collected. These were used as denominators to work out the overall prevalence of medication errors. The following equations were used to calculate the incidence per 100 admissions (equation 4.1) and incidence per 1000 bed days (equation 4.2).

$$Prevalence\ per\ 100\ admission = \frac{Number\ of\ Incidents}{Number\ of\ Admission} \times 100 \quad \textit{Equation 4.1}$$

$$Prevalence\ per\ 1000\ bed\ days = \frac{Number\ of\ Incidents}{Number\ of\ bed\ days} \times 1000 \quad \textit{Equation 4.2}$$

4.2.8 Quality Assessment

A random sample of medication incident reports (20%) was reviewed to assess the quality of reporting. This is carried out on the Datix incidents only since it is the only currently used reporting system. The researcher used the following criteria were used to review each incident:

1. Did the report provide patient demographics (e.g. age/ gender)?
2. Was the date and time when the incident occurred or was identified reported?
3. Was the name of the medication(s) involved documented?
4. Were details of medication formulation or strength involved in the incident documented?

5. Was the stage at which the incident occurred documented and correctly identified (e.g. administration)?
6. Is the category of incident correctly identified (e.g. wrong dose)?
7. Were the professions of the staff involved in the incident reported (e.g. doctor)?
8. Is the description of the incident detailed enough?
9. Were the underlying causes of the incident documented?
10. Are there actions to be taken to avoid this incident from happening again?

Each medication incident was assessed and scored out of 10. The following scores determine the level of report quality in relation to opportunity for learning:

- A score between 9 and 10 is excellent.
- A score between 7 and 8 is good.
- A score between 5 and 6 is average.
- A score between 3 and 4 is poor.
- A score between 1 and 2 is inadequate.

4.2.9 Ethical Consideration

There was a requirement to ensure that all data recorded complied with the hospital's information governance policy. Therefore, the researcher removed all identifiable information of the persons involved, the person who reported the incident and patient information. As discussed in the methodology chapter of this thesis, an ethical approval was obtained.

4.3 Results:

4.3.1 Characteristics of Patient Safety Incident Reports

There were 1686 patient safety incident reports documented at the PICU between 1st January 2007 and 30th September 2012. As presented in Figure 4.1, the highest number of reports relates to medications which account for 35% (n= 583).

This is followed by health and safety incidents (13%, n= 224), equipment (10%, n= 162), communications (9%, n= 147), self-extubations (8%, n= 135), bed management and other staffing issues (8%, n= 133), other not classified incidents (6%, n= 97) which includes, for example, incidents relating to security issues or raising concerns regarding patient wellbeing at home, incidents relating to services from other departments (5%, n= 83) which includes examples of delayed response or delayed transfer of patient's records, extravasations (4%, n= 69) and tissue viability (3%, n= 53). There were a total of 1207 paper based reports for the period of January 2007 to March 2011. Medicine related reports accounted for (20%, n= 237). In the period between March 2011 and September 2012 there were 479 Datix reports. Medicine incidents accounted for 72% (n= 346).

As the aim of this study is to review patient safety incident reports that are directly related to medication use in PICU, a total of 1103 incidents were excluded. The incidents that related to medication use (n= 583) were analysed further.

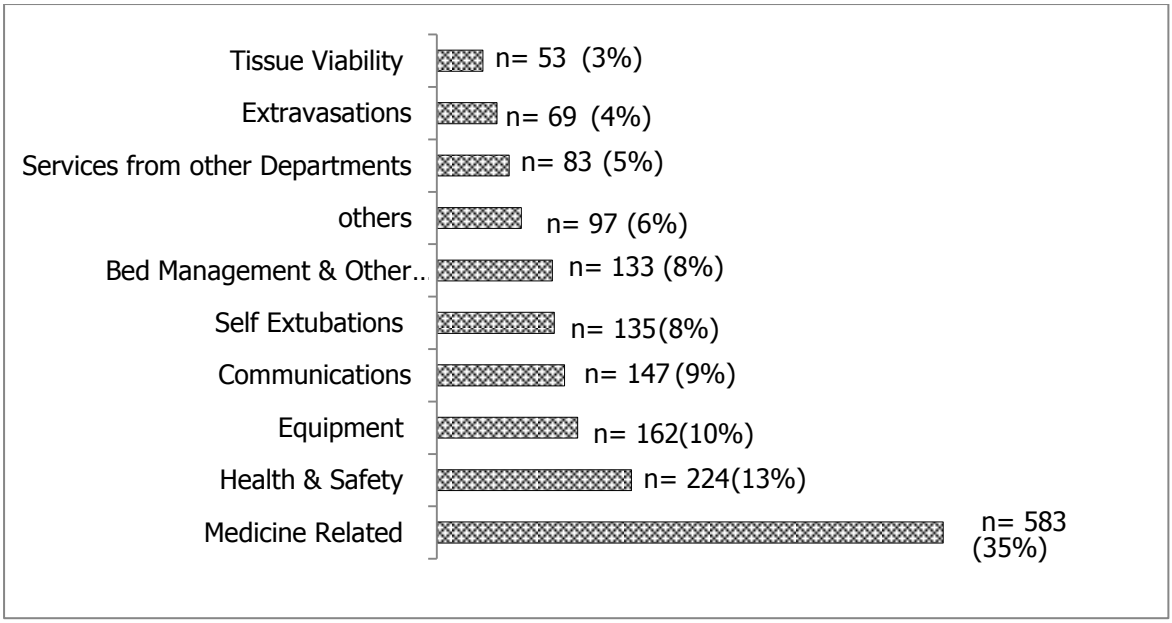

Figure 4.1: Distribution of patient safety incident reports in PICU (n= 1686) for period of 1st January 2007 to 30th September 2012

4.3.2 Nature of Medicine Related Incident Reports

A breakdown of all medicine related incidents (n= 583) shows a further division into six main categories: near-miss (i.e. error intercepted before a dose administered, 17%, n= 95), prescribing errors not prevented before administration (24%, n= 141), incidents at administration stage (30%, n= 176), issues relating to supply from pharmacy or other departments (8%, n= 48), storage or control drug (CD) balance issues (11%, n= 64), and total parenteral nutrition (TPN) incidents (10%, n= 59). This is illustrated in Figure 4.2 that shows the breakdown in a pie chart.

In order to meet the study objectives, incidents relating to CD balance discrepancies, supply and TPN reports were excluded (n=171). Therefore, the incidents of the following nature were further analysed: administration incidents, incidents relating to both the prescribing and administration stages, and near misses. These yielded 412 reports, representing 71% of total medicine related reports and 24% of the overall patient safety incident reports. Table 4.1 provides examples of these incidents.

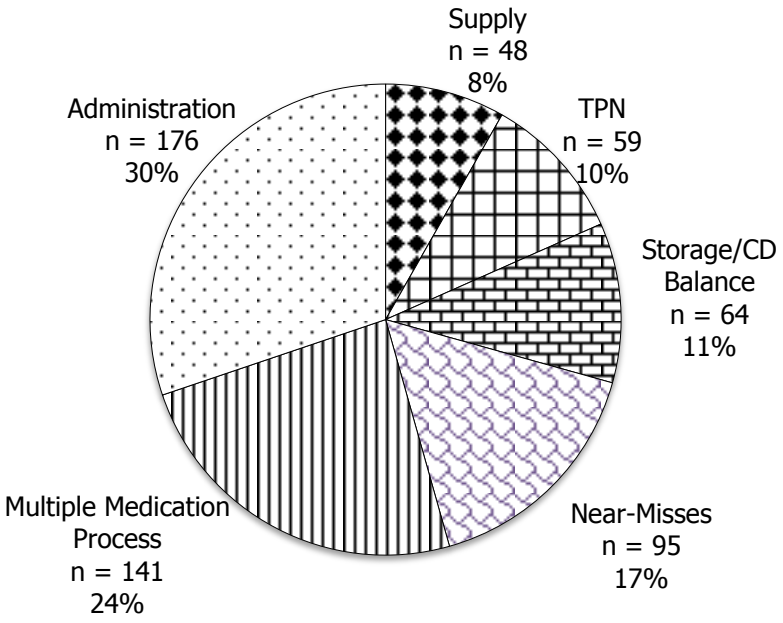

Figure 4.2: Breakdown of medicine related incident reports

Table 4.1: Examples of Incidents reported

Class of Error	Subtype	Incident as reported
Multiple Medication Process Incidents	Wrong Diluent	Morphine and Midazolam infusions prescribed in 0.9% Sodium Chloride. Made up in 5% Glucose. Noticed at morning handover.
	Wrong Patient	Hyoscine patch was prescribed for the wrong patient and given when that patient should have remained only on Glycopyrronium Bromide oral solution.
	Wrong Dose	Piperacutin/Tazobactam (8 doses), ciprofloxacin (5 doses) and Vancomycin (4 doses) given as full doses to patient with long standing renal impairment.
Medication Administration Errors	Omission	Amikacin trough and hold reported performed at 02.00 on prescription chart, but was not administered. Night staff told day staff dose could be given. Amikacin level 1.2mg/l (range 1–10) reported at 06.26. Child septic with gram-negative rods in pus found in vaginal remnant.
	Wrong Dose	Checking drug infusions, child prescribed 132mg of midazolam documented on syringe that 26.4mg was in the syringe
	Extra Dose	Checking drug chart child was prescribed 530mg of midazolam as bolus PRN. Dose had been signed as given times 2. [given twice within 30minutes gap]
Near Miss Incidents	Wrong Dose	Dexamethasone prescribed as 160mg IV QDS. The dose that should have been prescribed was 4mg IV QDS. Prescription changed.
	Wrong Infusion Rate	Hydralazine infusion was prescribed with a calculation error therefore the rate prescribed was ten times too high. This incorrect prescription was then copied by another prescriber incorrectly. Drug was not administered.
	Illegal Prescription	Furosemide prescribed on drug chart but no dose given and not signed by doctor. No doses given by nursing staff

Near Misses Incident Reports

Near Miss Incidents are incidents of errors prevented before reaching the patient. There were 95 near miss reports found by the researcher. This represents 17% of all medication related incidents and 6% of patient safety incident reports. Figure 4.3 illustrates the different categories of near miss. They break down into: wrong doses prescribed (n= 44), prescribing wrong infusion rates (n= 17), failure to prescribe in accordance with the legal requirements of prescriptions (n= 13), prescribing wrong dose frequency (n= 10), documentation issues in prescription (n= 5), omission (n= 3) and prescribing wrong route (n= 1). There were other related incidents (n= 2) due to failure to prescribe appropriately.

No reports relating to a near miss during the administration process were identified. This includes the double-checking process and the preparation process.

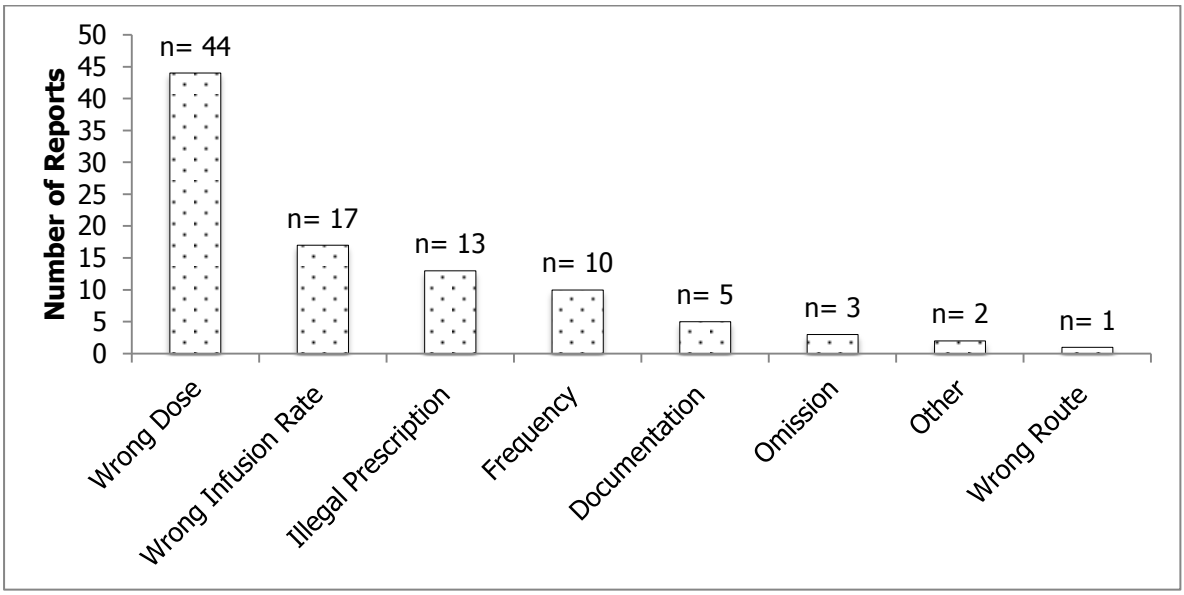

Figure 4.3: Nature of reported near miss incident reports (n= 95)

Review of the near miss incidents found Paracetamol (n= 7), Amikacin (n= 6) and Midazolam (n= 5) to be the drugs most reported as shown in Table 4.2. It is worth noting that Amikacin is a narrow therapeutic drug that requires careful adjustment of dose in accordance with weight and status of renal function.

Table 4.2: Top drugs associated with near miss reports

Drug	Number of Reports
Paracetamol	7
Amikacin	6
Midazolam	5
Hyoscine	4
Morphine	4
Veccuronium	4

MAE Incident Reports

The most prevalent incidents relating to medicine use were MAEs (30%, n= 176). These also account for 10% of all patient safety incident reports. It was possible to categorise these reports into various types as presented in Figure 4.4. These are incidents where the prescribed dose was correct but error occurred either during preparation or administration process. All MAEs reached the patient and were identified later by either a nurse or the ward pharmacist.

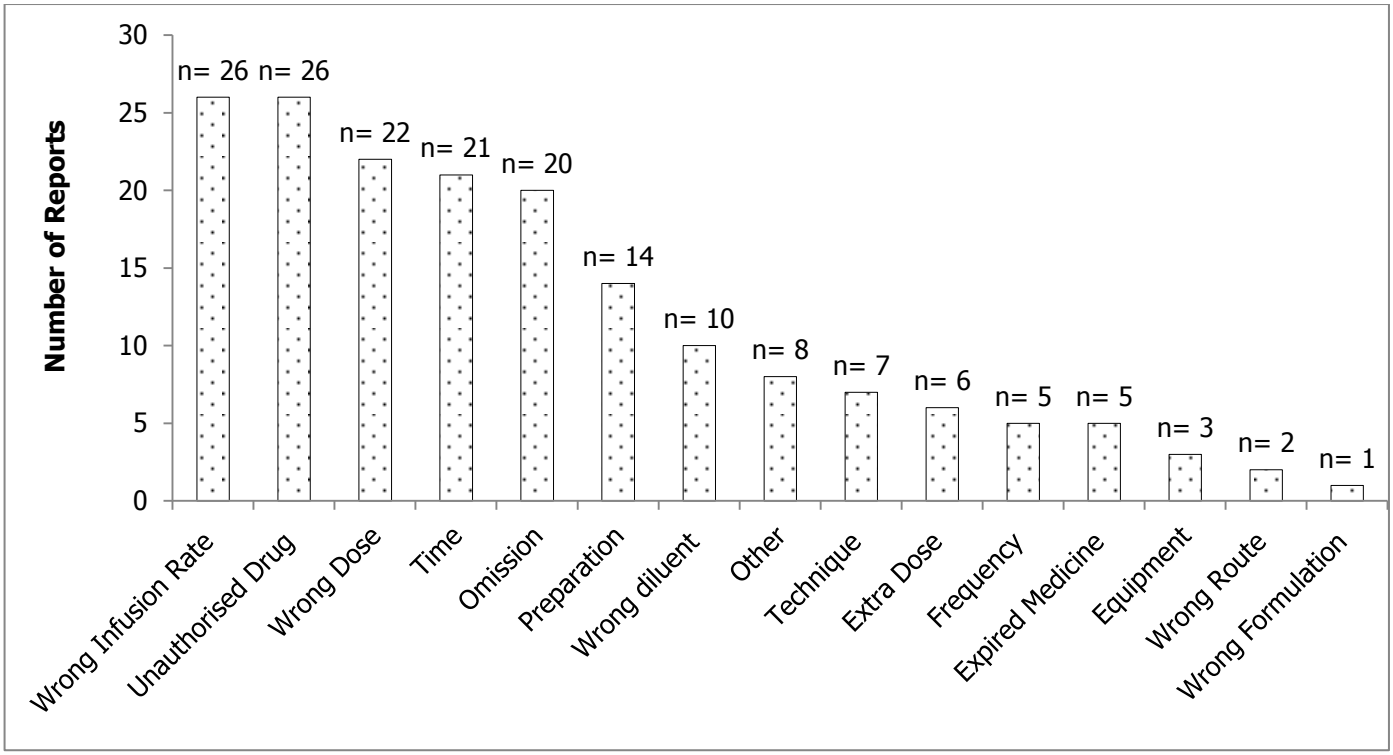

Figure 4.4: Breakdown of incidents relating to MAE (n= 176)

As it is demonstrated in Figure 4.4, the nature of MAE is extended over a number of types. Reports relating to wrong infusion rate are the leading category of MAE (n= 26) and administration of unauthorised drug (n= 26), followed by wrong dose (n= 22) errors, and time errors (n= 21). Table 4.3 represents the top five drugs that are associated with MAE reports. As can be seen Morphine is the most reported drug linked with MAE, followed by Midazolam and Vancomycin. It should be noted that all of these medicines are considered to be high risk medicines.

Table 4.3: Top drugs associated with MAE reports

Drug	Number of Reports
Morphine	15
Midazolam	12
Vancomycin	10
Amikacin	8
Phenobarbitone	8

Incidents Relating to Multiple Medication Process

There were incidents relating to failure to prescribe correctly that were not intercepted during the administration process (n= 141). These incidents were mostly identified by the ward pharmacist (n= 124). Figure 4.5 demonstrates the breakdown of these incidents. These incidents represent 24% of all medication related reports and 8% of all patient safety incident reports.

As can be seen in Figure 4.5, the majority of the incidents are due to dose given (n= 73), and followed by reports of prescriptions that are considered to be illegal due to failure to fulfil the prescription requirement (n= 47). Table 4.4 presents the most common drugs that are associated with this type of error. Once again high-risk medicines and narrow therapeutic agents are reported to be associated with these incidents.

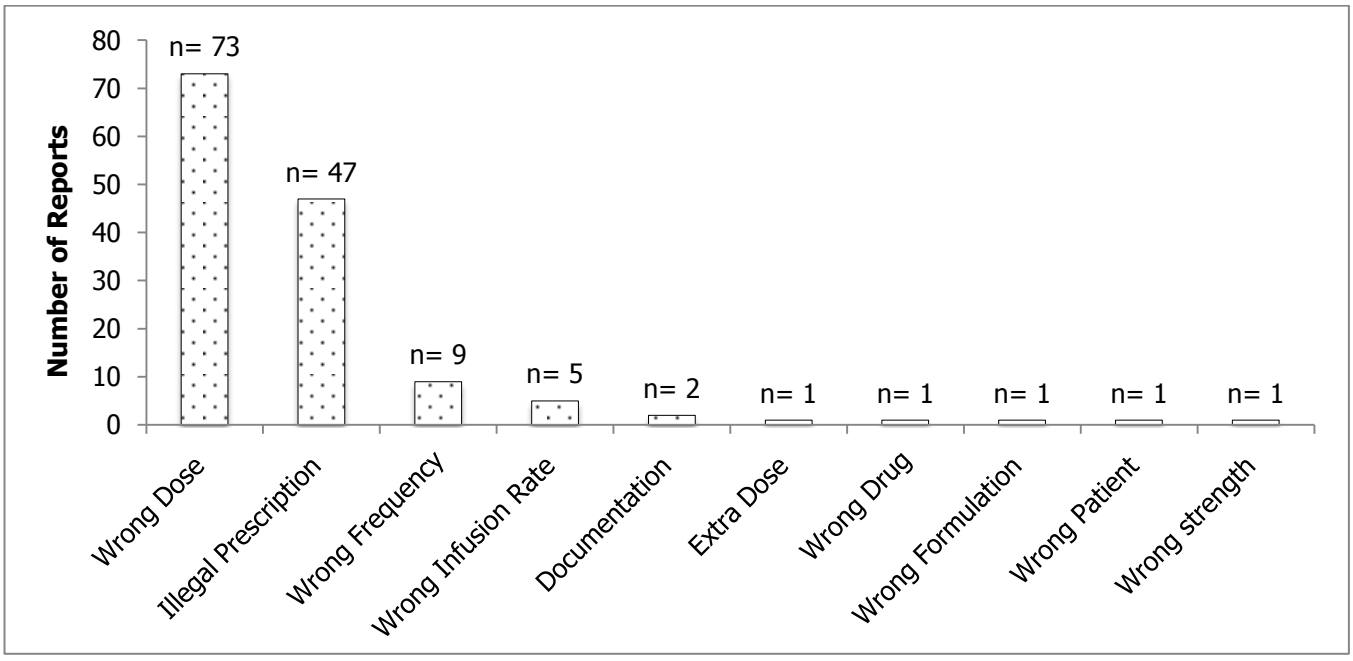

Figure 4.5: Nature of incidents relating to multiple medication process errors (n= 141)

Table 4.4: Top drugs associated with multiple medication process error

Drug	Number of Reports
Midazolam	11
Morphine	11
Veccuronium	8
Paracetamol	6
Vancomycin	6
Aciclovir	5
Amikacin	5
Ciprofloxacin	5

4.3.3 Medicine Incidents Severity of Harm

The PICU risk management team assess all incident reports in accordance with the NPSA scale of harm. Their assessment of the medicine related incidents found in this review (n= 412) were extracted and presented in Figure 4.6. As illustrated, the majority of the incidents did not lead to harm, but 12 incidents were found to involve severe harm and are listed in Table 4.5.

The level of safety using the NHS England Medicines Optimisation Dashboard is 30% in this PICU over the dataset collected. This represents the ratio of incidents documented with harm (low, moderate, severe and death, n= 125) over the total number of incidents (n= 412).

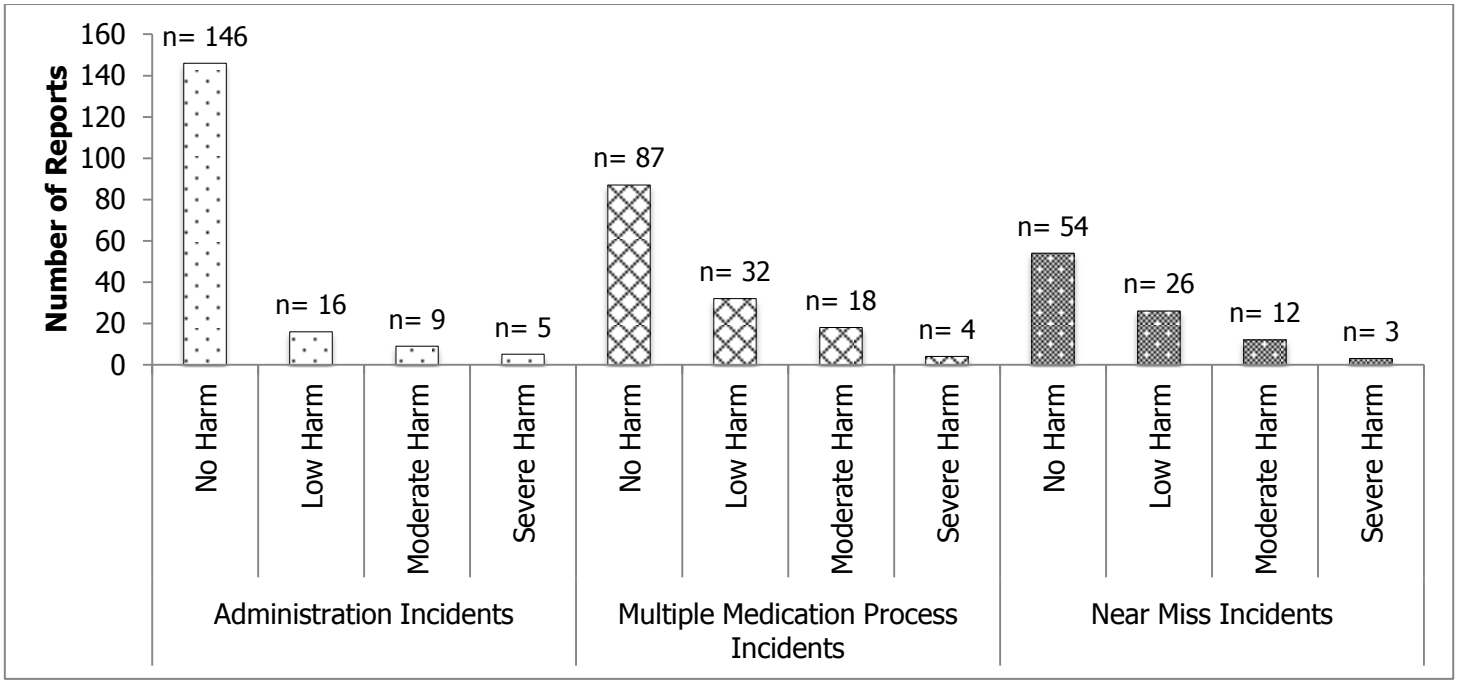

Figure 4.6: Severity of harm for medicine related incidents

Table 4.5: All severe incidents associated with medicine related reports

Category	Description of incident as reported
Multiple Medication Process Incidents	Patient was prescribed carbamazepine 750mg BD PO in error, dose should have been 150mg BD. 750mg Dose has been signed as having been given & documented as been given at 20:00 on xx/xx/07 (nursing staff not yet contacted to confirm what dose was administered) CBZ Level to be monitored pre-dose on xx/xx/07 (after 2 days) dose of 150mg already administered on 08:00 therefore too late to take level
	Incorrect dose of Vancomycin had been prescribed by Dr on the xx/xx/08. The dose had then been given over the next 3 days the level was found to be high.
	Four medications incorrectly prescribed, not signed and wrong dose calculated.
	Patient was prescribed aminophylline continuous infusion for diuresis. Recommended dose was 0.5mg/kg/hr due to interaction between amlodipine and aminophylline (usual dose range 0.5–1mg/kg/hr however calcium channel blockers may increase aminophylline levels therefore require lower end of dose range).
Near Miss Incidents	Amlodipine prescribed as 60mg QDS (max adult dose 10mg OD) prescribed in error was supposed to be nimodipine. No drug was given to patient
	Hydralazine infusion was prescribed with a calculation error therefore the rate prescribed was ten times too high. This incorrect prescription was then copied by another prescriber incorrectly. Drug was not administered.
	Vasopressin prescribed as units/kg/hour instead of minutes. Sodium bicarbonate infusion prescribed with dose and rate incomplete. Noradrenaline prescribed with no dose units specified.
Administration Incidents	Triclofos had been given at 06:00 but not prescription for it.
	Amikacin trough and hold reported performed at 02.00 on prescription chart, but was not administered. Night staff told day staff dose could be given. Amikacin level 1.2mg/l (range 1–10) reported at 06.26. Child septic with gram negative rods in pus found in vaginal remnant.
	Newly diagnosed diabetic patient, continued to have BMs >25 despite novo rapid insulin being given via pen. Thought to be a drug delivery issue. Discovered after Nurse in charge spoke with pharmacy and researched the pens that needle is not situated in pen as previously has been. needles need to be fitted to pen for each use. Therefore, patient had not received any of the novorapid insulin thought to have been administered.
	Pre-made syringe of milrinone being administered, concentration 50mg in 50mls. Prescribed for 10mg in 50mls. Pump also set for 10mg concentration not the 50mg/50ml being administered.
	Patient on Fentanyl infusion. Infusion made up not according to prescription chart and running above prescribed rate.

4.3.4 Prevalence of Medicine Related Incidents

The prevalence of medicine related incidents were calculated using the annual reports of PICANet. The total number of patient admissions and total number of bed days for the period of 1st January 2007 to 30th September 2012 were extracted from PICANet. Table 4.6 present the breakdown for each medication related incident category. The prevalence was expressed using two denominators: number of admissions, and number of bed days. As the table demonstrates, there is a positive correlation of reporting across six years. The prevalence of medication incidents were found to be seven reports in every 100 admissions and 10.4 reports per 1000 bed days. The prevalence of MAEs was found to be three in every 100 admissions and 4.4 in every 1000 patient days. As can be noted, the number of admissions post 2007 has steadily levelled out. It illustrates that there is a mean of 940 admissions per year (based on data between 2008 and 2011). This indicates the high demand on this small sized PICU (13 beds).

Table 4.6: Prevalence of medicine related incidents for period between 2007 and 2012

	Year						Total
	2007	2008	2009	2010	2011	2012*	
Number of Admissions	1473	892	953	934	983	675	5910
Bed Days	9792	5951	6066	6348	6568	5044	39769
Administration Incidents							
Number of Reports	41	37	16	13	21	48	176
Prevalence per 100 Admission	2.8	4.1	1.7	1.4	2.1	7.1	2.9
Prevalence per 1000 Bed Days	4.2	6.2	2.6	2.0	3.2	9.5	4.4
Near Miss Incidents							
Number of Reports	9	8	8	6	31	33	95
Prevalence per 100 Admission	0.6	0.9	0.8	0.6	3.2	4.9	1.6
Prevalence per 1000 Bed Days	0.9	1.3	1.3	0.9	4.7	6.5	2.4
Multiple Medication Process Incidents							
Number of Reports	20	11	37	26	25	22	141
Prevalence per 100 Admission	1.4	1.2	3.9	2.8	2.5	3.6	2.4
Prevalence per 1000 Bed Days	2.0	1.8	6.1	4.1	3.8	4.4	3.5
All Medication Related Incidents							
Number of Reports	70	56	61	45	77	103	412
Prevalence per 100 Admission	4.6	6.3	6.4	4.6	7.8	15.3	6.9
Prevalence per 1000 Bed Days	7.1	9.4	9.6	6.9	11.7	20.4	10.4

* Data up to 30th September 2012

4.3.5 Associated Factors: Patient Age

Not all reports collected stated patient's age or patient's date of birth. Only 217 reports documented this information out of the 412 reports. Since data collected were specifically from PICUs, it can be seen that reports affected patients of all paediatric age groups as illustrated in Figure 4.7. The most commonly reported errors were associated with patients aged between 0 to 2 years old (n= 111), followed by those aged 3 to 5 years old (n= 37) and then patients aged 12 to 14 years old (n= 29).

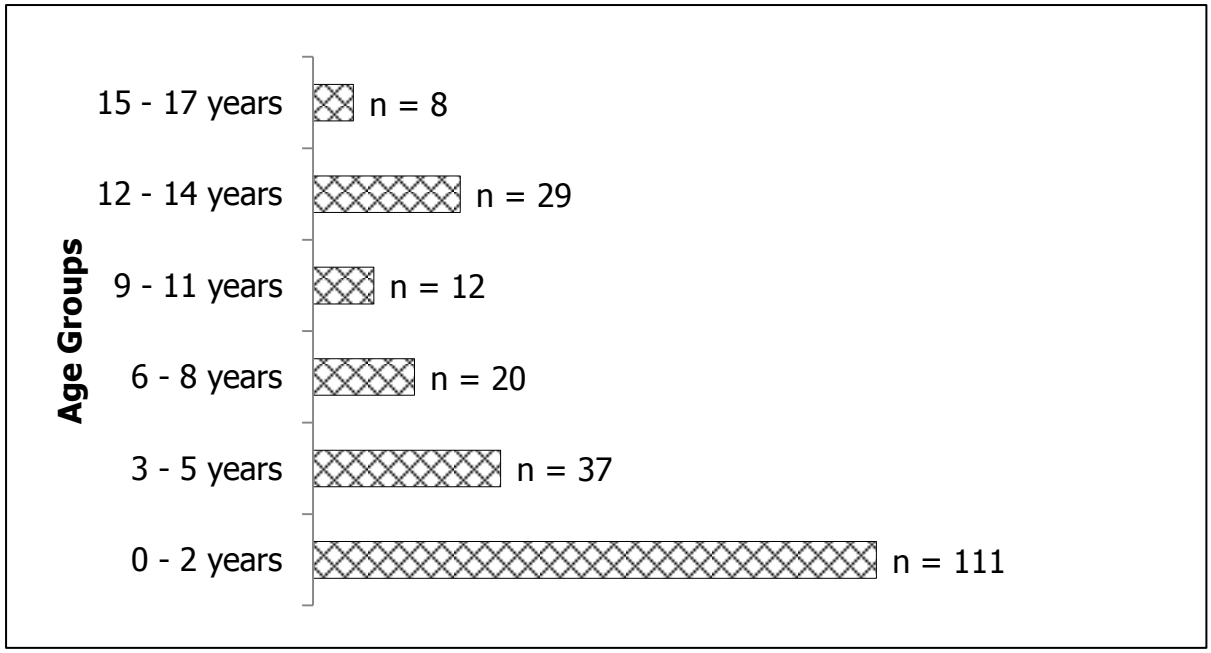

Figure 4.7: Medicine related incidents according to age-group of patients in PICU (n= 217)

4.3.6 Associated Factors: Seasonal Variation

It was possible to investigate seasonal variations of incident reporting within the unit. Figure 4.8 reveals in chart (A) the medicine related incident (n = 412) reporting per month over the period from January 2007 to September 2012. It illustrates that festive and summer holidays are associated with lower numbers of reporting compared to mid seasons. This can also be seen in chart (B) which demonstrates a similar pattern. Moreover, differences in reporting also exists across weekdays as shown in chart (C). Weekends are associated with a lower number of reports than the first three days of the week. Further variation can be observed across the 24 hour cycle as shown in Figure 4.9. However, the data represents time that incident was reported as well as time that the incident actually occurred. Nevertheless, it can be seen that errors are more likely to be picked up at the beginning of each shift (8am or 8pm).

4.3.7 Associated Factors: Therapeutic Agents

In this study, 101 different therapeutic agents were identified as being associated with medication related incidents. Table 4.7 represents the number of reports for each therapeutic agent. As can be seen, the most associated agents are: Morphine (n= 30), Midazolam (n= 28), Amikacin (n= 19), and Vancomycin (n= 18). Additionally, a total of 13 high risk medicines and narrow therapeutic agents have been associated with 159 incident reports. This represents 38% of the incidents reviewed in this analysis (n= 412). Figure 4.10 demonstrates the reported therapeutic agents group. Antimicrobials are the most reported group of medicines (n= 119), followed by sedation agents (n= 71) and cardiovascular agents (n= 70).

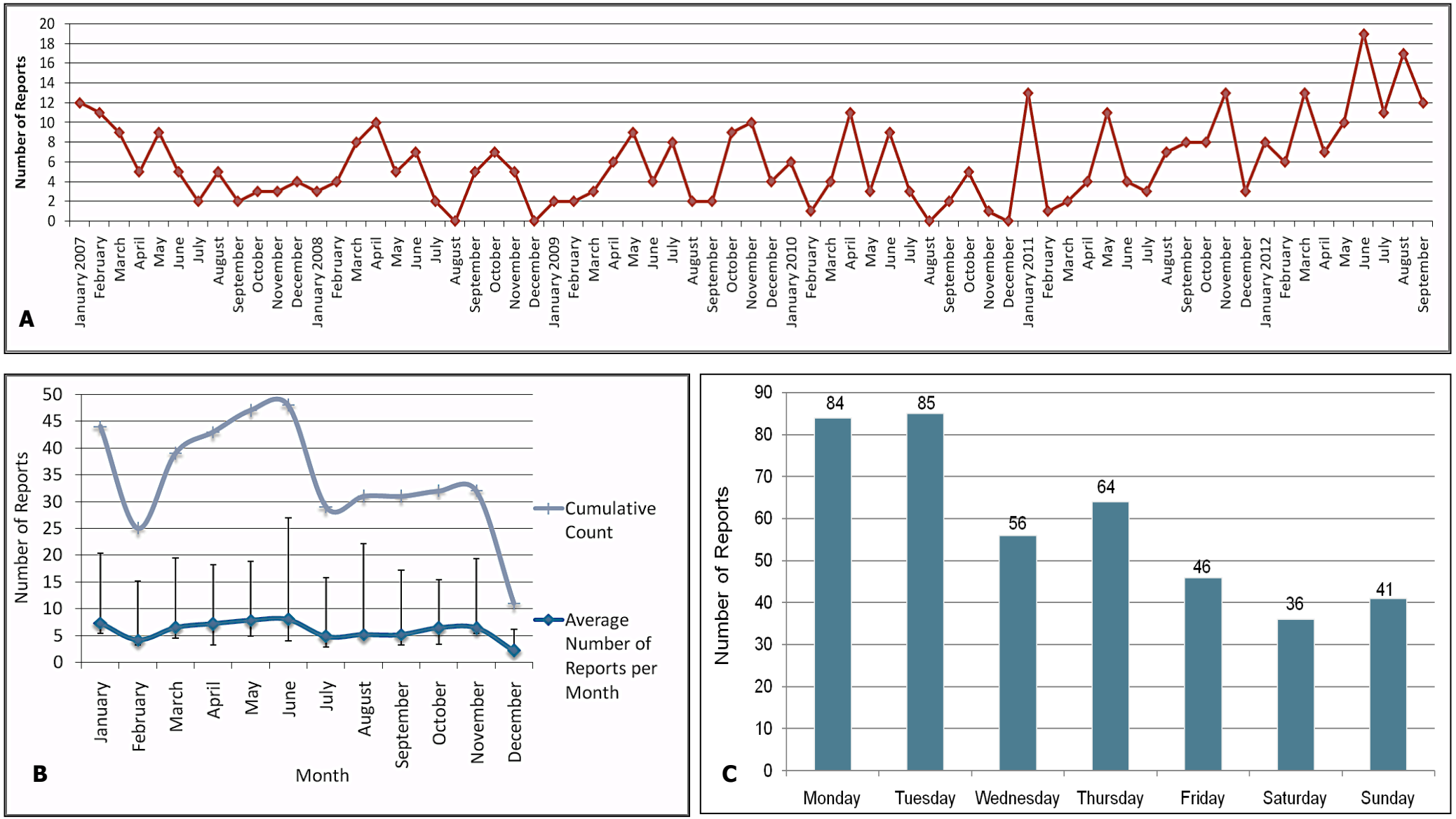

Figure 4.8: Graph (A) shows the distribution of reports (n= 412) over 5 years and graph (B) shows the cumulative count of reports for each calendar month with the average number of reports per month. Whereby, chart (C) shows the breakdown of reports

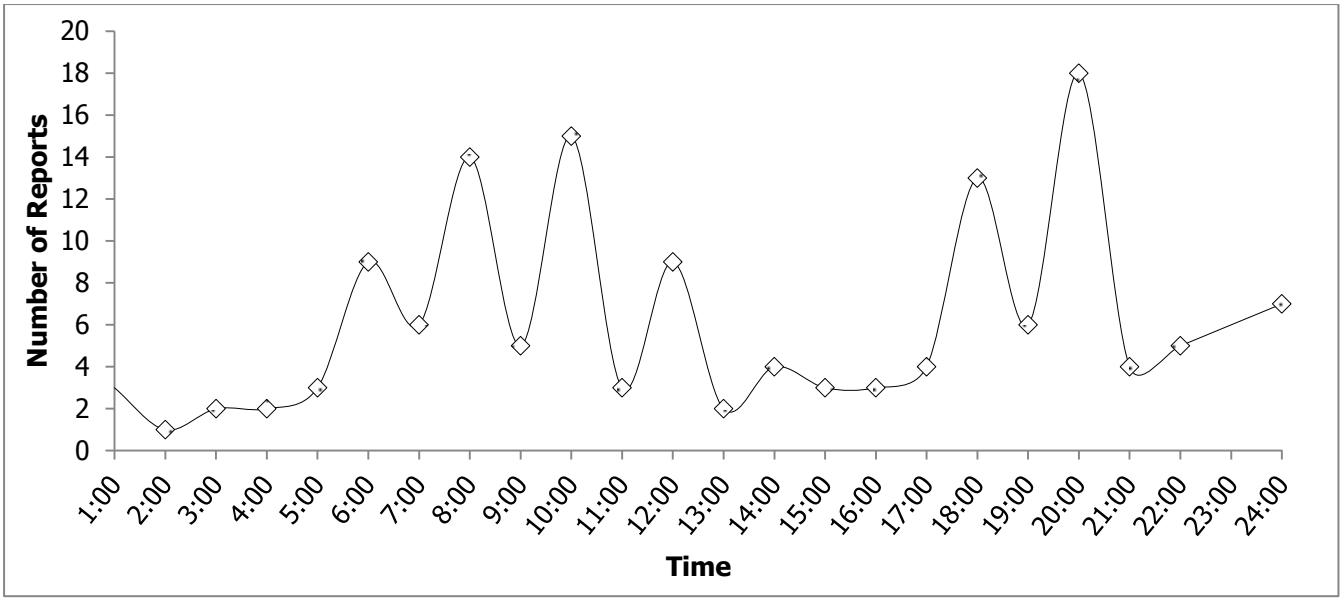

Figure 4.9: Hourly fluctuation of medication error reporting in PICU (n= 141)

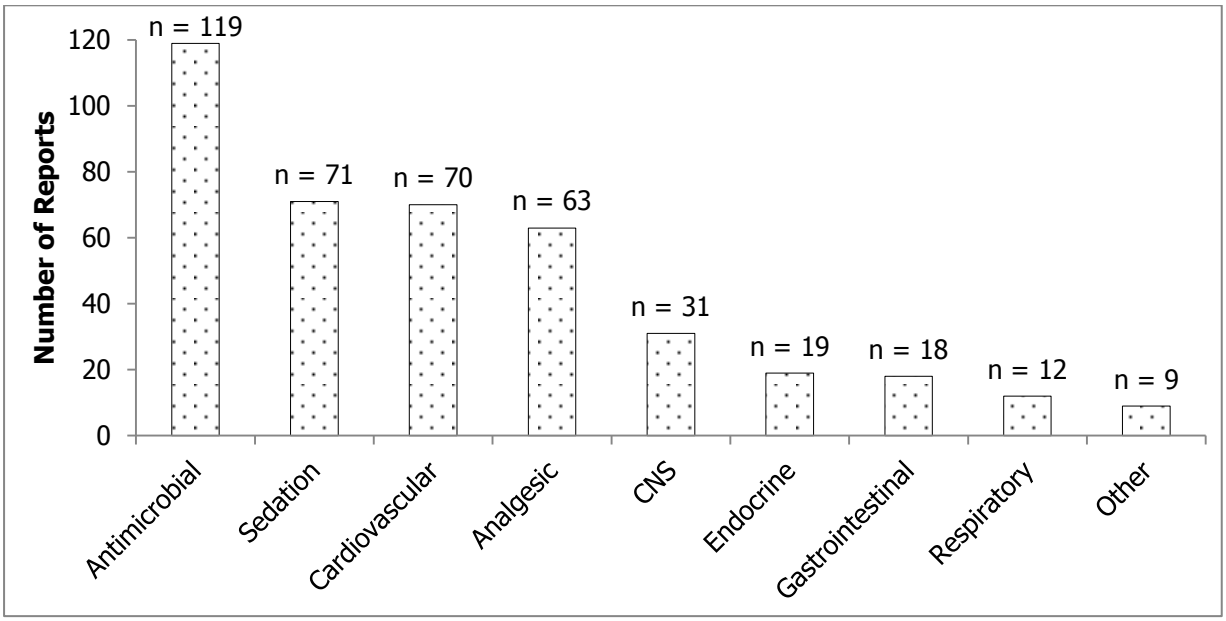

Figure 4.10: Therapeutic agents associated with medicine related incidents (n= 412)

Table 4.7: List of the number of medication related incident reports for each therapeutic agent

Drug	Reports	Drug	Reports	Drug	Reports
Morphine [HR]	30	Sodium Nitroprusside	3	Magnesium Sulphate	1
Midazolam [HR]	28	Spironalactone	3	Montelukast	1
Amikacin [HR]	19	Teicoplanin	3	Movicol	1
Vancomycin [HR]	18	Ursodeoxycholic Acid	3	Mycophenolate	1
Paracetamol	17	Hydrocortisone	3	Omeprazole	1
Veccuronium [HR]	17	Metronidazole	3	Ondansetron	1
Clonidine	12	Adrenaline	2	Oseltanivr	1
Noradrenaline	10	Amlodipine	2	Pancuronium	1
Phenobarbitone [HR]	9	Amphotericin	2	Pentoxifylline	1
Aciclovir	8	Ampicillin	2	Potassium Canrenoate	1
Fentanyl [HR]	8	Baclofen	2	Prednisolone	1
Furosemide [HR]	8	Chloramphenicol	2	Propofol	1
Rantidine	8	Cotrimoxazole	2	Pyridoxine	1
Hyoscine	7	Epoprostenol	2	Rocuronium	1
Cefotaxime	6	Hydralazine	2	Sirolimus	1
Ciprofloxacin	6	Ipratropium	2	Sodium Chloride	1
Piperacillin/Tozobactam	6	Pentamidine	2	Sulfasolazine	1
Potassium Chloride [HR]	6	Remifentanyl [HR]	2	**Total**	**412**
Azithromycin	6	Sildenafil	2		
Alimemazine	5	Sodium Bicarbonate	2		
Aminphylline	5	Sodium Feredetate	2		
Chlorphenamine	5	Spironolactone	2		
Dexamethasone	5	Diazepam	2		
Erythromycin	5	Amiodarone	1		
Insulin [HR]	5	Amoxicillin	1		
Ketamine [HR]	5	Atricurium	1		
Meropemum	5	Azathrioprine	1		
Milrinone	5	Carbamazepine	1		
Triclofos	5	Choral Hydrate	1		
Clarithromycin	4	Clindamycin	1		
Gancicilovir	4	Clobazam	1		
Octreotide	4	Co-Trimoxazole	1		
Phenytoin [HR]	4	Colomycin	1		
Salbutamol	4	Dapsone	1		
Co-Amoxiclav	4	Digoxin	1		
Ambisone	3	Flucytosine	1		
Chloral Hydrate	3	Folic Acid	1		
Ciclosporin	3	Foscarnet	1		
Domperidone	3	Glycopyrrolate	1		
Dopamine	3	Glyceryl Trinitrate	1		
Fluconazole	3	Levomepromazine	1		
Methyprednisolone	3	Loperamide	1		

[HR] High Risk Medicine

4.3.8 Quality of Medication Related Incident Reports

A random sample (20%) of the medication related incident Datix reports were selected to assess the quality of reporting. The 35 randomly selected incidents were reviewed against set criteria and it was found that the majority of the incident reports were of a poor level (n= 24). Table 4.8 illustrates the findings and provides examples for each quality level. This assessment is aimed at level of opportunity for learning from the incident.

Table 4.8: Findings of quality assessment for learning and examples

Quality Level	Total (%)	Examples
Poor	24 (69%)	Patient prescribed midazolam and vecuronium infusions with no dose or rate prescribed. Both drugs had been administered against illegal prescription.
Average	5 (14%)	Amphotericin prescribed for TDS, transcribed incorrectly from ward electronic charting. Dose of 4mg/kg TDS not 4mg/kg Once a day.
Good	5 (14%)	Patient prescribed both long acting and short acting insulin, both medication dispensed as flexpens, no needles were dispensed with the pens and no patient information leaflet was available. As a ward we are unfamiliar with this method of administering insulin as we usually give it iv as an infusion. consequently I was unable to deliver the dose of short acting insulin as prescribed and had to request an alternative preparation from pharmacy, this led to a delay in the patient receiving the drug and a potential problem with managing blood sugars, on reflection it was unclear as to whether the long acting insulin had been given appropriately as there were no needles available at this time either.
Inadequate	1 (3%)	Medication administered via the incorrect route
Total	35 (100%)	

4.4 Discussion

The aim of this study was to identify retrospectively baseline characteristics of MAEs reported in a PICU. The study characterised medication related incident and it was also possible to identify factors associated with these incidents. The severity of harm associated with these incidents was also reported. Additionally, assessment of quality of reporting of medication incidents was carried out.

This analysis of patient safety incident reports in the PICU of a London based children's hospital over a period of 68 months (5.6 years) found 1686 reports. The most reported incidents were related to medicines (n= 583, 35%). It was found that 412 incidents were specifically associated with medication use in the PICU. This includes errors in prescribing and administration processes. The 412 incidents represent 24% of all reported patient safety incidents (n= 1686). The most reported incidents related to medication administration incidents (n= 176, 43%), followed by prescribing errors that were not intercepted (n= 141, 34%) and near miss incidents (n= 95, 23%).

Medication administration incidents are errors in preparation or administration process when using a correct prescription. However, the hospital standard procedure for medicine administration requires staff to ensure that the prescribed dose is within the prescribing protocol. Therefore, failure to do so will constitute an administration error. This type of incident was classified in this report as a multiple medication process error. This is to reflect that a better physical barrier is required to avoid these errors. This is indicated by the fact that the majority of these incidents were only identified by the PICU pharmacist after the dose had already been given. It is known that the pharmacist does play a major role in reducing medication errors (Manias, Kinney, Cranswick, Williams, & Borrott, 2014b) but they will not be always present in the PICU. On the other hand, near miss incidents that are intercepted before reaching the patient are considerably lower. This illustrates a real problem and the need to introduce measures to support staff picking up these incidents more.

Over the study period of 5.6 years, there were a total of 5910 admissions to this small sized PICU (13 beds). This represents a total of 39769 bed days. The prevalence of medication related incidents was 6.9 reports in every 100 admissions and 10.4 reports per 1000 bed days. This is broken down into: administration error prevalence of 2.9 per 100 admissions and 4.4 per 1000 bed days, multiple medication process incidents are 2.4 per 100 admissions and 3.5 per 1000 bed days, and near misses were 1.6 per 100 admissions and 2.4 per 1000 bed days. However, this is considerably lower than that reported by Raju, Kecskes, Thornton, Perry, and Feldman (1989) and Vincer et al. (1989), which was 14.7 MAE per 100 admission and 13.4 per 1000 patient days respectively.

The systematic literature review found the rate of MAEs using analysis of medication error reports was between 29 and 76 in every 100 ME reports in children's hospitals. Despite heterogeneity of data, this represents 12552 hospital ME reports in children of which MAEs account for 50% (Doherty & McDonnell, 2012; Frey et al., 2002; Hicks et al., 2007; Manias et al., 2014a; Miller et al., 2010; Ross et al., 2000; Sadat-Ali et al., 2010; Simpson et al., 2004; Stavroudis et al., 2008). Therefore, the findings of this study are in line with other research. However, as far as the researcher is aware, this is the first study that identified incidents due to failure in multiple medication processes. This is important as it demonstrates the complexity and the multifaceted nature of MAE. Additionally, this reveals that current MAE definitions used require more clarification.

The majority of the medicine related incidents were due to either wrong dose or wrong infusion rate. This is concerning since this type of error can have a direct influence on the patient’s therapy. However, the risk management team identified most errors as being of low risk of harm. But it was not clear if this assessment of harm was based on the actual level of harm caused or the potential of harm it could cause. It is often difficult to establish the true level of harm due to the complexity of conditions under treatment. Hence, it is challenging to correlate harm or deterioration of a child’s health to a medication error; nevertheless, there were 12 (2.9%) incidents classified as severe harm. Moreover, this review utilised the new medicine optimisation

assessment of safety by NHS England (2014c). It found that in this PICU the safety of medication practice using NHS England medicine optimisation dashboard is 30%. Although there is no guidance on the meaning of this rate, a possible interpretation is that it indicates moderately severe harm. Since it illustrates that 30% of the incidents are associated with potential harm (low to death). It is understood that the lower the rate, the better the safety of medicine. Additionally, it can be interpreted as a need for medication safety improvement and used as benchmark for assessing suboptimal use of medicines in children over 1 to 2 years as recommended in the National Institute for Health and Care Excellence (2015) guidelines for Medicine Optimisation.

It was clear that the current reporting of medication incidents was focused mostly on incidents that have the potential to cause harm. This review found a worrying number of incidents relating to high risk or narrow therapeutic medicines, this indicated by the fact that top four drugs reported are Morphine (n= 30), Midazolam (n= 28), Amikacin (n= 19) and Vanomycin (n= 18), all of which could have a devastating effect on a child's health. This is a highly specialist area and these incidents should not be tolerated. It also proposes a question regarding the safety of the actual pharmaceutical preparations and how friendly it is in adjusting to a child's dose. Therefore, this is an issue of both human and systemic factors. Although medication incidents are the most reported incidents, it clear that there is an under-reporting culture, since, improvement of the reporting system has directly influenced the number of reports submitted. A positive correlation was seen following implementation of the electronic risk management system Datix in March 2011. This suggests that an infrastructure that supports ease of reporting and learning will lead to quality improvement. Moreover, the following can also contribute to under-reporting of MAEs:

1. Voluntary reporting of incidents; healthcare staff may only report direct serious or severe harm to patients.

2. Fear of disciplinary, dismissal or clinical duties restrictions.

3. Being blamed and recognised as incompetent and being subjected to negative attitude from colleagues and patients or patient's family.
4. Not receiving adequate training on what, how, when or where to report.
5. No clear definition of what contributes an MAE incident and not being able to recognise one.
6. Lack of feedback from management and the absence of shared learning from errors across the team.
7. The misconception of reporting as a comment on individual performance and not the overall system factors that contribute to MAE.
8. Individual perception of MAEs and belief that an incident which did not cause harm is not worth reporting; difficulty accepting an MAE has occurred.
9. Poor design of the actual mechanism of reporting; paper based reporting will take longer to complete than electronic reports.
10. Pressure of daily clinical duties that are of higher priority than reporting.

As anticipated, the agents most associated with medication incidents are antimicrobials. Since these are the most used agents in this clinical speciality. The study also found a variation in time of reporting of medication incidents. It is found that the beginning of a shift is the peak slot of reporting. This could indicate the presence of a blame culture. But it could also indicate that alertness level is highest during that time. This is probable since the new staff are not tired yet and not involved in complex clinical duties straight away. It was found that weekend days are associated with the lowest number of reports compared to the first two days of the week. This has also been seen across the months of the year, where holiday and festive months are associated with lower reporting rates. A possible justification is the use of temporary staff compared to permanent staff who are more familiar with incident reporting procedures and have an awareness of the patient safety

culture policy. But this fluctuation in reporting could also be attributed to low staffing level, absences of managers and absences of experienced staff.

It has often been a criticism that medication incident reports do not provide sufficient amounts of information to support future learning. This was also established by the World Health Organization (2014) on reporting and learning systems. However, as far as the researcher is aware no previous attempts were made to assess the quality of reports. Therefore, this study assessed the quality of Datix reports using criteria developed by the researcher, as there were previously no criteria available to assess the quality. This criteria was developed in light of the recommendations by NHS England (2014b) of what constitutes a good report to facilitate learning. From a 20% (n= 35) random sample, the majority of the reports (69%) were found to be of a poor quality in relation to opportunity for learning. However, 29% were assessed to be of a good or average quality for learning. Nonetheless, it is important to praise these reports in order to identify lessons to be learnt and promote opportunities for change. As far as the researcher is aware, this is the first study that assessed the quality of medication error reporting.

The study had a number of potential limitations. Firstly, not all of the reports had the full information required for data collection. Secondly, the review did not investigate the actual harm caused by medicine related incidents. Thirdly, the study did not explore the causes of the incidents or the lessons learnt by staff involved. Fourthly, the review did not explore the incidents from the patient's perspective nor did it identify the number of patient's parents or carers who were informed of the error. Fifthly, the study did not distinguish errors caused by temporary or permanent staff nor the reported level of experience of who caused or identified the errors. Improvement of reporting quality will reduce these limitations and will provide better understanding of the scale of the problem. Additionally, this review did not attempt to identify incidents that are listed as never events by NHS England (2013) since there is not enough evidence of actual harm received by the patient. Additionally, the study supported the findings of the systematic literature review in developing an expert led definition of MAEs and their subtypes. This should include incidents of failure to intercept errors from other medication processes such

as prescribing, dispensing and monitoring. Moreover, a root cause analysis of specific MAEs such as wrong dose or wrong infusion rate will lead to a better understanding and identify contributory factors.

4.4.1 Conclusion

A considerable number of patient safety incidents are occurring due to medication use in PICUs. Reports relating to failures in administration processes are the highest. All patient age groups are affected and antimicrobials are associated with the highest number of reports. Medicines that are high risk and those with narrow therapeutic window are correlated with an increased risk of MAE. Reported level of harm is low, but severe harm was documented in 12 incidents. Findings of the study illustrated the complexity and multifaceted nature of MAE. The overall quality of reports is poor for learning but they can be utilised to explore risk trends. Root cause analysis is required in order to establish actual causes of incidents.

4.5 Study Contribution to Knowledge

1. First large scale UK based PICU study that characterised nature of patient safety incident reports over 5.6 years (n= 1686). Incidents relating to direct use of medicines in PICU accounted for the most (n= 412). Medication administration errors were found in 43% (n= 176) of all reported medicine related incidents (n= 412).

2. Identified new category of errors relating to multiple medication processes. Data was found to support the assertion that there were prescribing errors that were not intervened in before administration but were identified afterwards. The clinical pharmacist reported the majority of these incidents. This was found in 34% of all reported medicine related incidents (n= 412).

3. Severity of harm due to different types of medication incidents was reported. Majority of incidents were associated with no or low harm but severe harm was found in 12 incidents.

4. The overall prevalence of medication incidents in PICU was found to be 6.9 ME in every 100 patient admissions to the PICU. This is also

equivalent to 10.4 ME per 1000 PICU bed days. This is the first study to give this measurement since the Raju et al. (1989) and Vincer et al. (1989) studies.

5. Study utilised NHS England Medicine Optimisation dashboard for medication safety assessment. It found a ratio of 30% for incidents that caused harm over the total number of medication incidents. This is concerning since it represents the seriousness of medication incidents. Also the quality of reports were assessed, 69% of a random sample (n= 35) were found to be of a poor quality for learning.

Chapter 5: Prospective Observation of Medication Administration Practice of a London PICU

5.1 Introduction

One of the most efficient methods to investigate MAE is the prospective observation of medication administration practice. The concept of this method is to observe the administration process in real-time practice. Usually trained nurses are predominantly responsible for this process in hospital setting but doctors also administer medication in certain situations. It is important to note that this is not a method of appraising an individual's performance but it assesses the overall medication safety practice of administration. This includes the system infrastructure. There are two approaches for this method: disguised or undisguised. Both share similar benefits and challenges.

This method avoids the following significant barriers to self-reporting of MAE:

- Disagreement between staff of what constitute a reportable MAE.
- Concerns of the person involved in the MAE of the response from management and colleagues.
- The quality of reporting and time needed to document the error.

Therefore, prospective observation can eliminate some of the limitations of a retrospective review of medication incidents. Additionally, direct observation allows the researcher to collect information that is not being reported, for example, number of interruptions. Moreover, by using a good data collection tool and effective analysis of data collected, this method can be very accurate, reliable and precise. This methodological approach is supported by strong evidence and is considered the gold standard method for investigating

MAEs (Allan & Barker, 1990; Barker, 1980; Dean & Barber, 2001; Flynn, Barker, Pepper, Bates, & Mikeal, 2002; Murff, Patel, Hripcsak, & Bates, 2003; Thomas & Petersen, 2003).

However, this approach encounters a number of challenges that need to be taken into consideration. This includes issues relating to Hawthorne effect and ethical issues such as when to intervene. All these issues and others are required to be addressed at the methodological development phase.

The aim of this study is to investigate MAE using prospective observation of medication administration practice in PICU. The study objectives are as follow:

1. To investigate the incidence of MAE in PICU.
2. To determine the nature and type of MAE in PICU.
3. To assess the potential severity of harm caused by MAE in PICU.
4. To explore factors associated with MAE in PICU.
5. To compare findings of retrospective analysis of MAE reports versus MAE observed prospectively.

5.2 Method

5.2.1 Study Setting

The study was carried out at Great Ormond Street Hospital (London, UK) a paediatric intensive care unit (PICU) that host 13 beds, with approximately 1200 patients admitted annually.

5.2.2 Observation Criteria

The study did not observe administration of total parental nutrition, blood related products or blood transfusion. Only participants who consented for the observation of their practice when administering medicines were observed.

5.2.3 MAE Study Definition & Types

The study used the following MAE definition developed by Ghaleb et al. (2010):

"The administration of a dose of medication that deviates from the prescription, as written on the patient medication chart, or from standard hospital policies and procedures. This includes errors in the preparation, and administration of intravenous medicines on the ward."

This definition was selected for this study since it provides a complete understanding of what constitute an MAE and was developed through a process of two-round Delphi by experts in medication safety research. Therefore, there is no need to redevelop the definition since it has been shown to be valid and reliable (Ghaleb, 2006, pp. 49–86).

The definitions of MAE subtypes that were used in this study are presented in Table 5.1. The definitions were developed following a review of literature and discussion within the research team. The subtype definitions were adapted from Dean and Barber (2000) and Greengold et al. (2003). Definitions were found to be valid during the pilot study and fit for the purpose of this study following a review with the PICU clinical pharmacist.

Table 5.1: Definitions of MAE subtypes used during the observation study

Incident Subtype	Definition
Preparation	Incorrect preparation of the medication dose, an example incorrect dilution or reconstitution, not shaking a suspension, using an expired drug, not keeping a light-sensitive drug protected from light, not following non-touch technique for IV formulations, and mixing drugs that are physically or chemically incompatible. Additionally, failure to follow hospital standard operating procedures in medicine preparation and administration, or failure to follow specific manufacture's instruction in preparing the medication.
Wrong medicine	A dose of medicine administered that was not the drug prescribed. However, generic substitution was not considered an error.
Wrong Diluent	The use of incorrect diluent than that prescribed or recommended by the intravenous administration guide.
Wrong Infusion Rate	Administration of intravenous dose with incorrect rate of infusion as recommended by the intravenous administration guide
Wrong Patient	Administering a prescribed medication but to the wrong patient
Wrong Route	The administration of correct medicine by a route that was not prescribed.
Wrong formulation	The administration of the correct medicine by the correct route but in a formulation that was not the prescribed. Appropriate purposeful alteration to facilitate administration not considered an error.
Administration Technique	Giving the correct medication but improper administration technique used, an example is failure to use specific medication administration device or not measuring specific parameters prior to drug administration.
Dosage	The administration of the correct medicine by the correct route but in a quantity that was not that prescribed. This includes administration of the incorrect number of dose units, selection of the wrong strength of dose unit, and the measurement of an incorrect volume of an oral liquid. Where liquid preparations were not measured but instead were poured into ungraduated medicine cups, if failure to shake a suspension resulted in a visible concentration gradient, this was also considered a wrong dose error.
Extra Dose	The administration of an additional dose of a prescribed medication. This included the administration of a drug more times during the day than prescribed and the administration of an additional dose of a drug following its discontinuation.
Time	Administering a medication ± 1 hour of the prescribed dosage regime
Omission	A dose of medication that had not been administered by the time of the next scheduled dose. Doses omitted according to doctors' instructions, according to a nurse's clinical judgment (including where the patient refused the medication or was designated nil-by-mouth) or because the patient was not on the ward were not considered as omitted medicine
Unauthorised Medicine	The administration of a dose of a drug that was not prescribed for the patient concerned. However, if drug X was prescribed but drug Y given instead, this was classified as a wrong medicine error
Other	Any other error that is not mentioned above, errors such as violation of hospital Standard operating procedures. Additionally administration of a drug that had exceeded its expiry date or for which the physical or chemical integrity had been compromised.

5.2.4 Study Preparation

Approvals to conduct this study were obtained from the NHS Research Ethics Committee – Bloomsbury London (appendix 1) and GOSH Research and Development (appendix 2). Additionally, a written authorisation letter has been taken from the PICU Risk Manager/Sister to allow an undisguised observation of the current practice (appendix 3). The researcher was also given an honorary contract for purpose of conducting research in the hospital. Nursing staff was provided with an explanation of the purpose of this study using: a group presentation (appendix 7), distribution of study information sheets (appendix 8) and face-to-face discussions. It was made clear to nursing staff that the researcher will be acting in a professional non-judgemental way; interception will only happen if the error would result in harm to the patient and their personal identity will not be taken or recorded. Nursing staff were also asked to inform parents or patient's representatives if questioned, that the researcher will not be intervening in their child's therapy or treatment and is shadowing the nurse.

Moreover, the researcher undertook an extensive and comprehensive training by the PICU senior clinical pharmacist and a sister nurse to gain experience in the medication administration process and clinically screen drug charts.

5.2.5 Participants Recruitment & Consent Procedure

A series of study introductory presentations (appendix 7) given over one month (January/February 2013), twice weekly during nurse's study days to introduce the study, collect informed consents and answer any queries or worries were carried out. A study information sheet (SIS) was given to each nurse (appendix 8). Also, an email was sent to all members of staff containing the presentation with the SIS by the PICU risk manager to inform them of the study. An informed consent was obtained at the end of the presentation and discussions (appendix 9).

At the beginning of each observation slot verbal consent is taken from the nurse in charge of the PICU on that day. Before each observation, verbal consent is also taken from the person preparing and administering medication to ensure that it is appropriate for the observer to be present. An informed

consent was also requested for those that did not sign one already. Moreover, posters were displayed for both staff and patient's parents and visitors to inform them of the study (appendix 10).

5.2.6 Observer Medicine Administration Training

The Senior PICU Specialist Pharmacist conducted a series of training sessions with the observer. The training consisted of tutoring on specific PICU pharmaceutical calculations, effective review of drug charts, and use of PICU guidelines for prescribing and administration of medicines since the researcher is community pharmacist trained. The observer also shadowed the PICU pharmacist and nursing staff over a period of three months to gain experience in medicine administration practice since the observer is a community pharmacist. Another aim for this was for the nursing staff to be familiar with the observer in order to reduce Hawthorne effect.

5.2.7 Pilot Study

Undisguised pilot observations were carried out over three weeks (March 2013) covering different time slots, weekdays and weekends. The majority of the observations were carried out in the presence of a senior PICU clinical pharmacist to ensure reliability and accuracy of the observation. The clinical pharmacist also provided guidance on clinical queries for the observer. Each observation was recorded on a paper-based data collection form (appendix 11). The aim of this pilot study was: to validate the method of medication administration observation and the tools used to collect data, and to explore the logistics in place at the site of observation.

A total of 14 day shifts (8am to 8pm) and three night shifts (8pm to 8am) were observed. Sixteen nurses participated, 214 doses were observed being administered to 20 patients aged between one month and 15 years old and giving 35 different medicines. MAEs were identified in 54 doses (25.4%). On three occasions, two MAEs were identified in the same observation. One intervention was required (when an Aciclovir infusion was about to be administered but it was noticed by the observer that it had expired two months ago). Figure 5.1 show the nature of MAE identified in this pilot study.

Key findings of this pilot study suggested the need to develop a standard procedure for observation. Also the need for agreed criteria on when to intervene in MAEs to ensure consistency and the observer's ethical duty. Additionally, it was discovered that having a paper-based data collection was not ideal. This is since issues of documentation quality and validity were identified; along with logistics issues of keeping the paper forms safe. Moreover, paper-based data consumes more time in the extraction of each observation into a Microsoft Excel worksheet. Additionally, it is more likely to encounter a transcription error due to poor/fast handwriting or missing information therefore, reducing the data reliability. Thus, an iPad based data collection tool was designed by the researcher to ease entry of observation. It improves the quality of data and facilitates an accurate analysis. The iPad-based data collection form can also allow real-time monitoring of each observation.

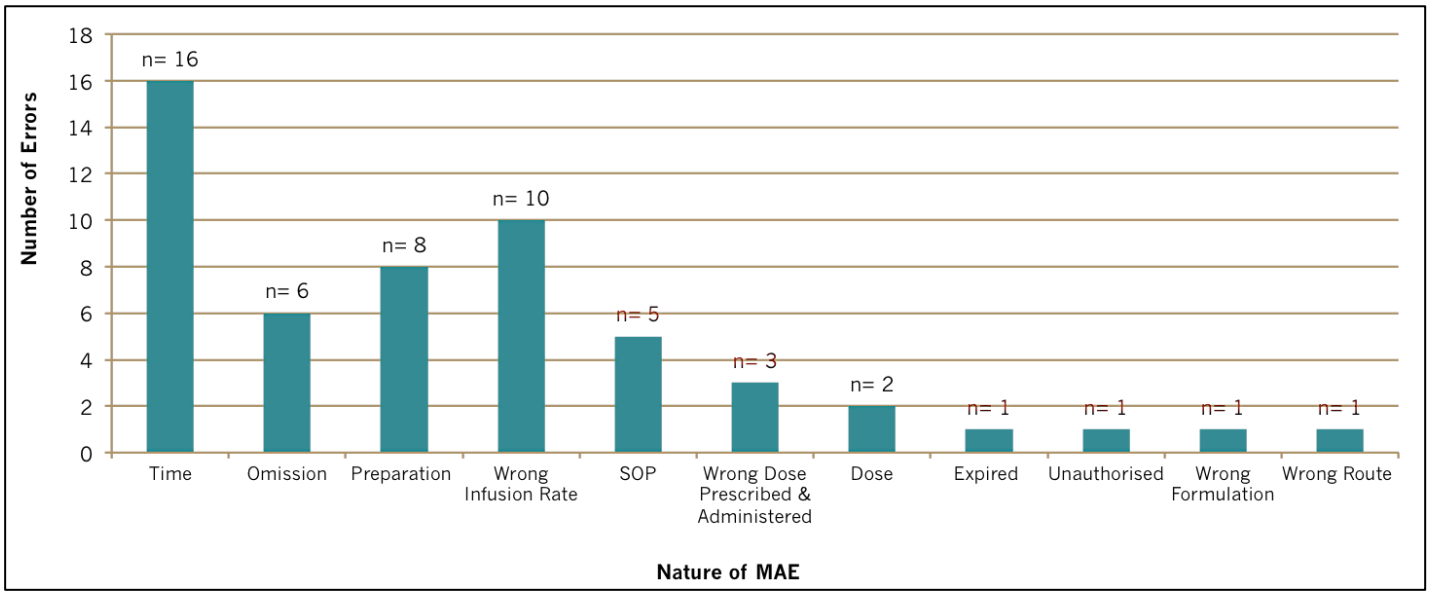

Figure 5.1: Nature of MAE identified during pilot study

The iPad based data collection tool was piloted over three days (8am to 8pm). It was possible to observe 12 patients. A total of 51 doses were observed with an MAE rate of 25.4% (n= 13 MAEs). This is an identical finding to the initial pilot study, suggesting the high robustness of the method used in observation. Dose errors were found in seven observations, followed by preparation errors (n= 4) and errors in time given (n= 2). The iPad pilot

data was analysed and presented by the researcher to the Senior PICU Specialist Pharmacist. Minor recommendations were made. Once the changes were made and validated to ensure the tool was fit for purpose, the research team agreed commencement of the observations.

5.2.8 Standard Observation Procedure

The following standard observation procedure was developed and agreed by the research team in response to the findings of the pilot study:

1. Introduce the study to the nurse in charge to gain verbal consent to carry on the observation by giving out SIS and addressing any queries appropriately.
2. Approach bed site nurse by handing out the SIS and take informed consent if not taken previously. A verbal consent is needed before each observation.
3. Follow hospital infection control procedure when at patient's bedside and during time at the PICU.
4. To review all medications the patient is due prior to observation, cross-check the following against the GOSH Rough prescribing protocol (Sharma & Booth, 2013) and record in the observation collection tool that:
    a. Doses are within the recommended prescribing limits.
    b. All legal prescription requirements are followed.
    c. The prescribed dose is judged clinically appropriate if a pharmacist has reviewed the drug chart.
5. Once the dose is due, check and record the following:
    a. Medication administration SOP, involving aseptic procedure, five rights and preparation steps taken by the nurse.

b. For intravenous infusion medications, cross-check against GOSH Intravenous Administration Guide (Medicines Information, 2013) for advice on dilution requirement and infusion rate for individual drugs.

6. If an error is noticed, clinical significance of the error needs to be judged by the observer before intervening at the last point of medicine delivery to the patient in accordance with the MAE Interception Criteria. This error needs to be documented as an MAE. However, if the nurse discovers the error before administration, then it is not an error.

7. Document all the observations on the iPad-base data collection form.

5.2.9 MAE Interception Criteria

A Senior PICU Specialist Pharmacist, Paediatrician Consult Doctor and a Senior PICU Nurse have agreed the following criteria. If during an observation, a potential MAE is about to occur and was noticed by the observer, then the observer will have to intervene at the last point of medicine delivery if any of the following conditions were met:

1. The error involves a narrow therapeutic window medicine and the drug levels exceed the reference range.

2. Renal impaired patients given unadjusted normal doses.

3. Medicine infused exceeds the recommended infusion rate per protocol.

4. Therapeutically dangerous overdose, for example 10 fold overdose.

5. Inappropriate preparation practice of medicine that may lead to patient harm, for example infusing a solution with precipitated particles.

5.2.10 Data Collection Form

Initially a paper-based form was designed to collect observation data but findings from the pilot study addressed issues that required changes to the tool. Therefore, it was decided to design a data collection form based on an iPad Application (FormConnections). It allowed ease of data entry, extraction, analysis and avoided transcription of data (Figure 5.2). The form allowed the collection of the following data:

1. Observation date and time.
2. Patient reference number, age and weight.
3. Medication prescribed: name, dose, frequency, formulation and route.
4. Indication if a pharmacist clinically checked the drug chart.
5. Total number of doses due for the day and time of the next scheduled dose.
6. Medication administered: name, dose, formulation, route, infusion rate, diluent used, technique of administration and time given.
7. Indication of if an error occurred and total number of interruptions that occurred during the preparation and administration processes.
8. Nature of MAE identified and participants' demographic information such as level of experience.

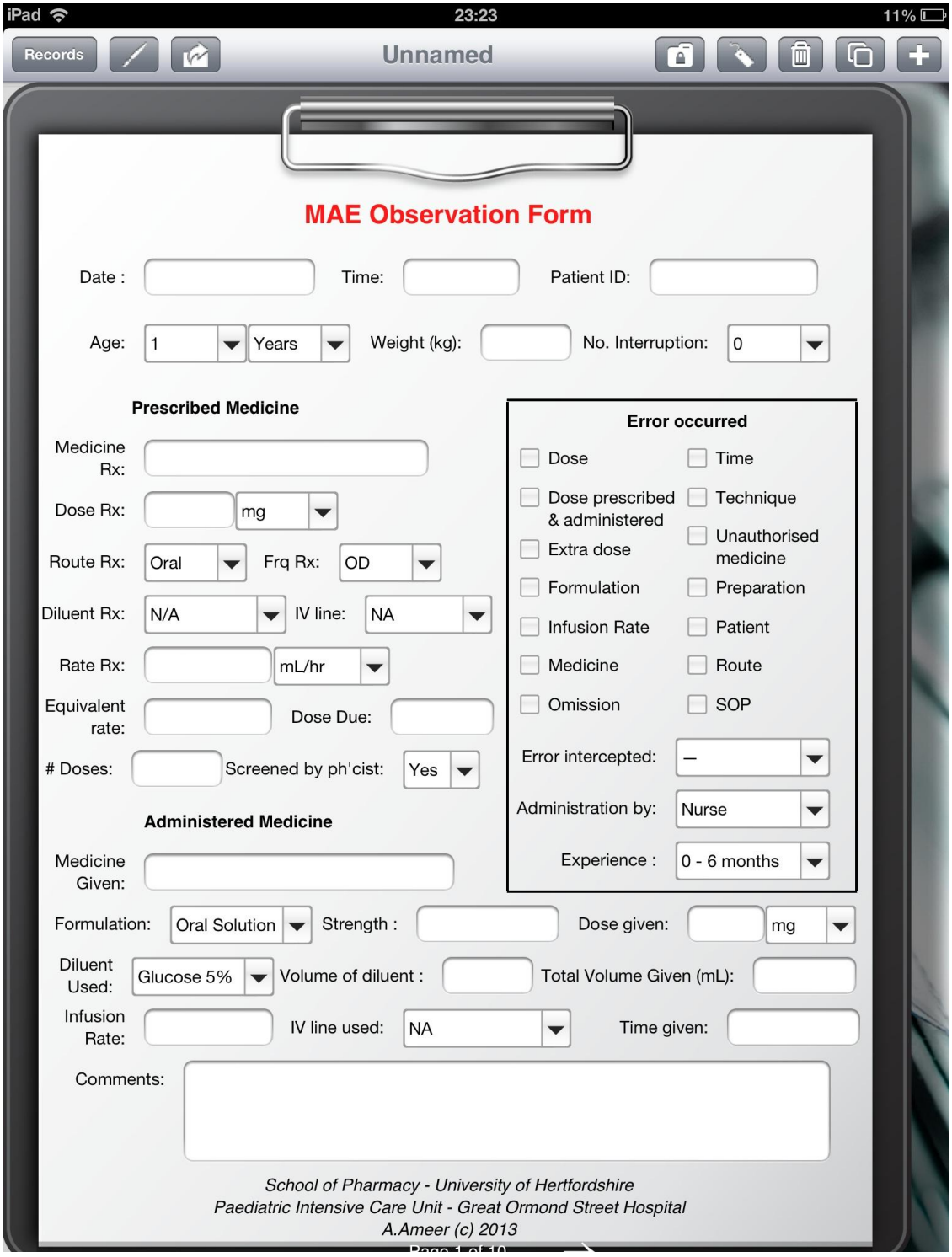

Figure 5.2: iPad data collection form used in medication administration practice observations

5.2.11 Number of Observations (Sample Size)

Statistical advice has been taken to work out the minimum number of observations required based on the reported incidence of MAE in PICUs from literature that used the prospective observation method. A statistician has performed the following:

1. A fixed effect model was identified to be 0.2942 (95% confidence interval (0.2882–0.3003) based on systematic review of MAE error rate. For the random effect model it was very similar 0.2992 with wider 95% confidence (0.2094–0.3976) due to large differences among the studies.

2. Given the fixed effect rate from above and Ghaleb et al. (2010) of 0.191 the effect size was assessed on 0.2419872 level using a Cohen's measure. Such an outcome can be classified as a small effect size.

3. Assuming the 5% significance (type I error) and 90% power (1-type II error), the minimal sample size needed to find the effect size significant is 179 doses.

The recommendation from the statistical consultant suggests that a minimum of 179 dose observations is required to achieve a 20% MAE rate. However, this study will be aiming to reach the highest possible number of dose observations.

5.2.12 Observation Process

The study was carried out after reaching agreement within the research team on the approach of observation, the tool used to collect data and when to intervene upon recognition of a potential MAE by the researcher. The observation was carried out for 14 days (8am to 8pm) and 14 nights (8pm to 8am) including weekends. This was between the period of September 2013 and November 2013. The researcher conducted all of the observations. The PICU nurse and pharmacist provided extensive training for a period of three months.

The researcher used the definition in section 5.2.3 to identify MAE by observing the preparation and administration practice of medicines in PICU. The observer approached the patient bedside nurse who had agreed to take part in this study as described previously. Before the observation the patient's drug chart was clinically reviewed and screened by the researcher using the current Rough Prescribing Guidelines to ensure there were no prescribing errors. It was assumed that if the PICU clinical pharmacist had screened the drug chart then it would contain a prescribing error. Patient parameters and prescribed medicines were documented in the data collection tool. The researcher also documented the time slots the patient was due their medications.

At the time the dose is due, the researcher approached the patient's bedside and waited for the nurse to start preparing and administering the patient medications. Using the standard operating procedure for medication administration in GOSH, the researcher observed the different steps involved and documented them on the data collection form. If a potential MAE was observed, the researcher referred back to the criteria of intervention and assessed the need to stop the MAE from happening. In the event that an intervention was required, the researcher politely asked the nurse to recheck before administering but at the very last point of medication delivery. This was documented as an MAE. However, if the nurse noticed the error prior to administration and acted without the researcher's intervention this was not documented as an MAE.

5.2.13 Observer Reflexivity

This study is a form of ethnographic research where the behaviour and practice of others is being observed and studied to inform outcomes. It is important that the observer's behaviour or judgement during the study is recognised. Since the observer's perception of the observed setting and knowledge of procedures will change through time. It is extremely difficult for the researcher to be neutral during observations due to the systematic methodology, definitions used and the researcher's professional background knowledge of medicines (Bryman, 2012). Hence to ensure that the observation is a true reflection of practice, the researcher spent a three

month period in training as described earlier to establish a professional relationship with the observed group and to gain a better understanding of the administration procedure. Also, during the observation, the researcher will ensure that he is positioned appropriately around the patient's medicine preparation trolley and not in the way of the observed group. In addition, the researcher's personal characteristics and interaction with the observed group will be professionally maintained throughout the study.

Additionally, to ensure consistency of the observations, the researcher reviewed all collected data after completion of the observations and before further data analysis. This is to ensure that each observation was documented and interpreted reliably.

5.2.14 Severity Assessment of MAE

Assessing the severity of MAEs identified in this study was carried out by a panel. This consisted of a consultant paediatrician, senior clinical pharmacist, sister nurse and the researcher. The MAEs were presented to the panel in the form of case vignettes (appendix 12) and the panel was asked to rank the potential for causing harm on a scale of zero to ten (where zero is no harm at all and a score of ten indicates the potential of death) individually and asked to send back their ranking via email to the researcher for analysis. A mean score for MAEs of between 1 and 3 indicates a low level of harm, a score between 4 and 6 is a moderate level of harm whereas a score between 7 and 9 is severe harm and 10 is indicating a potential of death. This method of assessing the potential of severity has been used in the General Medical Council PRACTICE study for prescribing errors in primary care settings (Avery et al., 2012). However, it was initially developed by Dean and Baber (1999) specifically to assess the severity of medication errors without knowing the patient outcomes. This method of assessing potential of severity was selected since it was found to be valid and credible (Taxis & Barber, 2003).

The reliability of the panel scoring was statistically assessed. Typically kappa coefficient is used to measure the level of agreement between participants. However, kappa coefficient is suitable for two raters only. Hence it cannot be used as measure of reliability in this study. Similarly, Pearson correlation

coefficient only relates the source of variance/error to one (Briesch, Swaminathan, Welsh, & Chafouleas, 2014). Therefore, this type of intraclass correlation cannot be applied in this study since there are four different individuals. They all have different professions and will view MAEs from completely different perspectives.

Alternative correlations are Analysis of Variance (ANOVA) and the Cronbach's Alpha. ANOVA allows multiple raters but attributes variance to one like the kappa and Pearson coefficients. However, Cronbach's Alpha will measure the reliability of the raters and measure which variable increases or decreases consistency. Cronbach's Alpha is the most commonly used test in psychometric studies to measure level of reliability. Therefore, it is chosen to assess the reliability of MAE severity rating.

5.2.15 Data Validation

The same expert panel that assessed the severity of harm for MAE were asked to indicate on the case vignettes if they agreed or disagreed that the observation contained an MAE. Consensus was measured by means of two out of the three experts in agreement.

5.2.16 Data Analysis

Data collected using the iPad application was analysed using Microsoft Excel 2007 (Microsoft, Redmond, Washington, US) and IBM SPSS Statistics 20 (Armonk, New York, US) programmes. The incidence of MAE can be calculated by dividing the number of MAEs observed by the total number of doses observed; this is the most common way of presenting incidence of MAE as demonstrated by the systematic review findings. This approach of expressing the incidence of MAE is simple since it does not require the researcher to collect additional variables or take into consideration conditions during analysis and interpretation of the data.

Another method is by using the total number of opportunities for error as a denominator. The definition for opportunities for error is the "sum of any dose given plus any dose prescribed but omitted" (Allan & Barker, 1990; Barker &

McConnell, 1962). Ghaleb et al. (2010) used this approach to calculate the incidence of MAEs in paediatric units. However, there are multiple opportunities for error since an error could happen in the preparation phase (e.g. using a diluent that is not per protocol) and another error could happen in the administration phase (e.g. infusing the dose at wrong rate). Therefore, two opportunities for error for each observation are needed for doses that require preparation such as intravenous medicine and oral antibiotics that require reconstitution with water or solvent. But if no preparation was needed and the dose was ready to be administered, there would be only one opportunity for error. Furthermore, each opportunity for error could have more than one MAE (e.g. administering at wrong infusion rate and two hours later than scheduled time).

For this present study it was decided to use the total number of doses observed as the denominator. This is since it is more representative and less confusing when analysing and interpreting the data. The opportunity for error approach requires additional calculations that may cause issues of reliability and validation of the data. Moreover, there is a chance that the rate of MAE exceeds 100% due to the various conditions that need to be fulfilled as described above. Additionally, using the total number of doses observed is a more convenient way for the purposes of a research audit trail. The data generated can be compared to other published research of a similar nature and be a benchmark for future research. Therefore, the MAE incidence was calculated as shown in equation 5.1 and will be expressed as a percentage. The Chi-square test was used to assess the significance difference of MAE incidence across day/night shifts and weekday/weekend shifts.

$$\text{Incidence of MAE} = \frac{\text{Number of MAEs Observed}}{\text{Total Number of Doses Observed}} \times 100 \quad \textit{Equation 5.1}$$

5.3 Results

5.3.1 Demographic Data

Direct prospective observation of medication administration practice at a London-based PICU in a children's hospital was conducted over 28 shifts. Each shift was covering 12 hours of the rota, either from 8am to 8pm or 8pm to 8am. An equal amount of observation was carried out for day (n= 14) and night (n= 14) and included both weekdays (n= 20) and weekends (n= 8). There were a total of 1953 scheduled doses during the duration of the observations. It was possible to observe 42.6% (n= 832 doses) of scheduled doses, suggesting a good representative data. The majority were of intravenous doses (n= 572), followed by oral doses (n= 242) and inhaled doses (n= 18).

In total, 42 nurses participated in the observations and 46 patients with a median age of 18 months (range 1 month to 16 years) were involved. There was good uptake by all PICU staff for this study and all were made aware of the purpose of the study. There was no objection by any member of staff to being observed. The nurse in charge and the doctors on duty supported the observer with their advice and resources. There was no discomfort reported by the patients or their representatives due to the presence of the observer. On six occasions, the parents of patients gave feedback to the researcher that they were satisfied and delighted that this study was being carried out. Also none of patient's parents or carers found the observer to be of concern.

Two hundred and eighty three (283) MAEs were identified. The observer intervened in five MAE cases before the error reached the patient at the last point of medicine delivery. No patient safety incident reports were submitted during the time of the observation to the reporting system Datix. Table 5.2 describes the overall demographic data of the study. There were also 20 MAEs that had been corrected by the nurse observed or by the second nurse checking the administration before reaching the patient. These were treated as a near miss and were not included in the count of 283 MAEs. The 20 MAEs that were intervened in by the nurse were relating to: wrong dose (n= 9), preparation error (n= 6), and infusion rate errors (n= 5).

Table 5.2: Medicine administration observation study demographic data

Characteristic	Day Shift (8am –8pm)	Night shift (8pm – 8am)	Total
Number of Shifts Observed	14	14	28
Number of Weekdays Shifts	10	10	20
Number of Weekends Shifts	4	4	8
Number of Nurses Observed	20	22	42
Total Number of Interruptions	603	225	828
Number of Patients Involved	19	27	46
Median Patient Age (months) (range)	36 (3 – 180)	12 (1 – 192)	18 (1 – 192)
Median Patient Weight (Kg) (range)	12 (4 – 50)	10 (1 – 60)	11 (1 – 60)
Total Number of Doses Observed	458	374	832
Number of Oral Medicines Observed (doses)	98	144	242
Number of IV Medicines Observed (doses)	349	223	572
Number of Inhaler Medicines Observed (doses)	11	7	18
Total Number of Potential Doses Due to be administered during study period	1018	935	1953
Medication Administration Errors	146	137	283
Observer MAE Intervention	5	0	5

The total number of MAEs identified by the research were found to be categorised into six MAE subtypes. These were namely: wrong dose errors (n= 165), preparation errors (n= 51), wrong infusion rate (n= 26), administration at an incorrect time (n= 25), wrongly omitted doses (n= 11), and wrong formulation used (n= 5). Each type of MAE will be individually discussed. Two MAEs were identified in the same observation of nine doses and in one observation three MAEs were observed.

5.3.2 Nature of MAEs Following Data Validation

An expert panel independently reviewed all the observations that were identified by the researcher as containing an MAE. The researcher identified 283 MAEs. However, 14 were excluded following the review since they were judged as not containing an MAE and thus this yields a total of 269 MAEs. Figure 5.3 represents the distribution of MAE across the different subtypes. As highlighted, the majority of errors is relating to dose (n= 152, 56.5%), followed by preparation errors (n= 50, 18.6%) and wrong infusion rate (n= 26, 9.7%).

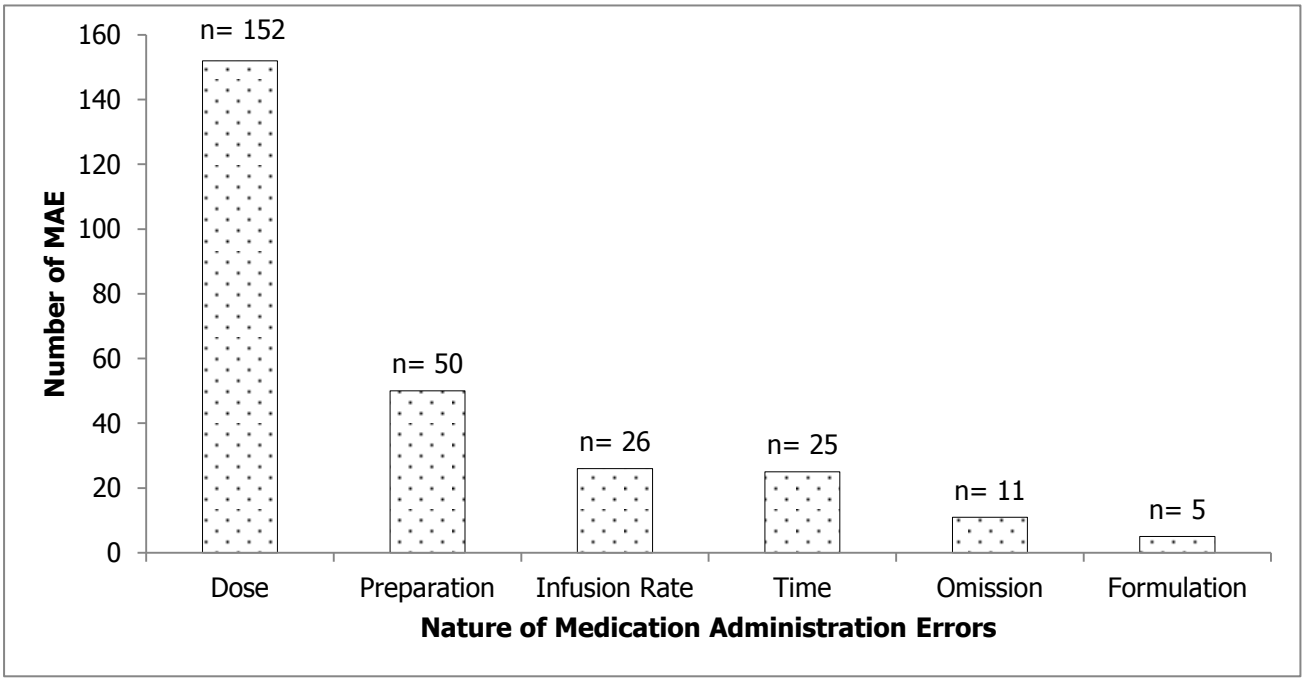

Figure 5.3: Overall nature of MAEs (n= 269) identified

5.3.3 Wrong Dose Errors

These have been defined as the administration of the correct medicine by the correct route but in a quantity that was not that which was prescribed. This includes administration of the incorrect number of dose units, selection of the wrong strength of dose unit, and the measurement of an incorrect volume of an oral liquid. Where liquid preparations were not measured but instead were poured into ungraduated medicine cups.

If failure to shake a suspension resulted in a visible concentration gradient, this was also considered a wrong dose error otherwise considered as a preparation error. The researcher observed a total of 165 wrong dose incidents.

Two subtypes of dose error were found during the observations. Firstly, there were doses given which deviated from the prescribed because they could not be accurately calculated (n= 69). This was due to the formulation used which is expressed with a concentration or strength that has a wide ratio. For example, a patient required 9mg of Ranitidine IV and it is only available as a 50mg/2mL vial, therefore the exact volume which should be drawn out from the vial is 0.36mL. However, in practice 0.4mL is given, and this would result in the patient receiving 10mg instead of the prescribed 9mg. It is not likely to cause any harm but it was considered to be an MAE.

Secondly, there were doses that deviated from the prescribed dose but that could have been given without difficulty (n= 96). For example, a patient that was prescribed 360mg of Sodium Valproate orally was given 8mL (320mg) from a 200mg/5mL oral solution instead of 9mL (360mg).

Table 5.3 represent the breakdown of dose error subtypes across day and night shifts. As can be seen, there were 62 incidents during the night where doses could have been administered accurately compared to only 34 incidents in the daytime shift. Moreover, Table 5.3 also shows that there is a problem with formulations with a difficult concentration ratio in both day and night-time shifts.

Table 5.3: Type of dose medication administration errors

Shift Observed	Dose Errors Type		Total
	Dose can be accurately administered	Dose cannot be accurately administered	
Day	34	31	65
Night	62	38	100
Total	96	69	165

A panel of three experienced PICU healthcare professionals validated the wrong dose MAEs identified by the researcher. Table 5.4 presents the panel's findings. The key outcome is that the panel found independently that the majority of observations did contain a wrong dose MAE. However, it also found that 18 observations should not be reported as containing a wrong dose MAE since the difference between the dose prescribed and that which was administered was negligible. Thus, it is decided to exclude these incidents (n= 18) from the count of wrong dose MAEs and that yields a total of 152 wrong dose incidents.

Table 5.4: Outcome of panel review of wrong dose MAEs identified by the researcher

Outcomes	**Example**
Full panel agreement wrong dose MAE occurred (**n= 134**)	Alimenazine 35mg oral prescribed. Alimenazine 30mg/5mL oral solution, 6mL (42mg) given
Two-thirds panel agreed wrong dose MAE occurred (**n= 18**)	Aciclovir 350mg IV prescribed. Aciclovir 500mg/20mL solution for injection, 15mL (375mg) with NS 100mL @ 100mL/hr
Full panel agreement no wrong dose MAE occurred (**n= 5**)	Metronidazole 130mg oral prescribed. Metronidazole 200mg/5mL oral solution, 3.2mL (128mg) given
Two-thirds panel agreed no wrong dose MAE occurred (**n= 8**)	Ibuprofen 75mg oral prescribed. Ibuprofen 100mg/5mL oral solution, 3.8mL (76mg) given

It is also possible to identify the drugs that are associated with the cause of wrong dose administered to the patient as seen in Table 5.5. Ranitidine is the therapeutic agent that is most often causing wrong dose MAEs (n= 33), followed by Piperacillin/Tazobactam (n= 16) and Morphine (n= 15). Additionally, the table shows that there were four high-risk medicines. Moreover, cumulatively, Antimicrobials are the main group of agents that are associated with wrong dose MAEs (n= 47), followed by agents of gastrointestinal drugs (n= 38) and those that are analgesic agents (n= 28). Furthermore, Table 5.5 illustrates the drugs with difficult pharmaceutical ratios of strength or concentration compared to the small volumes that paediatric patients require. Examples include Ranitidine 50mg/2mL, Dexamethasone 4mg/mL or Clonidine 150mcg/mL.

Table 5.5: Drugs associated with wrong dose MAE

Drug	Number of Wrong Dose MAE
Ranitidine [DF]	33
Piperacillin/Tazobactam	16
Morphine [HR]	15
Paracetamol	13
Aciclovir	10
Dexamethasone [DF]	10
Clarithromycin	7
Salbutamol	7
Azithromycin	6
Clonidine [DF]	6
Chloral	5
Lansoprazole	5
Phenyotin [HR DF]	5
Teicoplanin	4
Alimenezine	3
Cefotaxime	2
Sodium Valporate [HR]	2
Co-Trimoxazol	1
Flucloxacillin	1
Furosemide [HR DF]	1
Total	**152**

[DF] Drug Formulation with difficult strength expression
[HR] High Risk Medicine

5.3.4 Preparation Errors

Preparation errors were defined as incorrect preparation of the medication dose. Examples include: incorrect dilution or reconstitution, not shaking a suspension, using an expired drug, not keeping a light-sensitive drug protected from light, not following non-touch techniques for IV formulations and mixing drugs that are physically or chemically incompatible. It also includes failure to follow procedures for medicine preparation. There were a total of 51 incidents observed relating to preparation errors.

The incidents were broken down into six subtypes: failure to shake oral preparations (n= 12), failure to follow non-touch technique for IV formulations (n= 12), dose spillage (n= 11), failure to ensure powder was fully dissolved in diluent/solvent (n= 7), using incorrect diluent (n= 5), failure

to double check dose by another nurse (n= 4). An example of each subtype is demonstrated in Table 5.6.

Table 5.6: Examples of preparation errors observed

Preparation Errors	Example
Failure to shake oral preparations (n= 12)	Propranolol 9mg oral prescribed. Propranolol 10mg/5mL oral solution, 4.5mL (9mg) given but not shaken
Failure to follow non-touch technique for IV formulations (n= 12)	Piperacillin/Tazobactam 2475mg IV prescribed. Piperacillin/Tazobactam 4/0.5g powder for injection, NS 16.6mL, 11mL (2475mg) neat, dose spillage & non-touch technique not followed
Dose spillage (n= 11)	Benzylpencillin 500mg IV prescribed. Benzylpencilin 600mg powder for injection, NS 5.6mL, 5mL (500mg) to NS 15mL @ 30mL/hr, Dose spillage occurred when withdrawing from syringe containing drug.
Failure to ensure powder fully dissolved in diluent/solvent (n= 7)	Vancomycin 2g IV prescribed. Vancomycin 1g powder for injection, WFI 20mL x2. 40mL (2g) in Sodium Chloride 400mL @ 200mL/hr. Powder not fully dissolved in vial.
Using incorrect diluent (n= 5)	Midazolam 0 – 4 mcg/kg/min continuous IV @ 0-2mL/hr in Glucose 5% prescribed. Midazolam 50mg/10mL solution for injection, 32.4mL in sodium chloride 17.6mL @ 20mcg/kg/min (1mL/hr). Dose spillage noticed and wrong diluent used
Failure to double check dose by another nurse (n= 4)	Co-Amoxiclav 1.2g IV prescribed. Co-Amoxiclav 600mg powder for injection, WFI 10mL x2. 20mL (1.2g) neat given without double check.

The expert panel as described earlier, independently reviewed all preparation errors that were identified by the researcher. It was found that the panel was in full agreement that a preparation error had occurred in 39 observations. Also, in 11 observations there was a two-thirds agreement. However, the panel was in full agreement that no preparation error was present in one

observation. This was relating to the preparation of Rifampicin/Isonazide 750mg for oral administration, three tablets of 250mg Rifampicin/Isonazide were dissolved in 50mL of water. The researcher observed poor aseptic technique but the panel disagreed that this should be treated as a preparation error since it is not an intravenous preparation and it was within normal practice. Therefore this observation was excluded from the total count of MAEs and this results in 50 agreed preparation errors. Table 5.7 represent the drugs that are associated with preparation errors. As it can be seen, Morphine and Paracetamol are the drugs most correlated with preparation errors, followed by Cefotaxime (n= 7) and Midazolam (n= 4).

Table 5.7: Drugs associated with preparation errors

Drug	Number of Preparation Errors
Morphine [HR]	9
Paracetamol	9
Cefotaxime	7
Midazolam	4
Ceftazidime	3
Salbutamol	3
Aciclovir	2
Benzylpencillin	2
Co-Amoxiclav	2
Ibuprofen [HR]	2
Phenyotin [HR]	2
Flucloxacillin	1
Metronidazole	1
Piperacillin/Tazobactam	1
Propanolol	1
Vancomycin [HR]	1
Total	**50**

[HR] High Risk Medicine

5.3.5 Wrong Infusion Rate Errors

Wrong infusion rate errors were defined as the administration of intravenous doses with incorrect rate of infusion as recommended by the intravenous administration guide. During the observations a total of 26 incidents were

identified as containing a wrong infusion rate error. The majority of the incidents (n= 24) were fully agreed by the panel that they did contain a wrong infusion rate error and a further two incidents were agreed by two-thirds of the panel. There were two incidents where the nurse had selected an incorrect infusion rate expression (mcg/kg/**hr** was selected instead of mcg/kg/**min**). The researcher intervened in both incidents and this will be discussed more in section 5.3.9. Table 5.8 shows examples of the wrong infusion rate incidents that were observed.

Table 5.8: Examples of wrong infusion rate incidents

Prescribed Medicine	Administered Medicine	Correct Infusion Rate
Clarithromycin 90mg IV	Clarithromycin 500mg powder for injection, WFI 9.6mL, 1.8mL (90mg) in 50mL NS @ 100mL/hr (over 30min)	Over 1 hour
Metronidazole 75mg IV	Metronidazole 500mg/100mL solution for injection, 15mL (75mg) in G5W 85mL @ 400mL/hr (over 15min)	Over 30 minutes
Ranitidine 40mg IV	Ranitidine 50mg/2mL Solution for injection, 1.6mL (40mg) given in less than 2min	Over at least 5 minutes

Table 5.9 presents the drugs that are associated with causing wrong infusion rate errors. As it can be seen, Ranitidine is the agent that most often triggers a wrong infusion rate (n= 11), followed by Clarithromycin (n= 4) and Furosemide (n= 4).

Table 5.9: Drugs associated with wrong infusion rate errors

Drug	Number of Wrong Infusion Rate Errors
Ranitidine [DF]	11
Clarithromycin	4
Furosemide [HR DF]	4
Metronidazole	2
Cefotaxime	1
Midazolam	1
Paracetamol	1
Vancomycin [HR]	1
Vecuronium	1
Total	**26**

[DF] Drug Formulation with difficult strength expression
[HR] High Risk Medicine

5.3.6 Time Errors

Time errors in medication administration are defined as the deviation of the time a dose is given by ± 1 hour from the scheduled time. The researcher observed a total of 25 incidents that fell within the definition of time error with an average delay of 1 hour and 37 minutes (± 23 minutes). Examples of the errors are shown in Table 5.10. As described earlier, an independent panel reviewed all the incidents and gave full agreement that all the incidents were time errors. Table 5.11 represents the drugs that are associated with administration at the wrong time. As it can be seen, time errors are most prevalent with antimicrobial agents (n= 17 incidents) compared to the other therapeutic agents such as analgesics (n= 4 incidents) and cardiovascular (n= 3).

Table 5.10: Examples of wrong administration time incidents

Prescribed Medicine	Administered Medicine
Aciclovir 350mg IV	Aciclovir 500mg/20mL solution for injection, 14mL (350mg) in NS 100mL @ 100m/hr given 1hr:45min late
Benzylpencillin 500mg IV	Benzylpencillin 600mg powder for injection, NS5.6mL, 5mL(500mg) in NS 15mL @ 30mL/hr given 1hr:50min late
Dexamethasone 1.35mg IV	Dexamethasone 4mg/mL solution for injection, 0.3mL (1.2mg) given neat 2hr:10min late

Table 5.11: Drugs associated with administration time errors

Drug	Number of Time Errors
Cefotaxime	3
Morphine [HR]	3
Piperacillin/Tazobactam	3
Aciclovir	2
Ciprofloxacin	2
Meropenem	2
Metronidazole	2
Potassium Chloride [HR]	2
Benzylpencillin	1
Clarithromycin	1
Dexamethasone	1
Flucloxacillin	1
Ibuprofen [HR]	1
Propanolol	1
Total	25

[HR] High Risk Medicine

5.3.7 Omitted Doses

Omission has been defined as when a dose of medication was not administered by the time of the next scheduled dose. Doses omitted according to doctors' instructions, nurse's clinical judgment (including where the patient refused the medication or was designated nil-by-mouth) or because the patient was not on the ward were not considered omitted medicines. Thus, using this definition it was possible to identify 11 omitted medicine incidents without any reason or documentation. When these omission errors were presented to the review panel, there was full agreement on nine incidents and two-thirds of the panel agreed on two incidents being omission errors. Table 5.12 illustrates the drugs that are associated with omitted doses. As it is seen, the most common drugs that are associated with omitted doses are Furosemide (n= 3) and Paracetamol (n= 3).

Table 5.12: Drugs associated with omitted dose errors

Drug	Number of Omitted Doses
Furosemide	3
Paracetamol	3
Ranitidine	2
Chloral	1
Disopyramide	1
Morphine	1
Total	**11**

5.3.8 Wrong Pharmaceutical Formulation Errors

Wrong pharmaceutical formulation was defined as the administration of the correct medicine by the correct route but in a formulation that was not as prescribed. Appropriate purposeful alteration to facilitate administration was not considered an error. The researcher identified five incidents relating to wrong formulation. All five incidents were fully agreed by the expert panel to contain a formulation error. Table 5.13 provides some examples that were observed by the researcher. Furosemide was associated with formulation errors (n= 4 incident) and was followed by Co-Trimoxazol (n= 1 incident).

Table 5.13: Examples of pharmaceutical formulation errors

Prescribed Medicine	Administered Medicine
Co-Trimoxazol 480mg PO	Co-Trimoxazol 480mg/5mL solution for injection, 5mL (480mg) in NS 125mL @ 120mL/hr administered,
Furosemide 5mg IV QDS	Furosemide 20mg/5mL oral solution, 1.2mL (4.8mg) administered.

5.3.9 MAEs Intervened by Researcher

There were five MAE interventions during the study by the researcher. Table 5.14 lists all the MAEs that were intervened in by the researcher at the last point of medicine delivery. All five interventions were during the day shift observations. As can be seen in Table 5.14, incidents involving phenytoin occurred twice where the patient was about to be administered 17mg less than the prescribed dose. It was found later, when discussed with the PICU pharmacist, that this patient had been reported to have had a sub-therapeutic phenytoin plasma level for three days. The researcher intervention helped to identify the underlying cause.

Table 5.14: MAE intervened by the researcher

Prescription	Administration	Nature of MAE
Vecuronium 30mg (0-4mcg/kg/min) Continuous IV @ 0 - 2mL/hr for 1 year old patient (10kg) in 25mL Sodium Chloride 0.9%	Vecuronium Powder for Injection (10mg) dissolved with 5mL WFI x3 (30mg) and further diluted with Sodium Chloride 0.9% (10mL), infused @ 1mL/hr as 2mcg/kg/hr	Infusion Rate (2mcg/kg/**min** not per **hr**)
Phenytoin 125mg PO BD for 8 years old patient (27kg) ***[This incident occurred twice!]***	Phenytoin Oral Solution 18mL (30mg/5mL) prepared and double-checked. Intercepted before administration	Dose (20mL (125mg) not 18mL (108mg)
Midazolam 50mg (0-4mcg/kg/min) Continuous IV @ 0 - 2mL/hr for 1 year old patient (9.6kg) in 50mL Glucose 5%	Midazolam Solution for Injection 10mL (50mg/10mL) diluted to 40mL Glucose 5%, infused @ 1mL/hr as 2mcg/kg/hr	Infusion Rate (2mcg/kg/**min** not per **hr**)
Phenytoin 45mg IV BD for 1 year old patient (9.2kg)	Phenytoin Solution for Injection 0.6mL (250mg/5mL) prepared and double checked, but intercepted before administration	Dose (0.9mL (45mg) not 0.6mL (30mg)

5.3.10 Therapeutic Agents Correlating with MAEs

Figure 5.4 demonstrates the number of MAEs observed per medicine during the study. Ranitidine (n= 46) is the most associated medicine with MAE. Followed by Morphine (n= 28) and Paracetamol (n= 26). Figure 5.5 represents the therapeutic classes of agents and its prevalence of MAEs. It shows that antimicrobials (n= 93) and analgesics (n= 57) are associated with the most MAEs.

5.3.11 Incidence of MAEs

Incidence of MAE by doses observed

The incidence of MAE is calculated using the number of doses observed as denominator since both preparation and administration processes were observed for all medications. Table 5.15 presents the breakdown of MAE incidence across the two shifts and the subtypes of MAEs. As illustrated, the overall incidence of MAE identified in this study is 32.3% (per 100 doses observed). Night shifts were associated with a slightly higher incidence of MAEs (32.9%) compared to day shifts (31.9%). Dose errors are the leading type of MAE (18.3%), followed by preparation errors (6%).

Table 5.15: Incidence of MAEs by doses observed

MAEs Type (Numerator)	Number of Doses Observed (Denominator)		
	Day (n= 458)	Night (n= 374)	Total (n= 832)
Dose (n= 152)	14.2%	23.3%	18.3%
Preparation (n= 50)	6.8%	5.1%	6.0%
Infusion Rate (n= 26)	4.6%	1.3%	3.1%
Time (n= 25)	4.8%	0.8%	3.0%
Omission (n= 11)	1.5%	1.1%	1.3%
Formulation (n= 5)	0.0%	1.3%	0.6%
Total	**31.9%**	**32.9%**	**32.3%**

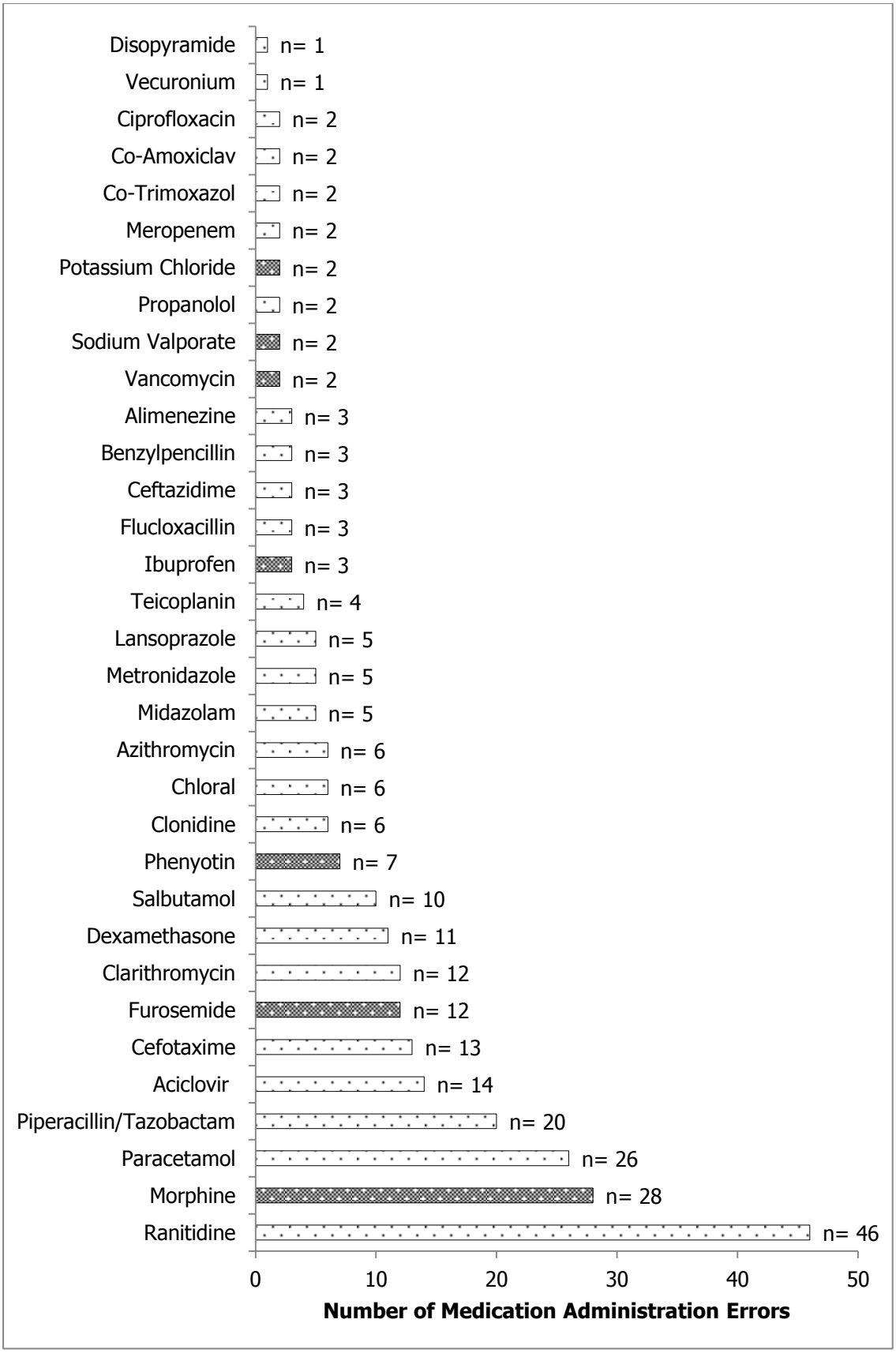

Figure 5.4: Number of MAEs identified per medicine, medicines marked with darker colour are high risk medicines or narrow therapeutic medicines.

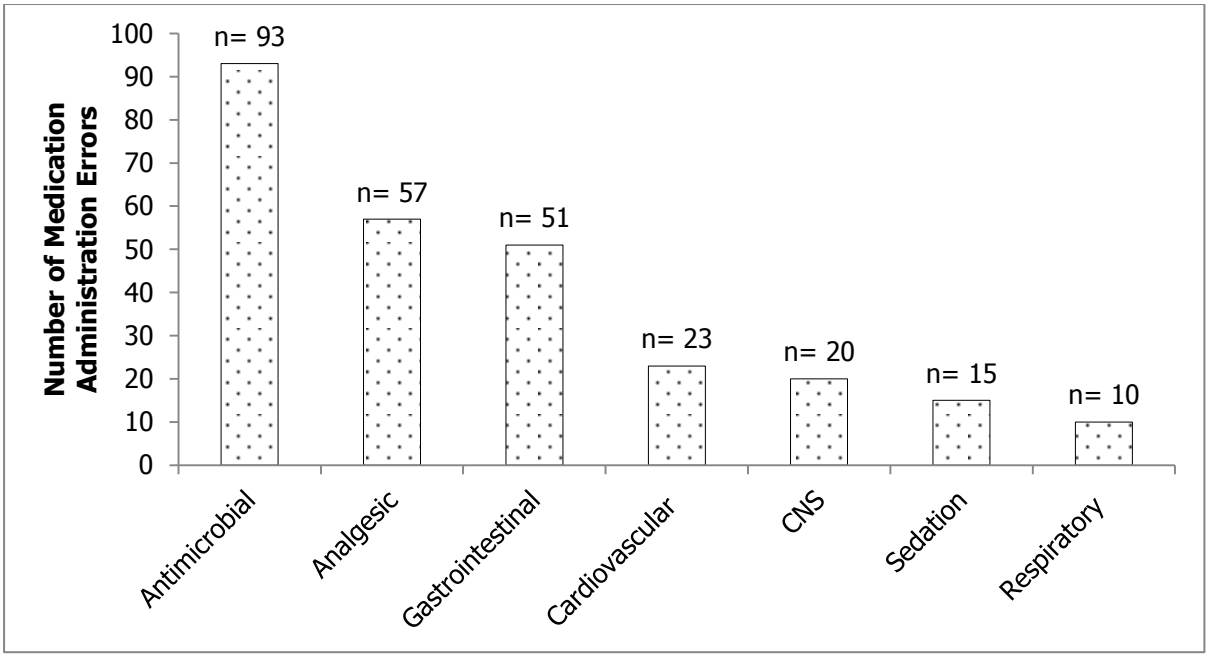

Figure 5.5: Number of MAEs in relation to therapeutic classes

Incidence of MAE by pharmaceutical formulations

Using the demographic data breakdown in section 5.3.1, it is possible to work out the incidence of MAE by pharmaceutical formulation as shown in Table 5.16. The majority of MAEs are associated with intravenous medicines (n= 170, 63.2%). However, intravenous MAE is in 29.7% of all observed intravenous medicines (n= 572).

On the other hand, the rate of MAE in oral preparations was 33.1% (n= 89) of the overall number of MAEs identified, but this represents an error rate of 36.7% (n= 89) of the total number of observed oral medicine (n= 242). It is of interest to note that all the doses that were given using an inhaler device at night (n= 7) had MAEs compared to 27.3% (n= 3) that were administered during the day shift. Inhaler device errors include administering the wrong number of puffs and not shaking inhaler before administration.

Table 5.16: Incidence of MAE by pharmaceutical formulations

MAEs per formulation (Numerator)	Dose observed (Denominator)		
	Day (n= 458)	Night (n= 374)	Total (n= 832)
Intravenous Medicine (n= 170)	29.5%	30.0%	29.7%
Inhaler Device (n= 10)	27.3%	100.0%	55.5%
Oral Preparation (n= 89)	40.8%	34.0%	36.7%

Incidence of MAE by number of patients

A total of 46 patients (day shift= 19; night shift= 27) were observed in this study. A minimum of one MAE occurred in 80.4% (n= 37) of patients. Day shift patients were at a higher risk of MAEs (84.2%, n= 16) compared to night shift patients (77.8%, n= 21). This represents that at least 1 MAE occurred in 8 out of every 10 patients. Chia-square test found a significant difference between patients of day shifts and night shifts ($p < 0.01$).

5.3.12 Correlation of MAEs with time of observation

In this study, 28 observations were carried out equally over 12 hours' rota for day (8am–8pm) and night (8pm–8am) shifts. The number of MAEs observed during the day shifts were 8.6% greater than night shifts as demonstrated in Table 5.17. However, it was found that this difference is not significant using a Chi-square test ($p > 0.05$). The breakdown of MAE into categories also showed no significant difference between the day and night using a Chi-square test ($p > 0.05$). Additionally, the number of MAEs varied across the weekdays as shown in Figure 5.6. As can be seen, the first day of the week is associated with the most MAEs (n= 58), followed by the last day of the week (n= 42). A total of 198 MAEs were observed in 606 doses administered on weekdays (32.7%) whereas 71 MAEs were observed in 226 doses administered on weekends (31.4%). The Chi-square test found no significant difference between rates of MAE across weekdays or weekends ($p > 0.05$)

Table 5.17: Breakdown of MAEs into day and night shifts

Type of MAE	Number of MAE identified		
	Day (%)	Night (%)	Total(%)
Dose	65 *(44.5%)*	87 *(70.7%)*	152 *(56.5%)*
Preparation	31 *(21.2%)*	19 *(15.4%)*	50 *(18.6%)*
Infusion Rate	21 *(14.4%)*	5 *(4.1%)*	26 *(9.7%)*
Time	22 *(15.1%)*	3 *(2.4%)*	25 *(9.3%)*
Omission	7 *(4.8%)*	4 *(3.3%)*	11 *(4.1%)*
Formulation	0 *(0%)*	5 *(4.1%)*	5 *(1.9%)*
Total (%)	**146 *(54.3%)***	**123 *(45.7%)***	**269 (100%)**

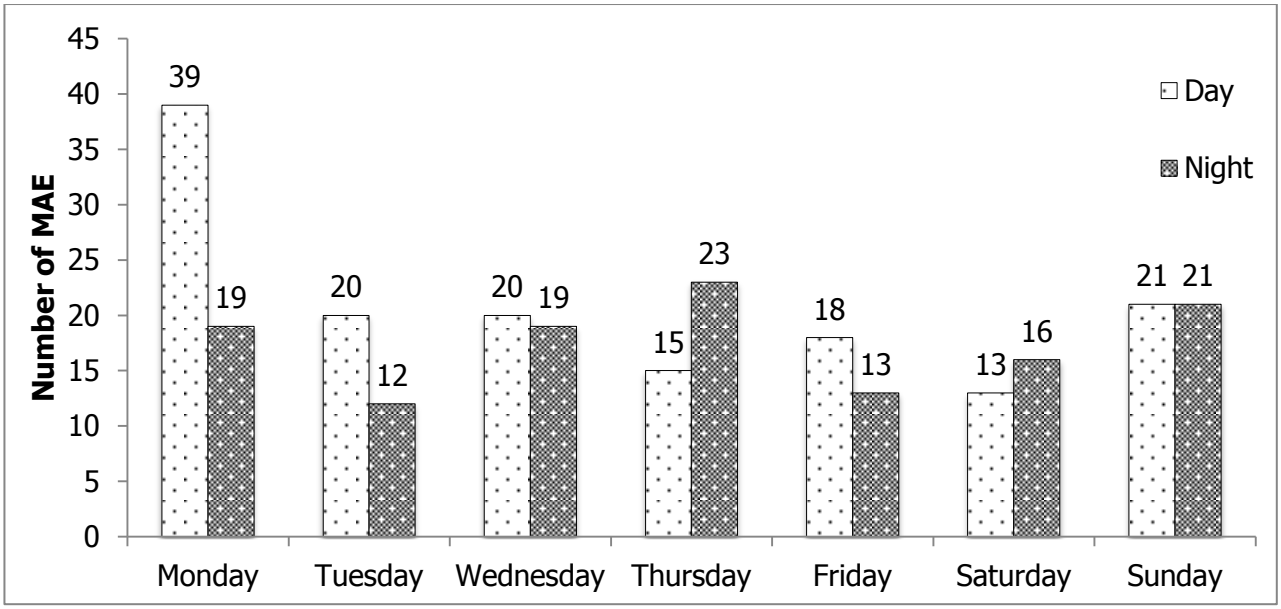

Figure 5.6: Variation of MAEs across the weekdays (n= 269)

5.3.13 Correlation of interruption to rate of MAEs

During the observation of the 832 doses, a total of 948 interruptions (day shift = 603; night shift= 345) were recorded. Observations that encountered MAEs (n= 269) were interrupted 333 times by other PICU staff members and patients' relatives. Night shifts were associated with lower numbers of interruptions (n= 127) compared to day shifts (n= 206). Using correlation matrix analysis in SPSS, it was possible to calculate the effect of interruptions and other variables on the rate of MAEs as illustrated in Table 5.18.

Number of Interruptions is the main variable that had a significant correlation with all other variables. Interruptions have a weak correlation with the time of observation (r^2= 0.174, $p < 0.05$), suggesting that the number of interruption is specific to a time slot and it is not continuous throughout. There is a strong correlation of interruption with number of MAEs (r^2= 0.708, $p < 0.01$). This illustrates that the number of interruptions increases the risk of MAEs.

Table 5.18: Correlations matrix for other variables with MAE

Variables		Time of Observation	Number of MAE	Number of Interruptions
Time of Observation	Pearson Correlation Sig. (2-tailed) Significant Correlation	1	0.040 0.700 No	0.174* 0.030 **Yes**
Number of MAE	Pearson Correlation Sig. (2-tailed) Significant Correlation	0.040 0.700 No	1	0.708* .000 **Yes**
Number of Interruptions	Pearson Correlation Sig. (2-tailed) Significant Correlation	0.174* 0.030 **Yes**	0.708* 0.000 **Yes**	1

* Correlation is significant at the 0.05 level (2-tailed).

5.3.14 Severity Assessment of MAEs

A panel consisting of three reviewers has independently rated the potential of harm for the MAEs identified (n= 269) on a scale of 0 to 10. As shown in Figure 5.7 there is a variation between the reviewers. It can be noted from Figure 5.7 that the ranking carried out by the experienced PICU risk management nurse is normally distributed across the four levels of harm (no harm= 49, low harm= 122, moderate harm= 91, severe harm= 7). Whereas, the pharmacist rating is normally distributed over three levels (no harm= 28, low harm= 205, moderate harm= 36). However, ranking carried out by the consultant PICU doctor is skewed left (no harm= 177, low harm= 89, moderate harm= 3). Shapiro-Wilks test of normality was conducted and it confirmed that ranking of severity by all three raters cumulatively is not normally distributed ($p < 0.05$; 95% CI). Cronbach's Alpha reliability test was carried out to evaluate the overall reliability of the raters and it found an overall alpha level of 0.442. This is poor since it is suggests it is 44% reliable as a group. However, the test found keeping the raters together has improved reliability by 2%.

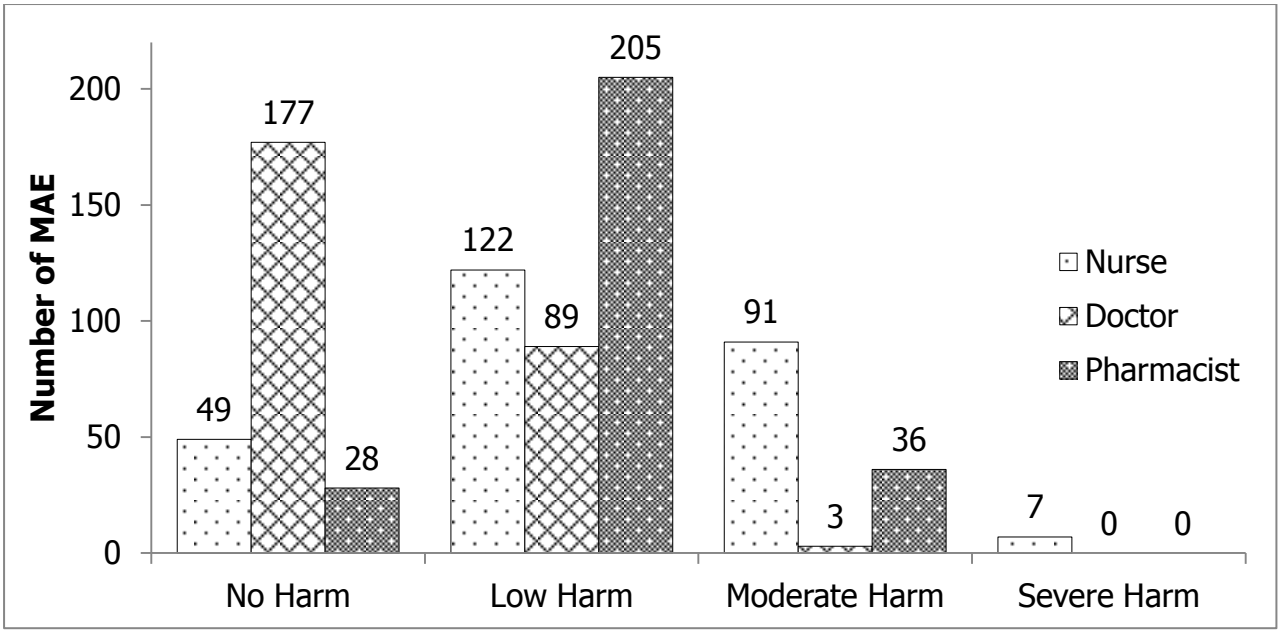

Figure 5.7: Breakdown of MAE's severity of harm by reviewer (n= 269)

The individual rater distribution of harm level on the scale of 0 to 10 in a histogram is illustrated in Figure 5.8. The histogram shows the wide variation of means between the raters. The first rater who is a doctor had a mean score of 0.54 (96% CI 0.43 – 0.64; SD 0.879) but the second rater who is a nurse had a mean score of 2.61 (95% CI 2.38 – 2.83; SD 1.853) and the pharmacist had a mean score of 1.53 (95% CI 1.40 – 1.67; SD 1.135). All three raters had outliers as demonstrated in Figure 5.8.

Furthermore, the assumption of homogeneity of variances was tested and found to be significantly different using Levene's test (F2, 91.647; $p < 0.05$) and therefore ANOVA cannot be carried out to test the significance of difference between the three means. But the robust tests of equality of means Welch and Brown-Forsythe both rejected the null hypothesis ($p < 0.05$) that states there is no significant difference between raters in assessment of level of harm since the data is not normally distributed. Therefore, a nonparametric test was conducted using the Kruskal-Wallis test. The difference between raters was again confirmed to be significant ($p < 0.05$; df 2). Moreover, the Mann Whitney U test also found a significant difference ($p < 0.05$) when pairing the raters (i.e. Doctor/Nurse, Doctor/Pharmacist and Nurse/Pharmacist).

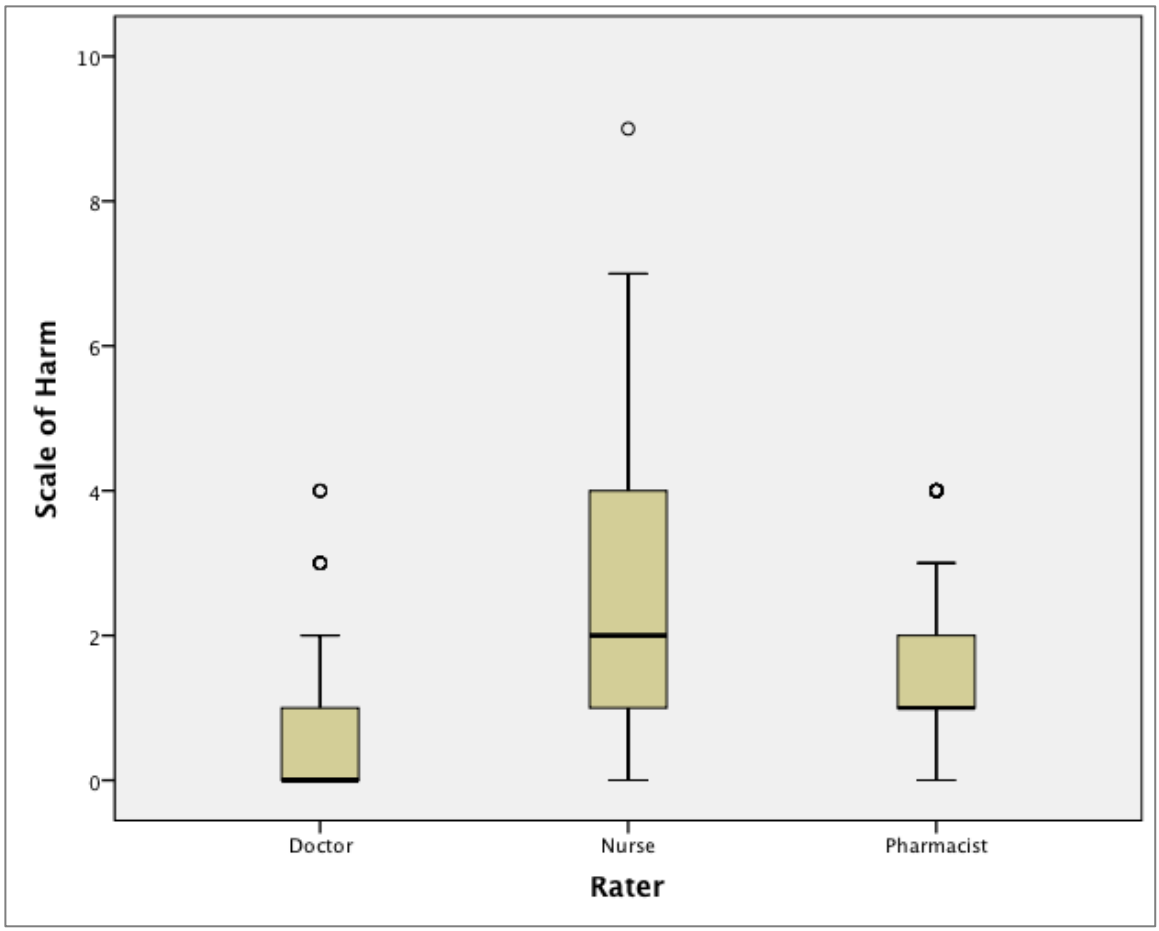

Figure 5.8: Histogram of raters' distribution of harm level with mean, median and range of distribution

Additionally, a nonparametric correlation using Kendall's Tau-b was carried out since it assumes complete nonlinearity unlike Pearson and Spearman correlations. Kendall's Tau-b as shown in Table 5.19 correlates significantly (p < 0.05) the ranking carried out by the nurse and the pharmacist. But the pairing of the doctor ranking shows very poor correlations with neither the nurse nor the pharmacist as expected.

Table 5.19: Kendall's Tau-b correlations of rater's severity ranking (n= 269)

Severity Correlation		Doctor Ranking	Nurse Ranking	Pharmacist Ranking
Doctor Ranking	Correlation Coefficient	1.000	.067	.035
	Sig. (2-tailed)	.	.245	.552
Nurse Ranking	Correlation Coefficient	.067	1.000	**.229**
	Sig. (2-tailed)	.245	.	.000
Pharmacist Ranking	Correlation Coefficient	.035	**.229**	1.000
	Sig. (2-tailed)	.552	.000	.

Following a series of statistical analyses, it was found that although the assessment of harm that was carried out by the doctor did not correlate well with the other raters, it does not affect the overall reliability of the severity of harm assessment and that the difference between the raters is due to the different clinical point of views. Therefore, the rating will not be aggregated together but will be presented separately as shown in Table 5.20. which demonstrates the breakdown of severity of harm per type of MAEs.

Table 5.20: Individual assessment of harm by three raters (n= 269)

Type of MAEs	No Harm			Low Harm			Moderate Harm			Severe Harm		
	D	N	P	D	N	P	D	N	P	D	N	P
Dose	127	9	3	25	86	126		57	23			
Formulation			5	5				5				
Infusion Rate	12	4	3	14	4	17		12	6		6	
Omission	6		6	5	10	5					1	
Preparation	23	22	1	24	11	42	3	17	7			
Time	9	14	10	16	11	15						
Total	**177**	**49**	**28**	**89**	**122**	**205**	**3**	**91**	**36**		**7**	

D Doctor
N Nurse
P Pharmacist

The breakdown of harm assessment reveals an interesting insight into the different clinical perceptions of the three professionals. Closer examination of Table 5.20 can provide trends, such as that dose error incidents were all judged by the doctor to be of no harm whereas the pharmacist assessed them as having a potential of a low harm instead. Also, there seems to be an agreement in nearly half of the cases between the nurse and the pharmacist of a moderate harm level to an MAE, whereas the doctor downgraded them to a low harm level. However, looking at MAEs relating to formulation, there is a clear disagreement among the raters. The pharmacist judged all five MAEs to be of no harm because although a wrong formulation was used, the actual dose given was still clinically suitable. Whereas the doctor has ranked them to have a potential of a low harm suggesting the new formulation may affect the clinical therapy. This seems to be agreed with by the nurse who ranked them to be of a moderate harm.

The same trend is noticed with wrong infusion rate errors where the doctor rated the incidents of no harm or a low harm. But the nurse and the pharmacist are shifting more into assigning a moderate or severe harm level to these incidents. A similar trend can be observed with preparation errors. Interestingly there seems to be some sort of consensus between the raters that omission and time errors are assessed as having a low potential for harm.

5.3.15 Comparison of Retrospective Analysis of MAE Reports versus MAE Observed Prospectively

The retrospective analysis of patient safety incidents relating to MAE found a total of 176 incidents. Table 5.21 presents the findings of the incident reports analysis compared to findings of this study using the same definitions. It is clear that this study found significantly more MAEs since 269 MAEs were identified during the 28 day observation compared to 176 reports of MAEs over six years. This study was able to identify a similar pattern of MAEs as it can be seen that the number of dose errors found during the observation study was much higher than that found retrospectively. However, it is interesting to note that there were no unauthorised drug incidents during this study in contrast to the patient safety incident reports. Also, it is evident that this study did not capture all MAEs that were reported. This includes incidents of wrong route and others such as equipment failure.

Table 5.21: Comparison of the MAE identified retrospectively using patient safety incident reports and prospective observation of practice

MAE Subtypes	Incident Reports (n)	Prospective Observation (n)
Preparation	36	50
Wrong Dose	33	152
Wrong Infusion Rate	26	26
Unauthorised Drug	26	
Time	21	25
Omission	20	11
Wrong Route	2	
Wrong Formulation	1	5
Other	11	
Total	**176**	**269**

5.4 Discussion

A direct prospective undisguised observation of medication administration process was conducted in the PICU of a London based children's hospital. This was carried out using a validated method and definition of MAE developed by Ghaleb et al. (2010). Undisguised observational method to identify MAEs in practice has been proven to be a valid and reliable method (Dean & Barber, 2001) and it has been used previously to study MAEs in children's hospitals (Chua et al., 2010; Ghaleb et al., 2010; Taxis & Barber, 2003). In this study the method of Ghaleb et al. (2010) was used but with a number of modifications.

The first difference was that in this study the researcher clinically reviewed drug charts before the observation of the medicine preparation and administration. This was to identify possible MAEs prior to the observation and allow time for the researcher to check if the dose prescribed for the patient was within the recommended prescribing protocol. Therefore, this will enable the researcher to intervene quickly in a serious MAE if not spotted by the nurse. Whereas iGhaleb et al. (2010) study, the drug charts were screened after the observation. However, this approach relies solely on the observer's clinical knowledge during the actual observation and there would be no system to check whether the dose that is being administered has been prescribed correctly but is based on an assumption that the dose prescribed is correct. Which is questionable since the retrospective review of medication error incidents showed that 24% (n= 141) of the reports (n= 583) were due to administration of medicine that was incorrectly prescribed. This is important since the definition for MAE used in this study includes deviation from hospital standard procedures, and these procedures require the nurse to check that medicine prescribed is correct before administration.

The second modification to the method was relating to the tool used to collect the observation data. Ghaleb et al. (2010) used a paper based data collection tool but in this study an iPad based data collection tool developed by the researcher was found to be more reliable and accurate. It also made the observation more discreet since less writing was involved and the researcher was more focused on the actual observation. Moreover, the tool enabled

more reliable data transfer since no transcription was required and this saved a lot of time in the data analysis phase.

The third modification of the method was that the researcher developed criteria for when to intervene in the event of observing an MAE. The criteria was modified and agreed by a consultant paediatrician, senior registered PICU nurse and a senior clinical PICU pharmacist. As far the researcher is aware, this is the first study that set specific conditions for when to intervene during an observation. The advantage of this approach is to make sure that consistency is maintained throughout the study, not relying solely on the observer's clinical judgement on when to intervene and ensuring that the study is reflective of normal practice and is not altered by the presence of the researcher (although it was found by the Dean and Barber (2001) validation study for observational method that MAE intervention does not change the rate of MAE).

The fourth modification made was that the researcher received extensive training from a senior clinical PICU pharmacist and a senior registered nurse. This was to ensure the validity of the observations and to develop the required skills and knowledge. Also it reduced the Hawthorne effect. This approach was taken instead of prolonging the observation length since it would ensure a better quality of data and also it was found that the rate of MAE does not change significantly over prolonged observations (Dean & Barber, 2001). This training also helped to improve the reflexivity aspect of this ethnographic study. The researcher was able to develop professional relationships with the observed group to ensure a true reflection of actual practice.

As a result, this study was able to effectively investigate the incidence, nature and severity of MAEs in PICUs, as well as factors that lead to MAEs. In this present study, 42 nurses were observed administering 832 doses from a possible 1953 scheduled doses to 46 patients aged between one month and 192 months (16 years) old. The study was able to capture 42.6% (n= 832) of the total scheduled doses during the observation of 28 shifts. Each shift lasted 12 hours, either 8am to 8pm or 8pm to 8am. The researcher was able to identify 283 MAEs. This demonstrated an incidence rate of 34% of the total

observed doses. The researcher identified at least two MAEs in the same observation on 12 occasions.

A panel of three members consisting of a doctor, nurse and a pharmacist who have clinical PICU and medication safety experience, individually reviewed all the 283 MAEs. Panel members have agreed that an MAE occurred in 95% (n= 269) of the possible MAEs observed. Therefore the incidence of MAE in this study is 32.3% of the doses observed. This panel acted as an additional method of results validation and ensured intra-consistency of the data since the researcher solely carried out the observations. Whereas, other studies that conducted this type of research used two or more observers and assessed the inter-reliability to validate the data (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Buckley, Erstad, Kopp, Theodorou, & Priestley, 2007; Dean & Barber, 2001).

The incidence of MAEs found in this study is consistent with the current literature. The systematic review study in this thesis found that incidence of MAEs cumulatively using observational methods is 34% (n= 2346 MAEs) per the total number of doses observed (n= 6894 doses) despite heterogeneity.

Following review of the MAEs by the panel, the 269 MAEs were found to be divided into errors relating to: wrong dose (n= 152, 56.5%), preparation (n= 50, 18.6%), wrong infusion rate (n= 26, 9.7%), wrong time (n= 25, 9.3%), omission (n= 11, 4.1%), and wrong formulation (n= 5, 1.9%). The researcher intervened in five MAEs before the medicine reached the patient at the last point of medicine delivery. The interventions involved three doses that were about to be given with an under dose and two incidents that were involved with an incorrect infusion rate programmed into the infusion pump. The study also identified that Ranitidine is associated with the most MAEs (n= 46), followed by Morphine (n= 28) and Paracetamol (n= 26). There were also six high risk medicines that were associated with 56 MAEs. Additionally, it was observed that Antimicrobials had the highest number of MAEs (n= 93), followed by Analgesics (n= 57) and gastrointestinal agents (n= 57). This was anticipated since these therapeutic agents are the most used in the PICU.

The panel was also asked to assess the potential of harm using a validated scale that was developed by Dean and Baber (1999). It was clear that healthcare professionals perceived the harm of MAEs differently since the reliability assessment of the reviewers using Cronbach's Alpha was 0.442. Also the distribution of rating is noticeably different. A consultant doctor's assessment is noticed to be skewed to the left (i.e. MAEs were mostly of no harm or low harm) whereas the assessment by the senior registered nurse, who is also a risk manager of the PICU, was normally distributed between no harm and severe harm. On the other hand, assessment by a clinical pharmacist was normally distributed between no harm and moderate harm. This variability could be related to the fact that healthcare professionals are educated and trained differently. The clinical priorities of healthcare professionals will be different. For example, doctors will be focused on the status of the actual clinical condition and treatment plan rather than the delivery of medication. Pharmacists would be concentrating on the safety of the prescribed treatment and its delivery methods. However, nurses are interested in the patient's experience of aspects of the treatment. Therefore, the potential of harm will vary accordingly.

The most prevalent type of MAE is the wrong dose administered to patients, since this contributed to 56.5% (n= 152) of all MAEs. This represents an MAE rate of 18.3% of all doses observed. This is first study that reports such a high rate of dose errors compared to other studies such as Ghaleb et al. (2010) which reported dose error as 9.3% of all MAEs observed and Prot et al. (2005) which identified 15% of all MAEs to be related to wrong dose. The fact that the researcher clinically reviewed drug charts before the administration process may have contributed to this high rate, since as far the researcher is aware no other study has used this approach before. Night time observations were associated with more wrong dose errors (n= 87) than daytime observations (n= 65 MAEs). This could be contributed to by the poor lighting conditions, fatigue and the fact that small doses are required to be drawn out from pharmaceutical formulations that are expressed with a wide ratio of active ingredient per diluent. For example Ranitidine intravenous ampule is available as 50mg/2mL. This can cause great difficult in drawing out the correct volume in order to achieve the correct prescribed dose.

The second most common type of MAE observed in the PICU was relating to the incorrect preparation of the dose before administration. A total of 50 preparation errors were identified and agreed by the panel, this is representing 18.6% of all MAEs. This is consistent with the findings of Ghaleb et al. (2010) that reported preparation errors to be 20.7% of all MAEs identified.

Administration of medicines using the wrong infusion rate was the third most common type of MAE observed in this study. It contributed to 9.7% of all the MAEs. Many of these MAEs were related to administering Ranitidine (n= 11) too quickly since it is meant to be administered over at least five minutes but it is commonly being given bolus over one to two minutes. This could have the potential to cause bradycardia when given intravenously. Wrong infusion rate has been associated with intravenous therapy and has been documented previously by Ghaleb et al. (2010) to account for 19.8% of all MAEs and by Cousins et al. (2005) to be 35.6% of all MAEs. It is important to note that both studies were conducted in a number of hospitals whereas this study was carried out in a single unit, hence this may have been a factor in the low incidence rate of wrong infusion rate.

In this present study, administration of medications at the wrong time by ±1 hour was included since it was associated mostly with Antimicrobials and a delay in receiving these doses at the correct time will have an impact on the clinical treatment and recovery of patients. A total of 25 doses (9.3% of all MAEs) were given at a wrong time. Delay in treatment was primarily due to interruptions caused by other healthcare professionals and patients' visitors. However, other studies reported wrong time error in a range between 12.5% (Cousins et al., 2005) and 40.3% (Feleke & Girma, 2010) of all MAEs as highlighted in the systematic review study.

Other MAEs that were observed by the researcher were due to doses being omitted without clinical or logistical reasons (4.1%). This is consistent with findings by Ghaleb et al. (2010) that identified omission errors to be 5.1% of all MAEs. Moreover, administration of medicines in a pharmaceutical formulation that is different to the prescribed has been found in 1.8% (n= 5) of all MAEs. However, the appropriate dose was given for the alternative

formulation. This change of formulation was not required since the patient's clinical situation was not changed at the time of the observation and the correct formulation was available to be used.

Current published research correlates an increased rate of MAEs with the use of intravenous medication therapy in children's hospital settings. An example is the investigation by Taxis and Barber (2003) in children's hospitals in the UK and Germany. They have found 212 MAEs in observations of 430 intravenous drug doses (49.3%) whereas this present study found 170 MAEs associated with observation of 572 intravenous doses (29.7%). This difference could be attributed to the difference in healthcare practice across the two studies and study clinical setting. The PICU is a specialist area with one-to-one nursing; hence less opportunity for error compared to general wards.

Another finding of this study is that overall, there were more MAEs during the day observations (n= 146) than the night observations (n= 123). Van den Bemt et al. (2002) found a similar correlation. However, correlation of time of observation to number of MAEs is of no significance ($p > 0$ .05). It was also found that an increase in level of interruptions during medication preparation and administration does correlate positively with increased risk of MAE ($r = 0.7$; $p < 0.05$). Additionally, there was no significant difference between the rate of MAE during weekdays or weekends ($p > 0.05$). This is an important finding since it illustrates that the practice of medication administration across the week is similar and the risk of MAEs across the week remains equal.

It was interesting that this study found more MAEs than the retrospective analysis of patient safety incident reports since there were 269 MAEs identified during the 28 days observation while there were only 176 MAEs over six years' worth of patient safety incident reports. It is important to note that this is not like for like comparison between the methods. This is due to the fact that reporting of errors is voluntary and there are factors that hinder reporting as explained in the previous chapter. However, the increased number of identified MAEs through the prospective observation could an indicator of the method strength but also an indication of the poor reporting culture of medication errors. Additionally, this study was able to identify a

similar pattern of MAEs. However, it was remarkable to see that there is a minimum of a 4-fold hike in the number of wrong dose incidents. This is alarming, since wrong dose incidents can potentially put patients at risk of serious harm. However, it was also noticeable that there were no unauthorised drug incidents during this study in contrast to the patient safety incident reports. Also, it is evident that this study did not capture all MAEs that were reported. This includes incidents of wrong route and others such as equipment failure. The presence of the observer may have contributed to reduction of these errors. However, not enough supporting evidence is available.

This study could have encountered a number of potential limitations. First, the observations were carried out over 28 shifts, which can be considered as a moderately small sample size. However, this is common in this type of research due to the difficulties associated with conducting observational methods and observer fatigue. Second, the actual clinical outcomes of the MAEs were not followed up, since the patients in the PICU were suffering from complex conditions. It would not be possible to find out whether the patient is suffering directly because of an MAE or due to deterioration of their clinical condition. Third, it was not possible to find out if the nurses were aware that they have made MAEs and if they learnt from their mistakes. A future recommendation would be to carry out a failure effect mode analysis of the administration process. This should be based on baseline data and expert consensus. The analysis will help to identify areas of high-risk practice and potential consequences.

5.4.1 Conclusion

In conclusion, this observational method of medication administration practice found a high rate of MAE in PICUs. It involves a range of medications, some considered high-risk. Findings suggest a need to develop a set of safety measures to deal with the issue from different perspectives such as wrong dose errors and interruptions. Also the need to improve system factors that cause MAEs such as the use of standard concentrations of intravenous infusions or use of pharmaceutical formulations that are not

difficult to prepare doses from. The findings of this study will contribute to the development of these safety measures in the next study of this thesis.

5.5 Study Contribution to Knowledge

1. Development of data collection tool for both research and practice use purposes to measure safety of medicine administration in PICU.

2. Development of strong method for observation with criteria for when to intervene in the event of identifying MAE. Method was able to observe 42.6% (n= 832) of all scheduled doses (n= 1953).

3. First study to build upon the practitioner-led definition of MAE that was developed by Ghaleb (2006). The study identified an MAE rate of 32.3% (n= 269) of all doses observed (n= 832).

4. Assessment of harm severity of MAE by practitioners and identified the different attitude towards MAE seriousness by different healthcare professionals.

5. Evidence found correlating increased risk of MAE with level of interruption.

6. Confirmation of the gross underreporting of MAE by healthcare professionals. Over 28 shifts, a total of 269 MAEs identified compared to 176 reported MAEs over 5.6 years by healthcare professionals.

Chapter 6: National Survey of Interventions Used for Prescribing & Administration Errors in Paediatric Intensive Care Units

6.1 Introduction

Findings from the systematic literature review identified a number of interventions to reduce MAE. As was highlighted in chapter three, these interventions are limited. It was concluded that there is a need to explore other interventions that are used in everyday practice. The review also found the complexity of medication administration errors and that this type of error has a multifaceted nature. In the light of these findings, a national survey of both prescribing and administration error interventions is to be carried out.

It was particularly identified that there have been no studies carried out in the UK that investigated MAE interventions in the PICU. This is extremely worrying since the focus in the UK based literature has been on quantifying the scale of the problem only. Unlike other research based in Canada and the US for example, that is moving towards implementing solutions by the use of educational programmes and advancing technology. Therefore, the aim of this study is to characterise existing interventions used nationally in PICUs to reduce prescribing and administration errors. The study objectives are as follows:

1. To characterise the interventions used in PICUs to reduce prescribing and administration errors.
2. To assess the impact of interventions used on reducing prescribing and administration errors.
3. To identify challenges and barriers for implementing interventions in practice.

6.2 Method

6.2.1 Study Setting and Participants Recruitment

There are 28 hospitals that have PICUs across the UK. To capture all these PICUs it was decided to distribute the questionnaire electronically via an interest group such as the Paediatric Intensive Care Society (PICS) and the Neonatal and Paediatric Pharmacists Group (NPPG) which have members across all 28 PICUs. Online distribution was chosen instead of a paper-based method in order to achieve the highest possible response and to make sure that the right person completes the questionnaire.

The participants were recruited to take part in this questionnaire by email. This was sent from the PICS and NPPG research heads. The email was attached with an invitation letter from the researcher (Appendix 4) to their members to take part in this study. The letter introduced the purpose of this study, explaining the overall aims and objectives. It contained a URL link to the questionnaire to be self-completed on the SurveyMonkey website. Participants were also informed that responses would be anonymised and that ethical approval was obtained for this questionnaire. Additionally, contact details for the researcher were provided in case participants had any enquires or were not sure about a question.

An additional email was sent two weeks after the initial invitation to non-respondent PICUs by the research heads of the PICS and NPPG. The researcher identified the non-respondents. Moreover, the researcher made telephone calls to the risk managers and chief pharmacists asking them to take part after four weeks from the follow-up email.

6.2.2 Sample Size

A purposive sample was used via the PICS and NPPG which have members who are doctors, nurses and pharmacists from all 28 PICUs. They represent more than 850 healthcare professionals. However, the sample size for this study was to receive at least one response from the 28 PICUs. The rate of response was calculated by equation 6.1.

$$Response\ Rate = \frac{Number\ of\ PICU\ represented}{Total\ number\ of\ PICUs\ (28)} \times 100 \qquad \text{Equation 6.1}$$

6.2.3 Questionnaire Development

The actual wording of the questions was developed in accordance with the objectives of this study. It was decided to have a short concise questionnaire. If an intervention is in place, the participant would be asked to describe the nature of that intervention. They will then need to indicate if the intervention was having an impact on the errors. Participants would then be asked to describe the challenges or barriers they faced when implementing the intervention. The researcher developed a draft questionnaire initially consisting of a mix of open and closed questions. The questionnaire collected the following data:

1. Hospital Name
    - Format: open question
    - Response: objective single line free textbox
    - Purpose: to identify which PICU this response is from in order to calculate the response rate and follow up non-respondent PICUs.
2. Nature of intervention for prescribing errors and/or MAEs
    - Format: open question
    - Response: objective multiple line free textbox
    - Purpose: This is where participants input the characteristics of the intervention in place in order to meet objective one of this study.
3. Intervention outcome/impact
    - Format: open question
    - Response: subjective multiple line free textbox

- Purpose: opportunity for the participant to highlight if the intervention was able to reduce medication errors and to express the how the intervention impacted on their practice. This component will meet objective 2 of this study.

4. Challenges/barriers to implementing the intervention

    - Format: open question
    - Response: subjective multiple line free textbox
    - Purpose: This is a subjective account of what the participants faced when implementing the intervention into practice. This will help to identify the different factors that need to be taken into account when developing an intervention. Objective 3 of this study will be met by this component.

The final questionnaire (appendix 5) also collected whether participants were interested in being informed of the overall study findings. It asked if they had any other comments regarding this study in order to allow them to express their thoughts.

6.2.4 Validity and Transferability

In order to find out whether the questionnaire is measuring what it is supposed to be measuring, construct validation was first carried out. A content validation process followed this. Two clinical pharmacy practice lecturers carried out a construct validation. They both have extensive experience in conducting this type of research. They were asked by the researcher to validate the questionnaire by checking that:

1. Questions asked reflect the aim and objectives of the study.
2. Questions are not ambiguous or have the potential to be misunderstood/misleading.
3. Questions are not double barrelled.

4. The overall structure of the questionnaire and wording of the questions is concise.

5. No problem of access to the questionnaire and navigation through the different sections of the questionnaire.

The research team assessed the extent to which the data collected addressed the aim and the objectives of this study. This content validation found that all the responses were relevant and suitable for the purpose of this study. The responses reflected the questions asked.

6.2.5 Credibility

There is no method available to check that the participant answers to the questions are truthful. However, this questionnaire was distributed to two networks that represent doctors, nurses and pharmacists. They are active in PICU care and research. Additionally, it is expected to have more than one response from the same PICU. This will help to see if the answers are correlating as a form of triangulation or participant validation. Moreover, it is assumed that all the responses are truthful since all participants are registered healthcare professionals. Their respected professional body governs them to be truthful.

6.2.6 Reliability and Dependability

Reliability and dependability relates to the extent to which the findings of this study are reproducible and replicable. There is no measure to estimate this, but all tools used to carry out this study have been provided. This includes the codes used to analysis the data. However, due to the nature of this study, which is to investigate the current interventions used in practice to reduce prescribing and administration errors in PICU, the findings might be different depending on when the study is replicated since it is expected that new interventions will be developed.

6.2.7 Pilot Study

It was decided not to carry out a pilot study for this survey since the sample of the participants is small and if a pilot study were to be carried out, the responses would then be excluded from the main findings. Thus, there is a risk of losing valuable data. Another concern about a pilot study is that it may introduce data contamination, as pilot participants will be included in the actual study. Leading to participants providing different data when responding to the main study.

6.2.8 Data Analysis

Responses from each participant were collected on a web-based portal (SurveyMonkey). Responses were extracted into a Microsoft Excel 2010 (Microsoft, Redmond, Washington, US) worksheet to manage the data analysis process. Each question was analysed independently. Basic descriptive analysis was carried out. However, due to the nature of this questionnaire, complex inferential statistical analysis (e.g. Chi-Square or T-Test) was not performed. Moreover, the questionnaire did not have specific factors that could be used to test internal reliability and stability over time nor to test for generalisability since participants and interventions will always be changing and not traceable. A mix analysis of themes and contents was conducted using Grounded Theory approach.

The Grounded Theory concept by Glaser and Strauss (1967) was used to analyse the data in this study. Grounded Theory is an inductive approach used to reach phenomena from the data. This concept is the most suitable approach for this study since there is a lack of a theoretical framework and this approach acts as a measure of conformability to ensure that the researcher's personal values or theories are not interfering in the conduct of this study and its findings (Strauss & Corbin, 1998). However, it is important not to ignore current literature to help with coding of the responses, since Grounded Theory is not a presentation of raw data but a method of systematically analysing the data thematically. Another consideration is that this concept is not a method of content analysis that presents the findings in a quantitative manner. However, content analysis was carried out to quantify

the number of code repetitions so as to highlight the frequency of interventions used in practice across the UK.

The data was analysed by the researcher using the Bryman (2012, p. 576) stages of qualitative analysis:

1. Responses for each question were read as a whole and codes emerging were highlighted.
2. Re-read of responses to label codes and emerging themes.
3. Systematic coding of responses.
4. Synthesis of major themes by connecting different codes together to help interpretation of the findings in relation to study objectives.

The research team reviewed all the codes used to mark responses and the themes produced. During thematic analysis, the researcher utilised Strauss's version of Grounded Theory which emphasises that analysis should be consistent with current knowledge and literature (Charmaz, 2005, p. 509). This approach was taken since it is in-line with the pragmatic thinking of the researcher. It also enables use of the terminologies found in the systematic literature review in chapter 3 of this thesis.

6.2.9 Ethical Consideration

The questionnaire gathered information regarding the current practice around interventions used to reduce prescribing and administration errors. This information is sensitive and can be misused. Therefore it was decided to anonymise all the findings. This will ensure that the responses of specific PICUs cannot be recognised and extracted. The identity of the participants or other related information that can be used to identify them was not collected to encourage questionnaire take up. Only the names of the hospitals were used for the purpose of calculating response rate and used to identify the participation spread nationally. Ethical approval was obtained from NHS REC to conduct this study as discussed in chapter 2.

6.3 Results

6.3.1 Demographics

The questionnaire was sent to 28 hospitals offering PICU care via two professional networks that represent more than 850 doctors, nurses and pharmacists. A total of 46 participants representing 23 hospitals across the UK and one from the Republic of Ireland responded to the survey. This yields a response rate of 82% (n= 23) from the UK, this rate is considered excellent. Figure 6.1 illustrates the geographical spread of the participants.

Table 6.1 shows the names of the hospitals that took part and the number of respondents from each organisation. Participants were from multidisciplinary professions. However, it was not possible to trace back the breakdown of participants by profession, level of experience, age or gender. This information was intentionally left out in order to increase the uptake of the survey. The researcher contacted the remaining five PICUs that did not respond to the invitation, but due to lack of interest and/or commitment to other clinical and research duties they did not take part. The raw data of each response per questions asked is presented in appendix 6.

Figure 6.1: Geographical spread of survey respondents

Table 6.1: Number of respondents from each represented hospital

Hospital	Number of Respondent
Birmingham Children's Hospital	8
Alder Hey Children's Healthcare Hospital - Liverpool	4
Great Ormond Street Hospital - London	4
Leeds Teaching Hospitals	3
Nottingham Children's Hospital	3
Royal Manchester Children's Hospital	3
Bristol Royal Hospital for Children	2
University Hospital Southampton	2
University Hospitals of Leicester	2
Cambridge University Hospitals NHS Trust	1
Evelina Children's Hospital - London	1
Freeman Hospital – Newcastle	1
Great North Children's Hospital - Newcastle	1
Hillingdon Hospital NHS Trust - London	1
Our Lady's Children's Hospital Crumlin – Dublin	1
Oxford University Hospital - John Radcliffe	1
Royal Brompton Hospital - London	1
Royal Hospital for Sick Children – Glasgow	1
Royal London Hospital - Barts	1
Sheffield Children's Hospital	1
The James Cook University Hospital - Middlesbrough	1
The Portland Hospital for Women and Children - London	1
The Princess Elizabeth Hospital Guernsey	1
Wirral University Teaching Hospital - Merseyside	1
Grand Total	**46**

6.3.2 Nature of Interventions in PICU

All the responses received were found to be relevant. Only two responses from the total of 46 responses indicated that no interventions were in place to tackle prescribing errors or medication administration errors. The rest of the responses all described interventions for prescribing errors or MAEs. A total of 38 responses indicated interventions related to prescribing errors, and 28 related to medication administration errors. There were 27 responses with interventions for both prescribing errors and medication administration errors.

Prescribing Error Interventions

The analysis of 38 responses that indicated prescribing error intervention identified the following themes:

1. **Education and Training**
    - Initiatives were identified that supported the preparation and learning of healthcare professionals involved in the prescribing process. These were categorised to the following subtypes:
        - **New Doctor Induction (n= 7):** This is a structured training programme which new doctors undergo to learn how to safely prescribe in PICU. It's also to make sure that they follow the standard prescribing practice in the unit before allowed to practice prescribing.
        - **Learning from Errors (n= 5):** This is a post-prescribing learning event where prescribing errors are used to support learning from mistakes. The aim is to avoid it happening again. This initiative was also used for group learning and sharing of experience.
        - **Pocket information Cards (n= 1):** This initiative provides prescribers with rapid access to prescribing information for commonly used treatments during the process of prescribing.
        - **Prescribing Information Stickers (n= 2):** This is another form of education initiative that provides important prescribing information for commonly used treatments

during prescribing. These stickers are usually placed on top of BNF or other key resources.

2. Error Monitoring and Reporting

- These are interventions used to raise awareness and support the management of PICUs to identify medication risks.
    - **No Blame Culture (n= 1):** Policy to promote non-punitive culture of dealing with errors.
    - **Error Incident Reporting (n= 3):** System in place to report prescribing errors in a confidential manner. It also supports reporting of near-misses.
    - **Error Instant Feedback (n= 6):** Mechanism to provide feedback in a rapid manner from the risk management team to the reporter or person involved in that prescribing error. This to speed up learning from mistakes and avoid them happening again in practice.
    - **Error Incident Audit (n= 3):** This is a regular review of prescribing incidents reported to identify trends of risk and support improvement.

3. Prescribing Policies

- These are improvement policies that are used in PICUs to prevent prescribing errors before and during the prescribing process.
    - **No Bedside Prescribing (n= 1):** Policy that isolates the prescriber from the highly demanding clinical area near the patient's side. This to carry out prescribing in less busy area in the PICU.
    - **Bedside Prescribing (n= 1):** This policy requires prescribers to be near the bedside of the patient to do the prescribing process and not in any other area.
    - **No Interruption (n= 2):** Policy that obliges other members of the healthcare team not to interrupt the prescriber when they are busy with the prescribing process.

- **Zero Tolerance Prescribing (n= 5):** This intervention consists of multiple prescribing policies. Only PICU registrars or consultants are allowed to prescribe. There are exceptions for post-operative and oncology patients. Prescribers to write charts at a designated prescribing desk/room. They will be free of interruptions. Violations to this policy would be treated seriously and are not acceptable.
- **Designated Prescribing Desk (n= 6):** A purposive desk in the PICU with resources to aid the prescriber.
- **Prescribing Guidelines (n= 3):** PICU specific prescribing guidelines or protocol for prescribers to adhere to for the most commonly used medicines with information of indication and doses for different age groups.

4. Quality Improvement Tools

- These are tools used during the prescribing process.
  - **Electronic Prescribing (n= 2):** This tool is designed to remove handwritten drug charts from the PICU. Requires prescribers to order medicines electronically.
  - **Drug Calculator (n= 3):** Electronic drug calculator to support prescriber in pharmaceutical calculations of doses and infusion rate of medicines.
  - **iPad Application (n= 1):** Prescribers to order medications wirelessly. They will be able to determine the correct dose and infusion rates using the specific patient parameters such as weight or renal function.
  - **Redesign of Drug Charts (n= 6):** Development of new drug charts that make prescribers clearly provide all the instructions necessary for the safe administration of medicines and clinical checking.

5. **Other Prescribing Error Interventions**
    - These are interventions that are used to reduce prescribing errors in the PICU but cannot be categorised with into the above themes.
        - **Pharmacist Presence (n= 2):** PICU pharmacists on rounds and carrying out a daily clinical check, instant prescribing information and guidance.
        - **Standardised Infusion concentration (n= 2):** Prescribers to express concentration of infusions that are commonly used in standard expression.
        - **Prescriber of the Week (n= 1):** An approach that is using celebration of success for prescribers with the lowest number of errors on a weekly basis.

Medication Administration Errors Interventions

A total of 28 participants responded with an intervention for MAE. The responses were categorised into the following themes:

1. **Education and Training**
    - This is a set of interventions that are used to educate and train practitioners to improve administration practice in PICU:
        - **Nurse Training (n= 7):** This is formal training of nurses in the practice of preparation and administration of medicines.
        - **Information Labels (n= 1):** Education method that is delivering quick guidance on the administration of commonly used medications. These labels are placed on key reference materials and on facilities that are used by nurses such as the preparation area or patient bedside.

2. **Error Reporting and Monitoring**
    - These are interventions used to raise awareness and support the management of PICU to identify risk.
        - **Error Incident Reporting (n= 4):** System in place to report MAE in confidential manner.

- **Error Incident Feedback (n= 4):** Mechanism to provide feedback by risk management team to the reporter or person involved. This is to encourage learning from mistakes and avoid them happening again.

3. Medicine Administration Policies

- These are improvement policies that are used in PICU to reduce MAE:
  - **No Unnecessary Night Administration of Medicines (n= 1):** This policy restricts administration of medicines during daytime to prevent MAE due to night-time conditions and availability of resources and staff.
  - **5 Rights Rule (n= 1):** This forms part of the standard operating procedure of medication administration that requires nurses to check before administration of medicines. Nurses to check that the right patient is given the right medicine with the right dose at the right time using the right route.
  - **No Harm Policy (n= 2):** Strict policy that requires nurses to be vigilant about what they are administering by ensuring that the dose is correct for that patient and ensures that they follow the appropriate procedure to prepare and administer medicine.
  - **No Punitive Policy (n= 2):** Open culture policy to support learning from errors and help foster improvements. This also assures nurses that MAEs that are not intentional will not be used against them.
  - **No Interruptions (n= 2):** Policy that imposes no tolerance to interruptions during medicine preparation and administration. This policy is part of the overall standard operating procedures of medication administration practice.

4. Quality Improvement Tools

- These are tools used in the administration process:
    - **iPad Application (n= 1):** This is a tool for nurses to review medication prescribed wirelessly. Being able to calculate the dose and infusion rates using the specific patient parameters such as weight or renal function. They can also review other resources such as intravenous administration guidelines for advice on compatible diluents and infusion rate.
    - **Pre-filled Syringes (n= 1):** This is the use of pre-filled syringes only in the PICU. Standardising infusion concentrations and preventing MAEs relating to preparation and dose errors. Another example of this is the Centralised Intravenous Additive Service (CIVAS).
    - **Dose Ready Reckoners (n= 1):** This tool aims to ease pharmaceutical calculation of doses in the PICU. It provides a quick dose determination guide in accordance with the different weights of children for the commonly used medicines.
    - **Smart Infusion Intravenous Pump (n= 1):** This tool aims to alert the nurse when setting up intravenous infusions if the dose or rate entered is outside the therapeutic range of that medicine, using a built-in database of the approved policy within the PICU. This tool will require the nurse to enter data relating to the patient such as weight and select the medicine prescribed and dose or infusion rate, and then it will calculate if that is a correct dose by alerting the nurse before commencement of the therapy.
    - **Standard Infusion Concentration (n= 2):** This intervention restricts the way pharmaceutical agents are expressed and presented. It ensures that all injectable formulations are expressed in a simplified form to ease preparation and administration.

- **Medicine Administration Guidelines (n= 5):** PICU specific administration guidelines for nurses to adhere to when administering medications, with information about compatibility, diluents and infusion rates.
- **Red Aprons/Tabards (n= 7):** This is a physical/visible tool to indicate that the nurse is engaged with medicine preparation and administration duties. To indicate that the nurse must not be interrupted.

5. Medication Chart Clinical & Double Checking

- These are interventions that are aimed at the process of clinical review of medication charts post-prescribing and prior to medicine administration to patients:
  - **Handover Chart Review (n= 1):** This is the inclusion of medication review as part of the handover process to ensure continuity of care and safe administration of medication.
  - **Pharmacist Clinical Review (n= 1):** Presence of PICU clinically trained pharmacist in the ward to review all medication charts to pick up MAEs and provide information on guidelines and recommend advice on compatibility of medications.
  - **Silent Double Checking (n= 1):** Intervention to ensure that the process of double checking by a second nurse before administrations is carried out in silence. This will prevent distraction and allow the second person to make an independent assessment of the prescribed and prepared dose.
  - **Double Checking (n= 2):** This intervention requires all medicines to be clinically checked by a second person before administration.

6.3.3 Impact of Interventions Post Implementation

The participants were asked whether an audit had been carried out to evaluate the impact and effectiveness of the interventions. If so, they were asked to provide the main outcomes of the audit. A total of 23 participants provided a response to this part of the question. These responses were themed as represented in Table 6.2. For other interventions, either the impact is still under review or participants did not evaluate its use in practice.

As can be seen in Table 6.2, participants stated that interventions were able to reduce medication errors in general. It was also noted that participants who used multiple interventions were able to reduce the severity of harm and increase number of error reports. Additionally, it is interesting to see that use of visible indicators such as the red apron had a mixed impact. Some participants were able to give numerical evidence to support their statements, for example:

Response 01 *"Significant reduction in prescription errors from 45 to 15 %".*

Response 07 *"Prescribing errors reduced from 1 per occupied bed day to 0.3 per occupied bed day."*

Response 41 *"……no errors detected in 3 years post implementation. Only 2 errors with miss-selection of infusions".*

Table 6.2: Impact of prescribing and administration errors interventions in PICU

Impact	Prescribing Error Interventions	Administration Error Interventions
Medication Errors Reduced	Drug Calculator Error Incident Audit Error Instant Feedback New Doctor Induction No Bedside Prescribing Pharmacist Presence Prescriber of the Week Redesign of Drug Charts Zero Tolerance Policy	5 Rights Rule Double Checking Error Incident Reporting Error Instant Feedback Handover Chart Review Information Labels Medicine Administration Guidelines No Harm Policy Red Aprons/Tabards Silent Double Checking Zero Tolerance Policy
Reporting Increased	Error Incident Reporting Error Instant Feedback No Blame Culture Zero Tolerance Policy	Error Incident Reporting
Interruption Continued	Zero Tolerance Policy	Red Aprons/Tabards
Severity Reduced	Designated Prescribing Desk	
Specific Guidelines Needed	Prescribing Guidelines	
Re-Education Required		Nurse Training

6.3.4 Challenges and Barriers to Interventions

Participants were also asked to describe any challenges or barriers they have faced while implementing interventions. Figure 6.2 illustrates the challenges and barriers identified from participants' responses. Themes were characterised into personal, systemic and cultural factors.

The personal factors relate to the individual healthcare professional's attitude towards the intervention. Whereas, systemic factors represent challenges due to the PICU setting of care. The cultural factor illustrates the challenges and barriers an intervention will encounter as a result of the interaction of a healthcare team within the PICU setting.

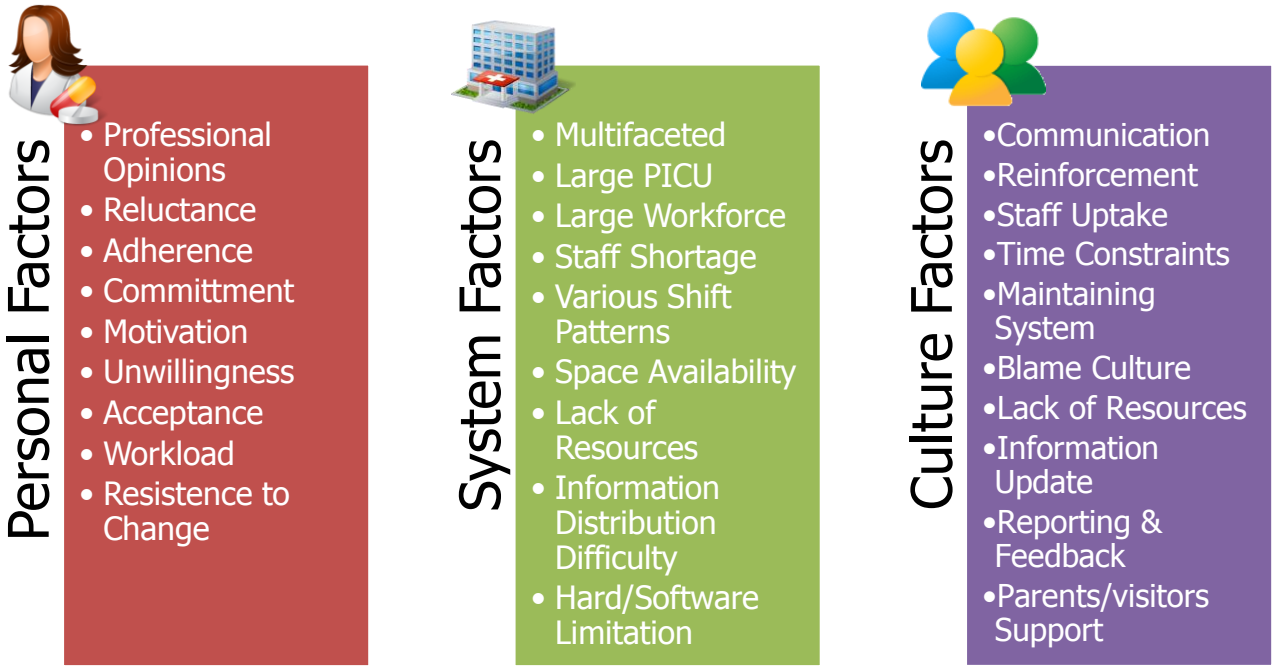

Figure 6.2: Challenges and barriers to success of prescribing and administration error interventions in PICU

Participants highlighted that there were a number of personal factors that influenced the success of the interventions. This included personal and professional opinions about what constitutes an error and reluctance to change their practice. It also includes issues relating to adherence to the new intervention and commitment to the new procedures. This is worsened by the increased workload. As a result an issue of maintaining motivation on an individual level is noted. The following responses exemplify these factors:

Response 02 *"Nursing staff attitude towards checking the drug chart. Doctors unwilling to use the dedicated prescribing area, Nurses having their opinion on what is and is not an error".*

Response 08 *"Lack of motivation and momentum after initial push".*

Response 12 *"Reluctance from nursing staff to change the way things are done and doctors not taking med errors seriously".*

Response 29 *"Ensuring staff adherence to rules!"*

Systemic factors that were raised by the participants were related to the difficulty in management of the intervention in relation to the PICU setting. This issue is illustrated with the following examples:

Response 16 *"Large workforce; difficulty in information distribution and reinforcement; time constraints; availability of space".*

Response 25 *"Errors on PICU are so multi-faceted that it is very difficult to identify whether the changes made have contributed to preventing further errors or not".*

Response 46 *"Nursing staff shortages, pharmacy staff shortages – I went on maternity leave and the work was not continued in my absence as there was no senior pharmacist cover".*

Participants also revealed the effect of the overall team culture on the success of the interventions. This includes issues such as the need for consistent reinforcement of the intervention, management of the actual intervention and involving patient's parents and visitors. Examples of these responses as follow:

Response 03 "Poor "buy in" from members of the MDT. Additional support required from parents & visitors for the success of a change in practice. Disposable high visibility drug tabards alone are not enough to reduce / eradicate interruptions during the drug administration process".

Response 18 "Need nursing staff to be fully on-board. Good team of nurse educators here who led it".

Response 42 *"People felt threatened at first now they help to develop the solution to prevent it happening again".*

6.4 Discussion

The aim of this study was to characterise the existing interventions used in PICUs in practice nationally for prescribing and administration errors. A validated online short questionnaire was able to attract a large response. All were from healthcare professionals that have PICU clinical duties. A total of 46 responses were received. This represents 23 hospitals (82%) from the potential 28 PICUs. This study was able to identify the nature of current national practice in tackling medication errors (specifically prescribing errors and medication administration errors) in PICU. It was also possible to explore the challenges and barriers in implementing these interventions. Additionally, key outcomes post interventions were found.

A number of interventions were identified for both prescribing (n= 21) and administration errors (n= 22) in the PICU. Similar interventions were identified by the systematic literature review in chapter 3. Moreover, the findings of this survey are also in line with the COSMIC study by Wong et al. (2007). COSMIC characterised the interventions used to reduce calculation errors in children doses. The study was also in the form of a questionnaire that was distributed to professional networks across the UK and Europe. Wong and colleagues identified interventions into technological, healthcare professional practice and others. This study was able to find all interventions characterised in COSMIC.

The characteristics of the interventions identified in this study were broadly themed into:

- Education and Training.
- Error Monitoring and Reporting.
- Prescribing / Administration Policies.
- Quality Improvement Tools.
- Medication Chart Clinical and Double Checking.

The interventions identified illustrate the complex, multifaceted nature of prescribing and administration errors in PICU. This is important since it confirms that a single intervention is not enough to tackle the problem.

Education and training is used for both prescribing and administration errors. These interventions aimed to reduce errors due to knowledge mishaps. This is carried out by a series of induction programmes for doctors and nurses and the use of specific medicine information in the form of cards and stickers. These interventions are useful in providing instant information on local prescribing and administration protocols. However, educational interventions require repeated cycles to have a long-term impact. Also the information cards and stickers will need regular updates to reflect changes in practice. Still yet, there was no mention of use of checklists or a trigger tool. Also, there is no mention of eLearning modules for administration or preparation of medicines. Especially as eLearning materials are becoming a major source of training for all healthcare professionals. Additionally, there was no mention of interventions targeting specifically high risk medicines or narrow therapeutic window medicines.

Error reporting and monitoring interventions are useful in identifying trends of prescribing and administration errors. Additionally, these interventions can give feedback to individuals who are involved in errors and also provide areas where change is required in the system. However, these interventions are subject to factors such as transparency, openness and safety culture as highlighted by Wakefield et al. (2001). Therefore, underreporting and poor quality of reporting is possible. This type of intervention is considered a risk management strategy and not necessarily an intervention to reduce the opportunity of error at the point of care. However, no dashboards were identified that can monitor the medication safety culture.

In contrast to interventions that are in the form of policies, these interventions are implemented as part of the standard operating procedures for the PICU when prescribing and administering medicines. Therefore, they are more likely to have a long lasting impact. For example specifying where prescribing should take place. Not allowing prescribing at the bedside would be ideal so that the prescriber is isolated from the busy clinical area. This will

enable prescribers to carefully check clinical resources and protocols. Also having a designated prescribing desk is useful to reduce interruptions and to move prescribing away from the busy nursing station. This is to enable better access to specific guidelines. An alternative approach is prescribing at bedside only. This will ensure no mixing up of patients and avoid the need for moving drug charts around the PICU. These interventions are often paired with a zero tolerance prescribing policy. This policy requires only senior staff to carry out prescribing in the PICU. This will minimise errors relating to knowledge such as choosing the right treatment with the right dose. This intervention was evaluated by the Booth, Sturgess, Taberner-Stokes, and Peters (2012) study which found a reduction of 44.5% of prescribing errors in PICU. These interventions can ensure safe prescribing in the PICU. In turn this can have an impact on administration errors.

Similarly, policies for medicine administration were identified in this study. It is interesting to find a policy that restricts when to administer medicines. Reducing administration of medicines at night when possible can reduce errors relating to factors such as night-time PICU condition, staffing level and availability of medicines. Also, this policy allows night-time nursing staff to focus on clinical duties. However, there must be careful consideration given to which medicines should not be administered at night. For example, antibiotics must not be omitted or delayed since a patient could develop sepsis. Other policies aimed to develop a culture of no harm by ensuring that the right patient is receiving the right medicine at the right time using the right dose and route. This is often supported by the no interruption policy which mandates that nurses must not be interrupted when preparing and administering medicines. In addition, a no punitive policy to enhance error reporting and learning from errors. However, this policy is questionable since it is not clear if reckless behaviour will be tolerated. If so, this may put patients at an increased risk of harm.

Other interventions that were found in this study are quality improvement tools. The Health Foundation (2013) explained that quality improvement is a tool that leads to change. Quality was defined in six dimensions: safe, effective, person-centred, timely, efficient, and equitable. Therefore, tools

were identified that introduced additional barriers in the system to ensure safe medicine practice. For instance, electronic prescribing was introduced in PICUs and the use of iPad based applications. These tools have the potential to reduce errors due to ambiguous handwritten prescriptions and dose instructions. It will also speed up the process of prescribing and allow a clinical pharmacist to check these prescriptions remotely. There have also been interventions that used electronic drug calculators for adjusting patient specific doses. These will reduce potential errors relating to pharmaceutical calculations. There is also a simpler intervention that redesigned the drug charts used. This intervention aimed to improve the presentation of the drug chart to make sure it provides clear instructions. Thus, allowing better clinical checking by both nurse and pharmacist.

Parallel quality improvement tools where used can make administration of medicine safer. This includes the use of an iPad-based application that provides electronically presented prescriptions. It can also allow the nurse to use a built-in drug calculator to aid pharmaceutical calculations. An alternative way to do this was by use of ready reckoners that can guide a dose depending on patient's weight. These tools can help in reducing dose errors. Another technological tool found is the use of smart infusion intravenous pumps. These are pumps with an integrated library of medicines programmed in compliance with the PICU prescribing protocols. This tool will alert the nurse if dose or rate entered falls out of the recommended limits. Nevertheless, it is important to note that it is possible new type of errors could emerge from these technologies. Also no bar code medicine administration intervention was identified. This could be due to the high cost associated with this type of technology.

A different approach to reduce administration errors is by the use of pre-filled syringes and use of standard infusion concentrations. Pre-filled syringes will ensure correct preparation of the medicine in an area away from distractions. Whereas the latter approach, involves changing the expression of medicine concentrations, hence making pharmaceutical calculations and preparation easier.

A frequent issue that is often associated with hindering the quality of medicine administration is interruptions. Therefore, red aprons or tabards were used to provide a visible indication for prescribers not to be interrupted. However, this approach lacked supporting evidence of its impact (Raban & Westbrook, 2013).

Additional interventions were also found to be supplementary to the medication administration process. This includes the need to review drug charts during handover. This could reduce communication errors that lead to administration errors and ensure continuity of care. Another intervention to ensure correct medicine is given is by means of a double check. A second nurse checks the prepared dose before administration by the first nurse. The first nurse usually talks through what has been done to the second nurse. However, this manner is prone to errors and it is likely that the decision making process by the second checker is influenced by the first. Hence, there was another intervention, which proposed that nurses must conduct this process of double-checking in silence. Additionally, to ensure that prescriptions were clinically suitable for the patient, a clinical pharmacist was introduced to the PICU. The presence of a specially trained PICU pharmacist can reduce prescribing errors and be a source of prompt guidance for medicine administration. Additionally, a pharmacist will act as a further barrier for unsafe practices.

The study also queried the impact of the interventions identified. The response was that most of the interventions were able to reduce medication errors in general such as by use of drug calculator, zero tolerance policy or handover drug chart review. Some helped to increase reporting as intended. It was interesting to find out that interventions to reduce interruptions were judged as not having much effect, this is a very similar finding as that by the systematic review of Raban and Westbrook (2013). Other interventions were either still under review or in an early stage of implementation. However, many of the responses were subjective and did not provide numerical supporting evidence. Therefore, responses may not be taken as a strong evidence of intervention impact but as a potential benefit indicator that needs to be studied thoroughly in the future research.

Additionally, participants were asked to identify challenges and barriers to the success of implementing these interventions. Reason's (1990) model of human errors was used to characterise these factors. They were classified into personal, systemic and cultural factors. The key highlight of these factors is that for an intervention to be success it is important to build a culture of safety. This can be achieved by developing a collaborative approach to learn from errors without pointing fingers and assigning blame to individuals. In return, there will be an increased openness and transparency and improved awareness of the seriousness of medication errors for patients and hospital care.

It is important to consider the findings of this study in light of its limitations. Firstly, the recruitment process was carried out through pharmacist and doctor-led groups but not nursing-led group. This may have led to under representation of nurse perspectives and input. Secondly, only one PICU took part from Scotland and none represented Northern Ireland. Thirdly, the content of the questionnaire did not collect data such as: if the interventions were delivered through research-focused programmes, the duration of intervention, or cost implications of the interventions. Fourthly, neither a patient's representative point of view nor the opinions of the intervention users were explored. This additional data could have provided more useful consideration for developing future interventions. Fifthly, the method did not address issues relating to intellectual property rights of interventions. This issue may have prevented some from sharing information.

Nonetheless, a future recommendation is to observe the various interventions in practice. This will lead to a better appraisal of use and impact. Moreover, seek users' opinions on these interventions. Additionally it would be of interest to explore medication administration error interventions used across Europe. This can lead to the development of evidence-based protocols for all the interventions for management of medication administration errors in PICU.

6.4.1 Conclusion

This study was able to identify 42 interventions used to reduce prescribing and administration errors in PICU across the UK. It was also able to identify challenges and barriers that hinder implementation of the interventions in practice. The study shed light on the importance of developing good medication safety practices that support a 'no blame culture' and enable learning from errors.

6.5 Study Contribution to Knowledge

1. Many of the interventions for administration errors are similar in nature to those used in prescribing errors. This includes: education and training, error reporting and monitoring, and no interruption policies.

2. Various interventions used nationally to reduce MAE in PICU practice that were not found in published literature such as: use of iPad based applications, information labels and cards, reducing night time medicine administration, pre-filled syringes, dose ready reckoners, handover chart review, and silent double checking. However, supporting evidence of intervention impact is limited.

3. The study identified factors that will influence the success of interventions in practice that were not known in literature. This includes: resistance from individuals to change, difficulties in adapting to the system, and blame culture.

Chapter 7: Safety Measures for Medicine Administration in Paediatric Intensive Care Unit

7.1 Introduction

It is evident now that the scale of MAE in PICU is large and complex. This was acknowledged following the series of studies that were carried out. Hospital MAE in children found in literature accounted for a mean of 50% of all reported medication error reports (n= 12552). It was also identified in a mean of 29% of all doses observed (n= 8894). This is consistent with the findings of the retrospective analysis of medication error incidents in PICU in this thesis as MAEs were found in 43% of all medication incidents (n= 412). Additionally, a total of 269 MAEs were observed in PICU medicine administration practice. This is represented as 32% per dose observed (n= 832) over 28 shifts. MAEs were mostly related to wrong dose, wrong infusion rate, preparation errors and time errors.

The findings suggest that multifaceted safety measures are required to tackle this problem since, there was a weak indication from the published literature that a single intervention would be enough. Additionally, the national survey of PICUs has demonstrated that multiple strategies and interventions to reduce MAE in practice are already being used.

This illustrates that MAEs are spread over a number of subtypes and processes. It is also affected by factors relating to the human factor (e.g. level of experience and interruptions) as well as the system (e.g. lighting during nightshifts and unfriendly pharmaceutical formulations). This was recognised following the retrospective review of patient safety incidents related to medication use. Additionally, prospective observation of the medication administration practice reached the same conclusion. Therefore, it is important to correlate the trends of MAE identified with the interventions

found in the literature and through the national survey of PICUs. This will lead to a recommendation of safety measures to reduce MAE.

The safety measures will aim to reduce MAE prevalence by 50% in accordance with the Secretary of State for Health's Sign Up to Safety Campaign (NHS England, 2014a). The campaign's target is to halve avoidable harm over three years. It is highly supported by the leadership and stakeholders of various health agencies. Additionally, this will also contribute to fulfilment of CQC and MSO responsibilities. Hence the aim of this study is to propose safety measures for MAE in PICUs based on the data found in this thesis and PICU practitioners' recommendations. The study objectives are as follows:

1. To characterise MAE contributory factors based on the opinions of PICU healthcare professionals.
2. To identify the nature of MAE intervention based on PICU healthcare professionals' recommendations.
3. To measure the level of usefulness of a preliminary set of safety measures.
4. To propose safety measures to reduce MAE in PICUs based on the overall findings of the thesis.

7.2 Method

7.2.1 Participants Recruitment

The participants were recruited to take part in this study by email. The PICU healthcare professionals at GOSH were contacted via the Lead Nurse and Clinical Lead Consultant independently. An email was sent to all the doctors and nurses containing a study invitation letter from the researcher (Appendix 13). The email also had a recommendation from both Leads to take part in the study. Moreover, the researcher sent out an email with an invitation letter (Appendix 14) to participants of the national survey study (Chapter 6) that wished to take part in related research.

The invitation letters introduced the purpose of this study, explaining the overall aims and objectives. It contained a URL link to the questionnaire to be self-completed on SurveyMonkey website. Participants were also informed that responses would be anonymised and that ethical approval was obtained for this questionnaire. Additionally, contact details for the researcher were given in case participants had any enquires or were not sure about a question.

7.2.2 Sample Size

The number of PICU healthcare professionals at GOSH is large and changes frequently. Thus, an opportunistic sampling method is chosen and response rate will not be calculated. However, the study in chapter 4 identified 23 participants willing to take part in related research. Therefore, the response rate for this cohort study is calculated by equation 7.1.

$$Response\ Rate = \frac{Number\ of\ responses}{Total\ number\ invited\ (23)} \times 100 \quad \text{Equation 7.1}$$

7.2.3 Preliminary Proposal of MAE Safety Measures

The researcher proposed preliminary safety measures in Table 7.1. This was in agreement with the findings of the other studies in this thesis. It also builds upon the findings of the systematic literature review. It may be noted that the six safety measures are focused on reducing dose, infusion rate and preparation errors during medicine administration. This is to reflect the trends identified in the retrospective and prospective studies.

These preliminary safety measures were included in a self-completed online questionnaire. This was to assess the perception, acceptability and usefulness by the end users. Additionally, opinions of other practitioners nationally in different PICUs were sought.

Table 7.1: Preliminary safety measures to reduce MAE in PICU

Preliminary Safety Measure	Target MAE
Centralised Intravenous Additive Service (CIVAS) for high risk drugs and drugs with difficult concentrations	Dose and Preparation Errors
Barcode medication administration technology combined with smart infusion pumps	Infusion Rate, Dose and Patient Mismatch Errors
Zero Tolerance Policy towards interruptions during administration	Dose, Preparation, Time and Omission Errors
Use of electronic calculator to help with preparation of dose e.g. calculate the actual volume needed to withdrawal, the amount of diluent and work out the rate of infusion	Dose, Infusion Rate and Preparation Errors
Extensive eLearning modules on medication administration process with demonstration videos	Dose, Infusion Rate and Preparation Errors
Step by Step flow chart easily accessible describing medication administration process and tips with pharmaceutical dose calculations for Intravenous medications	Dose, Infusion Rate and Preparation Errors

7.2.4 Questionnaire Development

The actual wording of the questions was developed in accordance with the objectives of this study. It was decided to have a short concise questionnaire. The participants were asked to describe the contributory factors of MAE, suggest methods to reduce MAE and give an assessment of the usefulness of the preliminary safety measures. The researcher developed a questionnaire consisting of a mix of open and closed questions in order to collect the following data:

1. Profession
    - Format: closed question
    - Response: objective single response tick box
    - Purpose: to identify if the respondent is a doctor, nurse or pharmacist.
2. Number of post registration experience in years
    - Format: open question
    - Response: objective single line free textbox
    - Purpose: to correlate responses with experience and profession.
3. Hospital Name (only for the external participants)
    - Format: open question
    - Response: objective single line free textbox
    - Purpose: to identify which PICU this response is from in order to calculate the response rate and follow up non-respondent PICUs.
4. Description of factors that lead to MAE in current practice
    - Format: open question

- Response: subjective multiple line free textbox
- Purpose: to collect the contributory factors of MAE perceived by the PICU healthcare professionals.

5. Description of method to reduce MAE in current practice
   - Format: open question
   - Response: subjective multiple line free textbox
   - Purpose: to identify safety measures of MAE perceived by the PICU healthcare professionals.
6. Rating the usefulness of the preliminary proposed safety interventions in section 7.2.3
   - Format: closed question
   - Response: subjective Likert scale
   - Purpose: This is a subjective rating in 6 point Likert scale (extremely useful, very useful, somewhat useful, not very useful, not useful at all and don't know). Responses will direct the final proposed safety measures.

The questionnaire also collected whether participants were interested in being informed of the overall study findings or taking part in related research. It also asked if they had any other comments regarding this study in order to allow them to express their thoughts.

7.2.5 Validity and Transferability

In order to measure whether the questionnaire is measuring what it supposed to be measuring, a construct validation was first carried out. A content validation process followed this. Two clinical pharmacy practice lecturers carried out a construct validation. They both have extensive experience in conducting this type of research. They were asked by the researcher to validate the questionnaire by checking that:

1. Questions asked reflect the aims and objectives of the study.
2. Questions are not ambiguous or have the potential to be misunderstood/misleading.
3. Questions are not double barrelled.
4. The overall structure of the questionnaire and wording of the questions is concise.
5. No problem of access to the questionnaire and navigation through the different sections of the questionnaire.

The research team assessed the extent to which the data collected addressed the aims and the objectives of this study. This content validation found that all the responses were relevant and suitable for the purpose of this study. The responses reflected that the questions asked were correct. The validated questionnaire is presented in appendix 15.

7.2.6 Credibility

There is no method available to check that the participant answers to the questions are truthful. However, this questionnaire was distributed to doctors, nurses and pharmacists that have PICU duties through a Clinical and Nursing Leads. Moreover, it was also sent to participants of a previous study that wished to take part in other research. Therefore, all the responses were judged to be truthful.

7.2.7 Reliability and Dependability

Reliability and dependability relates to the extent to which the findings of this study are reproducible and replicable. There is no measure to estimate that, but all tools used to carry out this study have been provided. This includes the codes used to analyse the data. However, the findings might be different depending on when the study is replicated as new development in medication administration practice is inevitable.

7.2.8 Pilot Study

It was decided not to carry out a pilot study for this survey since the sample size of the participants is small and if a pilot study were to be carried out, the responses would be excluded from the main findings. Thus, there is a risk of losing valuable data. Another concern of a pilot study is that it may introduce data contamination due to the fact that pilot participants will be included in the actual study, leading to participants providing different data when responding to the main study.

7.2.9 Data Analysis

Responses from each participant were collected on a web-based portal (SurveyMonkey). All responses were extracted into a Microsoft Excel 2010 (Microsoft, Redmond, Washington, US) worksheet to manage the data analysis process. Each question was analysed independently. Basic descriptive analysis was carried out. However, due to the nature of this questionnaire, complex inferential statistical analysis (e.g. Chi-Square or T-Test) was not performed. Moreover, the questionnaire did not have specific factors that could be used to test internal reliability and stability over time nor testing for generalisability. Since participants will always be changing and will not be traceable. A mixed analysis of themes and contents was conducted using Grounded Theory approach.

Grounded Theory concept by Glaser and Strauss (1967) was used to analyse the data in this study. Grounded Theory is an inductive approach used to reach phenomena from the data. This is the concept that is the most suitable approach for this study since there is a lack of a theoretical framework and this approach will act as a measure of conformability to ensure that the researcher's personal values or theories do not interfere in the conduct of this study and its findings (Strauss & Corbin, 1998). However, it is important not to ignore current literature to help with coding of the responses since Grounded Theory is not a presentation of raw data but a method of systematically analysing the data thematically. Another consideration is that this concept is not a method of content analysis that presents the findings in

a quantitative manner. However, content analysis was carried out to quantify the number of code repetitions to highlight the frequency of intervention used in practice across the UK.

The data was analysed by the researcher using Bryman (2012, p. 576) stages of qualitative analysis:

1. Responses for each question were read as a whole and highlight codes emerging.
2. Re-read of responses to label codes and emerging themes.
3. Systematic coding of responses.
4. Synthesis of major themes by connecting different codes together to help interpretation of the findings in relation to study objectives.

During thematic analysis, the researcher utilised Strauss's version of Grounded Theory that emphasises that analysis should be consistent with the current knowledge or literature (Charmaz, 2005, p. 509). This is approach that was taken since it is in line with the pragmatic thinking of the researcher. It also enables use of the terminologies found in the systematic literature review in chapter 3 of this thesis.

Moreover, Reason's (2000) model for error causation was used to map out the contributory factors of MAE. The model uses four domains for errors: organisational, error provoking conditions, supervision and unsafe acts. These domains are either as a result of an active failure or latent conditions. An active failure is a direct action taken that result in an error. Whereas, latent conditions are dormant factors in the system that when triggered will result in an error. Using this model to identify MAE causation as perceived by healthcare care professionals will lead to a better proposal of safety measures for MAE.

7.2.10 Proposal of Safety Measures for MAE

Triangulation of findings from the previous studies was carried out to propose safety measures. Moreover, the interventions identified by the systematic literature review and the national survey of PICUs were also used. Additionally, the outcomes of the questionnaire were taken into account to finalise the proposal.

7.2.11 Ethical Consideration

The questionnaire used in this study gathered information regarding the current practice around medication administration. This information is sensitive and can be misused. Therefore it was decided to anonymise all the findings. This will ensure that responses of specific PICUs cannot be recognised and extracted. The identity of the participants or other related information that could be used to identify them were not collected to encourage questionnaire uptake. However, only the names of the hospitals were used for the purpose of calculating response rate and demonstrating the participation spread nationally. Ethical approval was obtained from NHS REC to conduct this study as discussed in chapter 2.

7.3 Results

7.3.1 Demographics

The questionnaire was sent electronically for completion via SurveyMonkey ad attracted a good response rate. A total of 108 participants from GOSH completed the questionnaire. On average the participants had 8.7 years of experience (range 0.5–38 years). Participants who provided a description of contributory factors for MAE accounted for 61% (n= 66) of the respondents. Suggestions for MAE interventions were completed by 44% (n= 47) of the participants. Nurses provided the most responses. All participants rated the usefulness of the preliminary proposed safety measures. Table 7.2 presents the breakdown of the overall participants' demographics and rate of response.

Table 7.2 also illustrates the response rate by PICU healthcare professionals nationally. A total of 23 potential participants were identified. The participants who responded to the invitation accounted for 74% (n= 17). They represented 14 PICUs (50%) nationally. Amongst the participants they had a mean of 20.6 years of experience (10–38 years). The majority of the participants were PICU pharmacists (n= 12). All the participants provided descriptions of contributory factors for MAEs and possible MAE interventions. In addition, all the participants rated the usefulness of the preliminary proposed safety measures.

Overall, the questionnaire was completed by a total of 125 healthcare professionals (doctors= 45, nurses= 68, and pharmacists= 12). They have a mean of 10.3 years of post-registration experience (0.5 to 38 years). There were also a total of 83 responses of MAE contributory factors and 64 suggestions for MAE interventions. Moreover, all 125 PICU healthcare professionals rated the usefulness of the preliminary proposed MAE safety measures.

Table 7.2: Demographics data of MAE safety measures questionnaire

Characteristics	GOSH's PICU	National PICUs	Total
Number of responses	108	17	125
Doctor	42	3	45
Nurse	66	2	68
Pharmacist	0	12	12
Mean number of years post registration experience (range)	8.7 (0.5-38)	20.6 (10-38)	10.3 (0.5-38)
Doctor (range)	8.9 (1–24)	22 (20-24)	9.7 (1-24)
Nurse (range)	8.5 (0.5-38)	19 (14-24)	8.8 (0.5-24)
Pharmacist (range)	---	20.5 (11-38)	20.5 (11-38)
Number of responses to MAE contributory factors question	66	17	83
Doctor	22	3	25
Nurse	44	2	46
Pharmacist	---	12	12
Number of responses to MAE Interventions question	47	17	64
Doctor	19	3	22
Nurse	28	2	30
Pharmacist	---	12	12
Number of responses to preliminary safety measures question	108	17	125
Doctor	42	3	45
Nurse	66	2	68
Pharmacist	---	12	12

7.3.2 Contributory Factors for MAE

The questionnaire asked participants to describe contributory factors for MAE. Eighty-three (66%) participants completed this question. A thematic and content analysis using grounded theory approach was carried out on the responses. Table 7.3 presents the themes identified and their frequency of citation by the participants. A total of 28 themes were identified. The most frequent theme is distractions/distributions/interruptions (n= 35), followed by workload/pressure (n=20) and issues relating to pharmaceutical calculations (n= 10). The themes illustrate contributory factors relating to both systemic and human factors. Generally, the local and national responses are correlating. Table 7.4 presents the contributory factors against Reason's model of error management.

Table 7.3: Contributory factors for MAEs by PICU healthcare professionals

Contributory Factors	GOSH's PICU			National PICUs				Grand Total
	Doctor	Nurse	Total	Doctor	Nurse	Pharmacist	Total	
Distractions/ disturbance / Interruptions	10	18	28	1	3	3	7	35
Workload/Pressure	5	10	15	1	1	3	5	20
Pharmaceutical calculations	3	3	6	1	1	2	4	10
Availability of information/ resources	2	1	3			6	6	9
Fatigue/tiredness	1	7	8	1			1	9
Difficult doses/dilutions/ concentrations	1	4	5	1	1	2	4	9
Prescribing error	1	5	6			2	2	8
Time constraints	3	3	6	1		1	2	8
Access to information/resources	2		2	1	1	2	4	6
Patient's clinical condition	3	1	4			1	1	5
Lighting conditions	1	4	5					5
Staffing level	2	2	4			1	1	5
New staff members	2	2	4					4
Poor handwriting/style		2	2	2			2	4
Familiarity with PICU environment/drug/practice	2		2			1	1	3
Seniority/Authority	3		3					3
Carelessness/Personality	2	1	3					3
Double checking effectiveness	2		2			1	1	3
Knowledge deficits	2		2		1		1	3
Protocols/Resources complexity	2		2	1			1	3
Lack of paediatric experience		1	1		1		1	2
Lack of electronic calculations	2		2					2
Infusion pump set up errors		1	1			1	1	2
Multiple drug charts		1	1	1			1	2
Supporting other staff/ communication		1	1			1	1	2
No pre-prepared medications	1		1					1
Unauthorised administration	1		1					1
Lack of innovative solutions	1		1					1
Total	**54**	**67**	**121**	**11**	**9**	**27**	**47**	**168**

Table 7.4: Reason's model of error causation map against MAE contributory factors

Failure Pathway	Domain	MAE Contributory Factors
Active Failure	Unsafe Acts	Pharmaceutical calculations Prescribing error Poor handwriting/style Knowledge deficits Unauthorised administration Infusion pump set up errors
Latent Conditions	Organisational	Availability of information/resources Lack of electronic calculations Lack of innovative solutions Lighting conditions No pre-prepared medications Time constraints Seniority/Authority Protocols/Resources complexity Access to information/resources Multiple drug charts
	Error Provoking Conditions	Carelessness/Personality Difficult doses/dilutions/concentrations Distractions/ disturbance/Interruptions Familiarity with PICU environment/drug/practice Lack of paediatric experience New staff members Patient's clinical condition Staffing level Workload/Pressure
	Supervision	Double checking effectiveness Fatigue/tiredness Supporting other staff/communication

Reason's model in Table 7.4 illustrates that the majority of the contributory factors are of latent conditions (n= 22). However, it demonstrates that the contributory factors relating to human fallibility that is in the form of active failures or unsafe acts is minimum (n= 6).

7.3.3 Suggestions of MAE interventions by PICU healthcare professionals

Participants were also asked to describe interventions to reduce MAE in their practice. Sixty-four (51%) of the participants responded. Table 7.5 provides the themes of the interventions found in their responses. As can be seen, most of responses were relating to pre-prepared or standardised infusions (n= 16), following a method of reducing distraction, distribution and interruption (n= 15) and improving guidelines (n= 10). The responses also illustrate the need for implementing computer solutions to help to reduce MAEs (e.g. computer decision making support / electronic prescribing (n= 9)).

Table 7.5: Suggestions of MAE interventions by PICU healthcare professionals

MAE Interventions	GOSH's PICU			National PICUs				Grand Total
	Doctor	Nurse	Total	Doctor	Nurse	Pharmacist	Total	
Pre-prepared/ standardised infusions (1mg/mL)	4	2	6	2	1	7	10	16
Reduce distraction/ disturbance / interruption	2	8	10	2	2	1	5	15
Clearer/standardisation of guideline/monograph/ practice	3	1	4			6	6	10
Electronic access to information/resource	2	1	3		2	4	6	9
Improve double-checking	2	5	7		1	1	2	9
Computer decision making support /electronic prescribing	3		3	3		3	6	9
Age/weight banded doses/infusions	1	1	2				4	8
Better training/ simulation	3	2	5			3	3	8
More nursing staff		3	3			3	3	6
Increase pharmacy role/ support	1	1	2		1	1	2	4
Improve nurse's authority	1	2	3			1	1	4
Physical barrier/quiet area for preparation	1	1	2			2	2	4
Prescribe measureable doses		1	1	1		1	2	3
Error feedback	1		1		1		1	2
Doses with volume expression (i.e. mLs) on drug chart	1	1	2					2
Drug calculator aid	1		1			1	1	2
Reduce prescribing errors	1		1			1	1	2
Improve night time working		2	2					2
Reduce workload	1		1					1
Smart infusion pumps						1	1	1
Total	**28**	**31**	**59**	**8**	**8**	**36**	**56**	**115**

7.3.4 Usefulness of the preliminary proposed MAE safety measures

All the participants rated the usefulness of the six preliminary proposed safety measures for MAE. The findings of each safety measure are presented independently.

Centralised Intravenous Additive Service (CIVAS) for high risk drugs and drugs with difficult concentrations

This safety measure is aimed to help reduce dose and preparation errors. The responses in Figure 7.1 illustrate the usefulness of CIVAS for high-risk drugs and those with difficult concentrations as perceived by the participants. It is interesting to see that the majority of participants rated this either very useful (n= 53, 42%) or extremely useful (n= 62, 49%). This is also in line with the findings in the previous question. Moreover, none of the participants rated this safety measure as not useful at all.

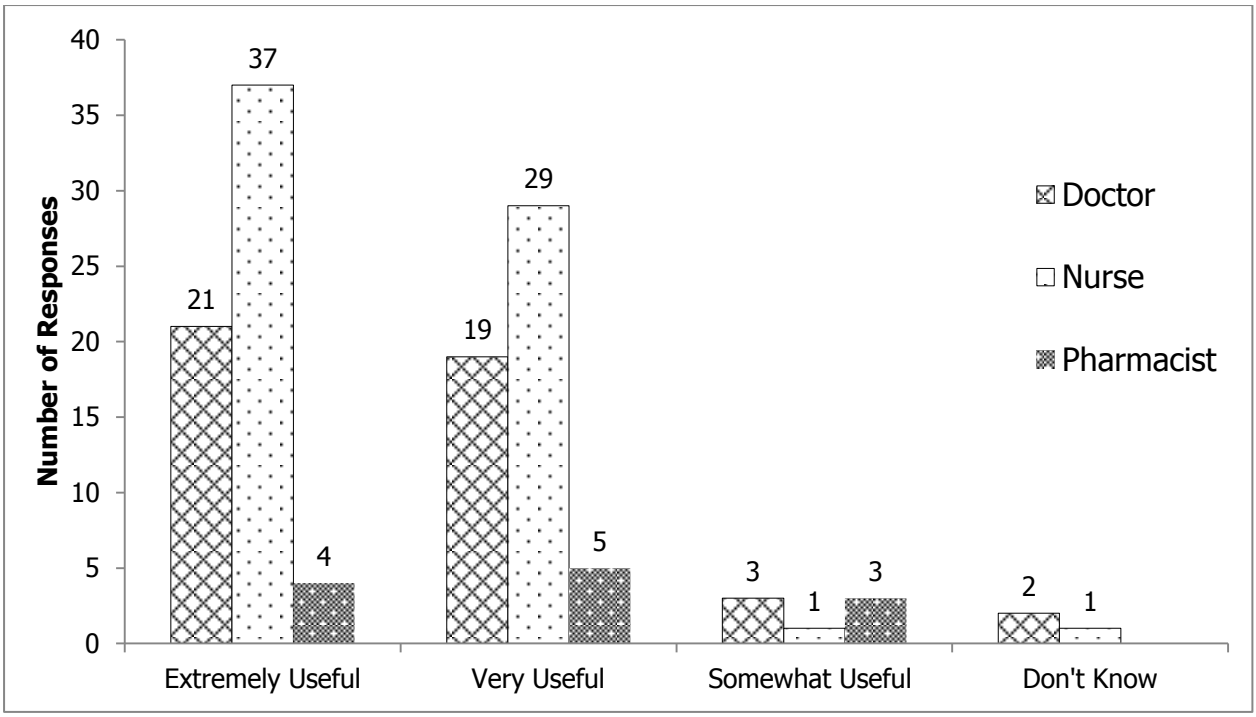

Figure 7.1: Usefulness of CIVAS as an MAE safety measure

Barcode medication administration technology combined with smart infusion pumps

This intervention is based on the implementation of barcode medicine administration with smart infusion pumps. This will ensure that the right patient is receiving the appropriate dose. A number of participants (n= 24, 19%) did not know if this would reduce MAE as presented in Figure 7.2. This is possibly due to not having had experience with this technology before. Only a small proportion of the participants perceived that this would be extremely useful n= 11, 8%). The mean response to this safety measure is that it would be somewhat useful (n= 34, 27%).

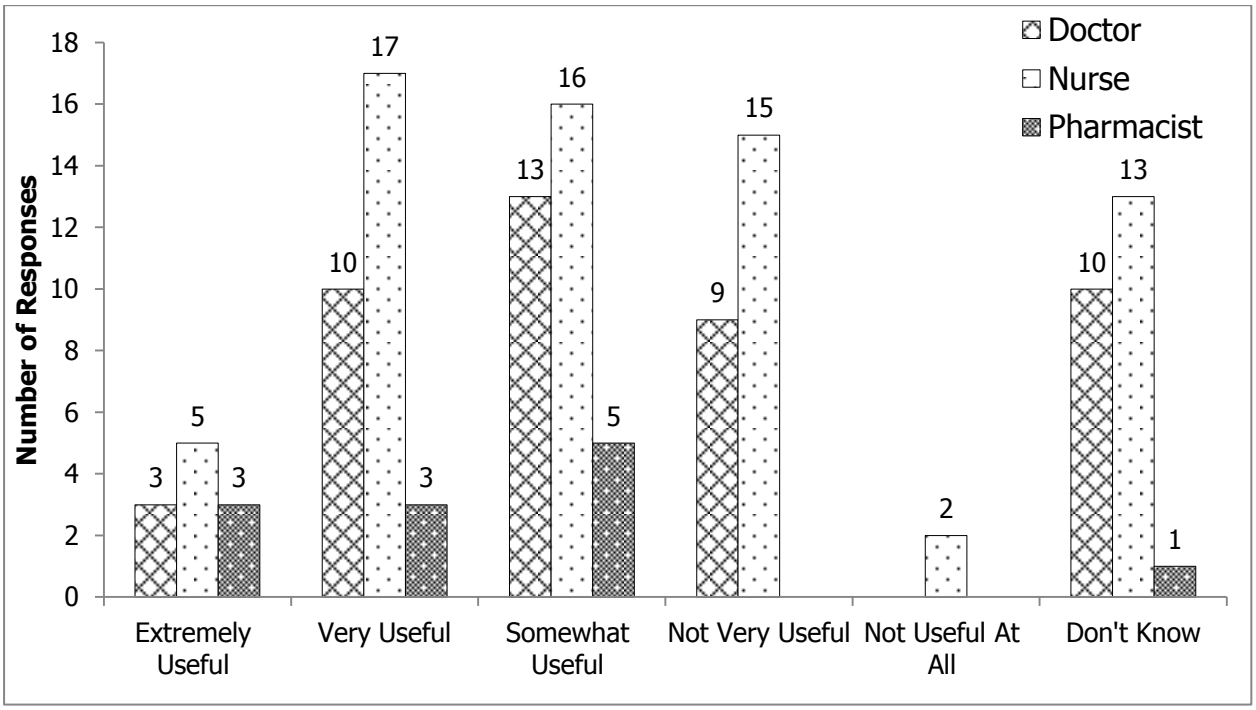

Figure 7.2: Usefulness of barcode medication administration and smart pumps as an MAE safety measure

Zero Tolerance Policy towards interruptions during administration

This safety measure involves implementing a zero tolerance policy towards interruptions. The responses to this safety measure by the participants were mostly extremely useful (n= 47, 37%) or very useful (n= 53, 42%). However, there were also uncertainties about its usefulness (n= 6, 4%). Nevertheless, the responses correlate with the findings of the previous question.

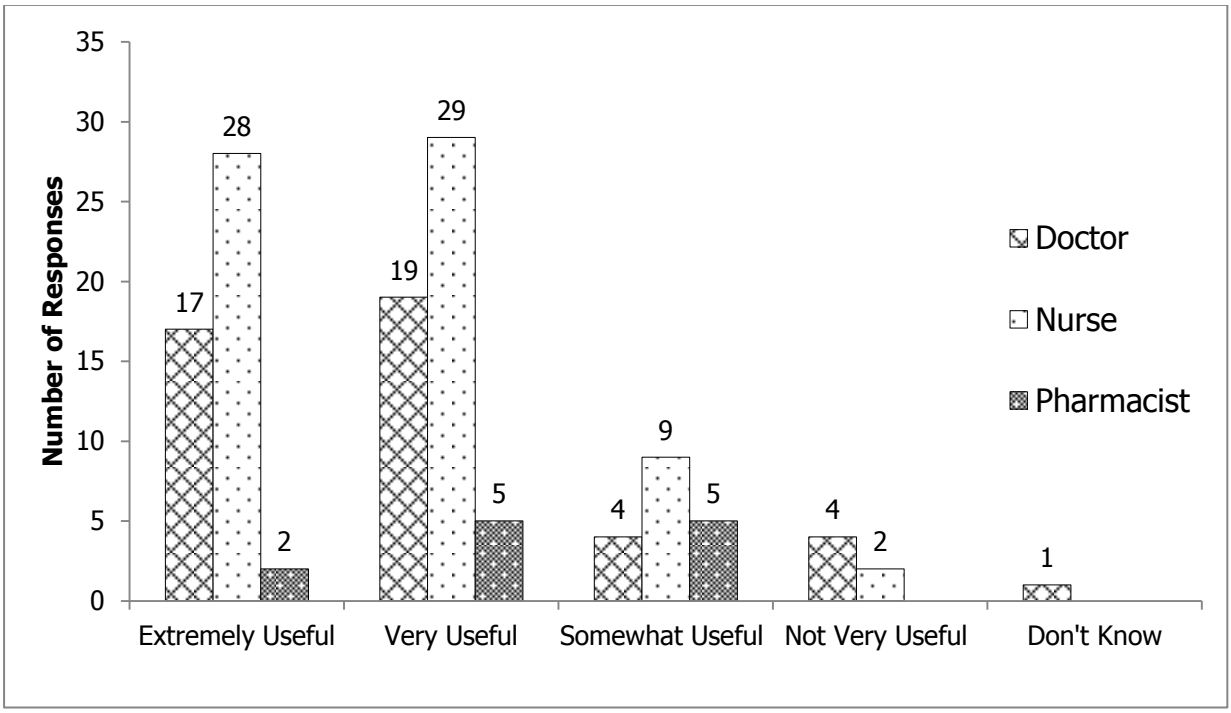

Figure 7.3: Usefulness of zero tolerance policy for interruptions as an MAE safety measure

Use of electronic calculator to help with preparation of dose e.g. calculate the actual volume needed to withdraw, the amount of diluent and work out the rate of infusion

Most of the participants found this type of safety measure for MAE as very useful (n= 57, 45%) as demonstrated in Figure 7.4. However, 8% (n= 11) finds this safety measure not very useful. It is interesting to note that the majority (n= 52, 76%) of the nurses who participated in this study found this safety measure to be either extremely useful or very useful in their practice.

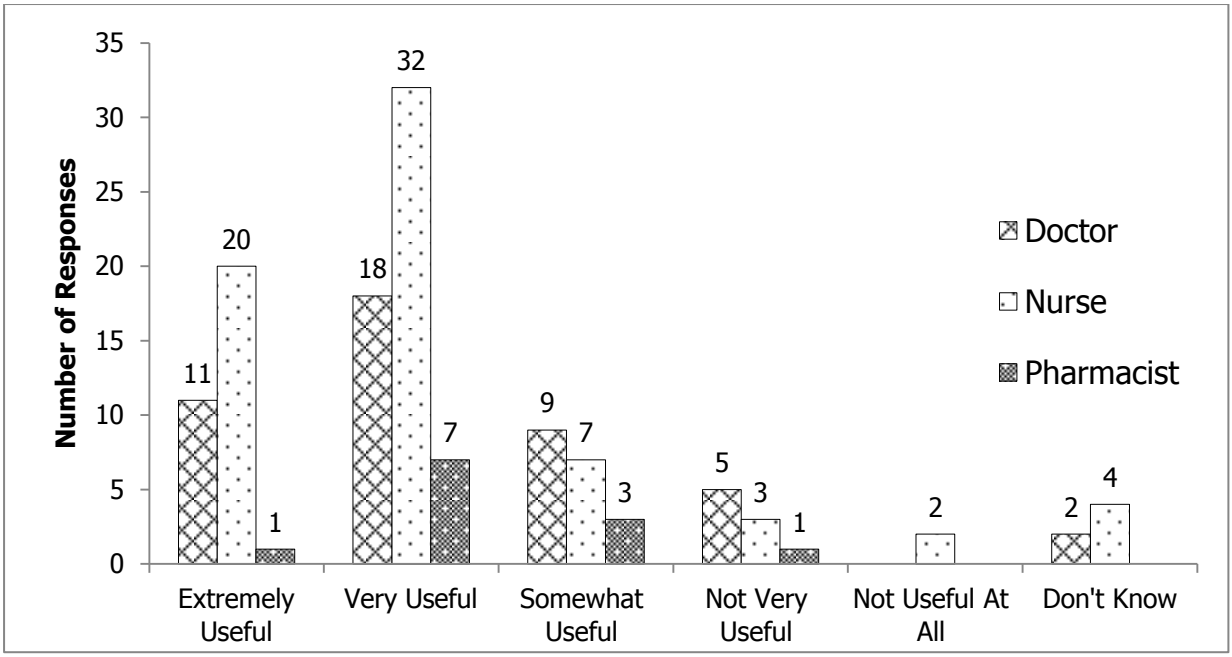

Figure 7.4: Usefulness of electronic calculators as an MAE safety measure

Extensive eLearning modules on the medication administration process with demonstration videos

The usefulness of this educational material to reduce MAE is weak. Since this is the only safety measure with a considerable response by participants (n=31, 24%) that it would either be not very useful or not useful at all in practice. However, 41% (n= 52) found it to be of some use.

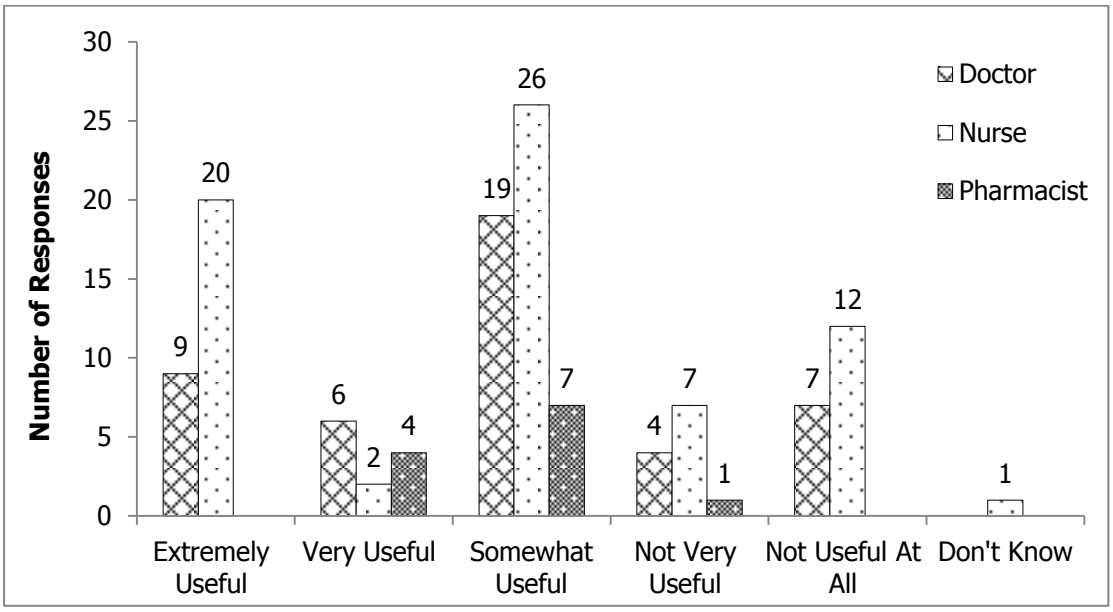

Figure 7.5: Usefulness of eLearning as an MAE safety measure

Step by Step flow chart easily accessible describing the medication administration process and tips with pharmaceutical dose calculations for intravenous medications

This safety measure is an attempt to standardise the practice of medicine administration. Most participants found this to be very useful (n= 53, 43%). This finding is in agreement with the previous question where participants expressed need for better standardisation of practice to reduce MAEs.

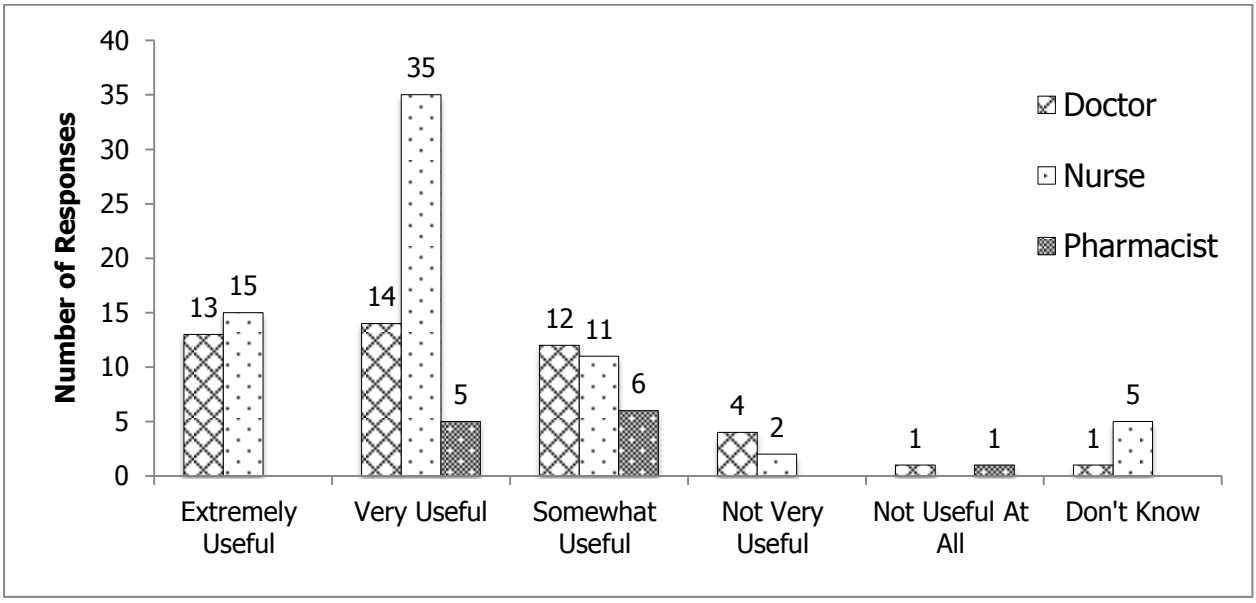

Figure 7.6: Usefulness of detailed flow chart as an MAE safety measure

Overall, the safety measure most rated to be extremely useful for reducing MAEs in practice was the use of CIVAS (n= 62) as presented in Figure 7.7. This was followed by a zero tolerance policy (ZTP) for interruption (n= 47) and use of computerised calculator to aid dose adjusting and infusion rate (n= 32).

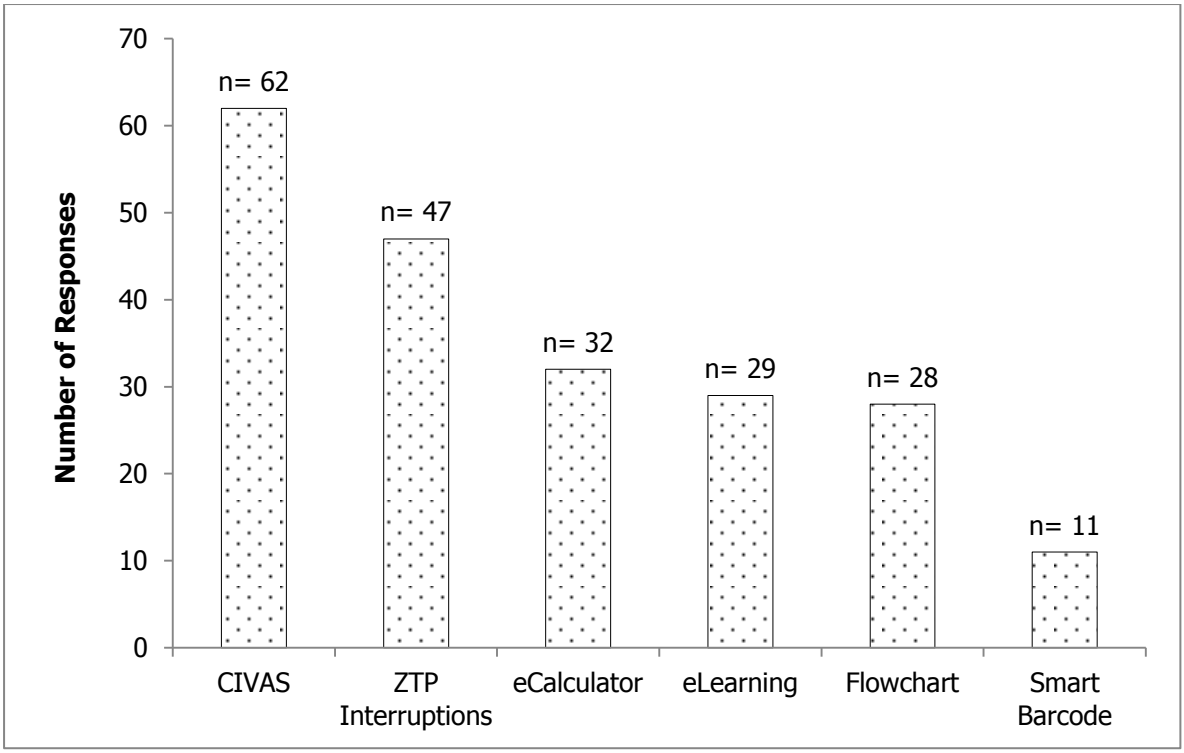

Figure 7.7: Participants rating of the preliminary proposed safety measures as extremely useful in practice in reducing MAE

7.3.5 Safety Measures for MAE

The following are the proposed safety measures based on the cumulative findings in this thesis:

1. Better lighting on preparation trolley and administration area.
2. Decision support tool with calculation aid, provide direct access to updated guidelines and learning materials.
3. Medicine administration checklist.
4. Pre-prepared infusions.
5. Standardise doses to age and weight bands.
6. Structured open dialogue double checking process.
7. Zero tolerance to interruption policy.

7.4 Discussion

The aim of this study was to propose safety measures to reduce MAEs in PICUs. A self-completed online questionnaire was developed to achieve this aim. The questionnaire collected the contributory factors for MAE as perceived by PICU healthcare professionals. The questionnaire also gathered suggestions for MAE interventions. Moreover, the participants were asked to rate the usefulness of preliminary safety measures proposed by the researcher. The participants were recruited through clinical and nursing Leads for a London-based PICU. Furthermore, the national survey in chapter 4 of this thesis identified a number of PICU healthcare professionals willing to participate in related research. They were invited to take part in this study too.

A good response rate was achieved by this questionnaire. In total, 125 PICU healthcare professionals took part in this study representing various PICUs across the UK. Cumulatively, 83 participants responded with contributory factors for MAE and 64 participants provided suggestions for MAE interventions. Moreover, the mean years of post-qualification experience was 10.3 years. This represents a good mixture of participants who are highly experienced as well as those with lower levels of experience. Therefore, this questionnaire has a good level of representation and generalisability.

Reason's model of error causation was applied to trace contributory factors of MAE. Reason's model argues that most errors are a result of latent conditions in the system. These latent conditions lead to errors triggered by an unsafe action. Meaning the system has pre-existing accidents waiting to happen. The findings of this suggest is in agreement with this argument since the contributory factors described by the participants mostly relate to latent conditions. Healthcare professionals identified factors that they feel are putting their practice at risk. Many of these latent conditions are opportunities for error remission. Moreover, the contributory factors causing MAE found in this study are in line with a recent system literature review by Keers et al. (2013a). The review examined all the MAE studies in hospital settings. Keers et al. (2013a) found that local working conditions profoundly affected the

prevalence of MAE. Therefore, an added strength of the findings is the consistency with current knowledge.

Contributory factors relating to active failures were viewed as a direct consequence of an unsafe act. This includes failure to perform pharmaceutical calculations to adjust suitable child doses or infusion rates and failure to intervene in a prescribing error before administration. These factors are considered to be slips and lapses since it is believed that the individuals administering are competent to carry out these duties. However, due to latent conditions they have failed to do so correctly. Other unsafe acts relate to violations of rules such as administration of unauthorised medicines and prescribers failing to order medicine clearly. It is difficult to determine if this is due to reckless behaviour or latent conditions. An additional unsafe act is knowledge based, this is the act of conducting a task without prior knowledge. Furthermore, unsafe acts can relate to failing to set up specific equipment correctly. Nevertheless, this can be attributed to a latent condition where the actual equipment is faulty and not the person setting it up. Little information is known regarding this new emerging type of MAE caused by equipment failure.

On the opposing failure pathway are the latent conditions that are contributing to MAE. As described earlier, these are conditions within the system or culture of the PICU that can lead to MAE. Healthcare professionals have identified a vast number of these worrying conditions. Many are relating to the organisational level. This includes failure to have adequate information or resources for healthcare professionals to consult or poor clarity and access to these resources. Additionally, lighting conditions during night shifts is a major risk factor. Especially as it is known that many of the labels/markings on vials are extremely small and can go down as low as font size 6 (e.g. Ranitidine). Poor lighting can also have an effect on performance and concentration. Moreover, lack of innovative solutions such as the introduction of iPad-based resources or computer-based drug calculators is also an organisational matter. Other examples include not using pre-prepared medicines or infusions. Another important matter is relating to seniority and authority of individuals, this is where a junior or less experienced individual is

afraid to question or raise a concern about the prescribed treatment. Also the time constraints placed by the organisation on individuals does introduce the risk of carelessness and rushing through tasks.

Latent conditions are also related to error provoking situations. These relate to the local culture of practice. The constant distractions, disturbances and interruptions are a common contributory factor. This is in the form of interruptions from other staff, patients' families and visitors and noise from bedside equipment. Also, the increased workload and pressure from peers is putting patients at risk. This is worsened by the understaffing level for this high risk area. Moreover, the experience level of staff and knowledge of local PICU practice is a key factor since medicine administration is a skill that requires both knowledge and practice. Also, prescribers are not taking into consideration the difficulty associated with small child doses. This results in problems during the administration process in adjusting the various concentrations to reach small doses. Furthermore, if these latent conditions are not tackled, carelessness among certain individuals will develop. It will become the norm to take risks unnoticed.

Another latent condition is the effectiveness of the double-checking process. It is now a must practice in every PICU to have a double-checking policy. However, it is not known how effectively that process is carried out. This was raised by a number of healthcare professionals. Also the level of support received by other staff was mentioned. Since, it is likely for patient’s acuity to be severe in this setting, support will be needed. However, workload and understaffing may hinder this. Hence, this will lead to staff fatigue and stress. All contribute to making a MAE.

The participants were also asked to describe what interventions they required to reduce MAE in their practice. A total of 64 (51%) participants responded with suggestions. This question was asked in order to propose safety measures based on the needs of the end users as well as on empirical evidence from this research. Most of the interventions described by the healthcare professionals were characterised previously in chapter 4 of this thesis. However, a key highlight is the need for standardisation of dosing in bands of age and weight. This will result in safer practice in terms of

preparation and administration since less pharmaceutical calculations will be needed. Also, standardisation of dosing will result in a more efficient administration practice since the same doses will be repeated among different patients hence improving their skill. Another suggestion that was not picked up previously is the improvement of night time working conditions. Lighting was a common issue, followed by fatigue and break allowance. Moreover, a strategy to improve the double checking process was identified. A more complicated suggestion is to increase staffing level in the PICU. As far as the researcher is aware, this is the first study that has identified improvement strategies to reduce MAEs based upon suggestions from front-line care providers.

The researcher also asked the participants to rate the usefulness of the preliminary proposed safety measures. These safety measures were developed upon examining the evidence of MAE found in this thesis. The first safety measure was to increase the use of pre-prepared infusions/CIVAS for high-risk medicines and for those with difficult concentration ratios. This was most rated as extremely useful (n= 62). This is not a surprising finding since it correlates with that fact that it will reduce workload, ease pressure and is the most commonly suggested intervention by the healthcare professionals themselves. The second safety measure that was found to be extremely useful is the introduction of a zero tolerance policy to interruptions (n= 47). This would be embedded into the standard practice procedures of the PICU. Breach of the policy should not be tolerated and actions should be taken against re-offenders. Once again this was expected since interruptions were identified as a major contributory factor to MAEs.

Other proposed preliminary safety measures related to adapting an electronic calculator, extensive eLearning material and a standardised flow-chart for the medication administration process. The participants found these to be mid to extremely useful safety measures. Additionally, once again these safety measures were correlating with the findings of the contributory factors and suggestions of MAE interventions. However, the least favourite safety measure was the use of the smart infusion pump combined with barcode medicine administration technology. A possible justification for this dislike is

that many professionals have no experience in using such methods of administration. Therefore, this explains the low rating of usefulness for this safety measure. Nevertheless, the overall findings of the preliminary proposed safety measures were positively correlating with the rest of the findings of this study and other chapters. This has strengthened the aim of proposing a set of safety measures to decrease prevalence of MAEs in PICUs.

As a result of the above findings and other evidence from: the systematic literature review, national survey of PICU interventions, retrospective review of patient safety incidents, and the prospective observation of the medication administration process. The following safety measures based on the evidence gathered are proposed to reduce MAE in PICU:

Better lighting on preparation trolley and in administration area

This is a basic safety measure to ensure that there is sufficient lighting for safe preparation and administration process. It applies to both day and night shifts. It was observed that during the night shift most of the lights in the PICU were dimmed. Whereas, during the day shift light is restricted due to bedside curtains blocking light. This will result in poor visibility for the safe preparation and administration of medicines. The advantage of this measure is that it is a relatively cheap method to reduce latent conditions for MAE. Especially, there is already a table lamp at each bedside that is not being used for this purpose.

However, there might be resistance from some individuals to taking up this safety measure. This simple method can also be adapted across other hospital settings since this extra light can improve the concentration of the person administering the medicine. No study has explored the effect of lighting on MAEs. Nevertheless, Buchanan, Barker, Gibson, Jiang, and Pearson (1991) presented the early findings of reducing dispensing errors in a pharmacy by having better lighting. The same principle should apply with MAE.

Decision support tool with calculation aid, provide direct access to updated guidelines and learning materials

This is becoming an increasingly required safety measure in medicine administration practice. It is common in practice that doctors, nurses and pharmacists use their personal smart phones to carry out calculations or to consult a clinical application. Examples include use of BNF and BMJ Best Practice mobile applications. Therefore, it is possible to have one application that puts together all the tools needed for safe administration. This application can include drug dose and infusion calculator, dilution help, access to guidelines and protocols and learning materials for help in the administration process. The advantage of this application is that it will ensure fast access to information at the point of care. It is reasonably simple to develop since many NHS hospitals now have access to platforms to develop these applications. This safety measure addresses the challenges faced by new healthcare professionals that are becoming more and more dependent on this type of technology. Also, this safety measure is adaptable to other hospital areas. An additional benefit of this safety measure is that it reduces the need for paper-based guidelines that are poorly designed. However, there are no studies that have evaluated the impact of such safety measures on the prevalence of MAE.

Medicine administration checklist

This is another simple safety measure that provides a step-by-step quick checklist for the preparation and administration processes. This would be in the form of a checklist. It will also include a calculation aid for dose adjustment and dilutions. The checklist would be placed on the preparation trolley and in the medicines room/cabinet. The checklist will need to be concise, clear and agreed by senior healthcare professionals. This is in order to ensure validity and accuracy. Moreover, the checklist can be printed into a material that illuminate in the dark. Additionally, this safety measure will provide a form of practice standardisation when preparing and administering medicines. It can also be adapted in other settings of hospital care. However, it would be difficult to measure if it is being used. Although, its impact is to be evaluated using direct observation or structured interviews/questionnaires methods.

Pre-prepared infusions

This is a more complicated safety measure to reduce MAEs. It requires wider adaption of CIVAS to cover all the mostly used therapeutic agents. This is challenging since it needs the development of an agreed business plan within the hospital pharmacy. However, it is easily implemented once the financial implications are cleared. Also, it can be evaluated using direct observation and retrospective analysis of incidents. If this safety measure proves effective for safety, it can be applied to other clinical areas.

Standardise doses to age and weight bands

This is a safety measure that is effecting prescribing as well the administration process. As is known, many therapeutic agents are prescribed using patient specific parameters such as weight. However, it is possible to band or group a range of such parameter into one dose. This is commonly used with some antibiotics. The advantage of this strategy is that it provides standardised doses for all healthcare professionals. This will lead to an easier clinical checking process for pharmacists and nurses. But it will also ensure that nurses are more familiar with dose adjustments across a wide range of patients. Hence, they would be building on knowledge and experience in medicine administration. Therefore, ensuring safety and lowering the chances of calculation errors across different medication processes. This safety measure already exists, but it requires adaption of a wider range of medicines. The development of this safety measure can be challenging since a consensus of dose bands between healthcare professionals is necessary. They would assess the therapeutic benefit against different indications. A classic example is that severe infections require double the usual dose. However, these challenges can be minimised by developing clear, well designed and accessible prescribing protocols and guidelines.

Structured open dialogue double checking process

Many of the errors identified in this thesis could have been prevented by using an effective double checking process before administration. It is now common practice to have a second person to double check. However, the effectiveness of that process is not clear. During the observation, it was

noticed that this process was not adequately utilised. It tends to be unstructured, quick and not focused on the actual process but was used for conversations outside the patient's care. This results in putting patients at risk due to ineffective double checking. In order to make use of this vital safety process, an open dialogue combined with a clear structure to maintain focus and ensure intervening in MAEs before these reach the patient. An open dialogue is chosen instead of silent double checking in order to maintain communication between the two individuals. Also it is evident that they will be communicating and a great resistance from staff is foreseen to the idea of silent double checking. This structured double checking can be implemented through a series of workshops during the monthly allocated times for learning and team briefing. It will require a long time and repeated cycles of education to ensure the effective implementation of this safety measure.

Zero tolerance to interruption policy

This is the most challenging safety measure to reduce the most claimed contributory factor of MAE as the systematic literature review found that there is a lack of evidence that supports the use of a visible indication for a healthcare professional not to be interrupted during administration. However, a culture change requires more than just a visible measure. Therefore, in order to enforce a culture that does not interrupt the administration process it is vitally important to reflect this in the standard operating procedures of the unit. It should be relayed that it would be unacceptable to interrupt anyone in the process of administering medicines. It would apply to all doctors, nurses, pharmacists and patient's visitors. It is important to have a strong nursing led no interruption stewardship in order to make this a success. Also, breaching of this no interruption rule should be treated seriously. This policy was successfully used for the prescribing process. Therefore, it is possible to adapt the same attitude for the administration process. This will also empower the nurse's authority and ensure less time is wasted on dealing with non-urgent requests.

In summary, a set of safety measures is proposed to tackle the multifaceted nature of MAE. To ensure safe administration practices in PICUs, age and weight based prescribing bands are recommended. This ensures that doses

and infusion rates are standardised and that there is less chance of calculation errors occurring before the administration process. Supported by a well-lit environment for both day and night shifts. Additionally, enable quick access to an electronic resource that aids calculations and contains guidelines. Increase the uptake of pre-prepared infusion medicines and a standardised approach to the double checking process. A medicine administration checklist and culture of interruption intolerance is needed.

Regardless of this study's fulfilment of the aims and objectives, a number of issues could have limited the data reached. First, the responses received by participants for the open-ended questions were mostly key terms and not detailed descriptions. Second, due to the first limitation the analysis was restricted to a characterisation of the responses rather than an exploration. Both could have been avoided by a better structuring of the questions. Thirdly, recruitment was opportunistic via email. The data synthesised would have been more generalisable if responses were collected directly from the healthcare professionals in person. This could have been done by the researcher being present in the PICUs and collected responses on an iPad. It would also have improved the response rate and the level of detail given in each response. Future research recommendation is to assess the feasibility of the proposed safety measures. This can be carried out by: 1) assessing suitability by medication safety experts, 2) implement in practice to evaluate impact on prevalence of MAE, 3) collect opinions of healthcare professionals subjected to these safety measures, and 4) explore the patient’s family's and visitor's perceptions of the implemented medicine administration safety measures.

7.4.1 Conclusion

This study was able to interest a large number of experienced PICU healthcare professionals locally and nationally. Many have provided MAE contributory factors and suggested methods to reduce it. It was found that interruptions, workload and pharmaceutical calculations are the most regularly identified MAE contributory factors. Also the majority of the contributory factors were of latent conditions that could lead to MAE. The participants mostly suggested that pre-prepared infusions, reduction of

interruptions and clear guidelines would lower MAE in their practice. The following safety measures were proposed: standardise dose by bands, improve lighting conditions, develop an electronic tool with a calculation aid and access to clinical resources, scale up the use of pre-prepared infusions, enhance the double checking process, adapt a medicine administration checklist, and enforce a culture intolerant to interruption. Future research includes the need to assess the feasibility of the proposed safety measures and implement them in practice.

7.5 Study Contribution to Knowledge

1. First study to explore contributing factors of MAE in PICU led by practitioners nationally regardless of making an error. MAE contributing factors were mostly related to: interruptions, workload and pharmaceutical calculations.

2. Reason's model for error causation used to characterise MAE contributing factors in PICU. It was found that most of the factors are latent conditions due to organisational level matters and error provoking conditions.

3. First study to identify the recommendation of PICU practitioners nationally for interventions to reduce MAE. Practitioners mostly suggested that: use of pre-prepared infusions, reduction of interruption and improving guidelines would lower MAE in their practice.

4. The following MAE safety measures are proposed in light of this study and the findings of the overall thesis: standardise dose by bands, improve lighting conditions, develop an electronic tool with a calculation aid and access to clinical resources, scale up the use of pre-prepared infusions, enhance the double checking process, adapt a medicine administration checklist, and enforce a culture intolerant to interruption.

Chapter 8: Overall Discussion

8.1 Introduction

Fortunately the majority of children grow healthily into adulthood without the need for serious medical attention. However, many require help and hospital support. It is estimated that 2.4 million children were hospitalised in 2012/2013 across England (Health & Social Care Information Centre, 2013). The vast majority of these admissions are believed to be cared for with the highest standards of quality. Moreover, some children require more intensive care under round the clock supervision of healthcare professionals. The PICANet reports a total of 60343 paediatric intensive care admissions (up to 16 years old) for the period between 2011 and 2013 across the UK. This represents a 4% increase in admissions (PICANet, 2014). The mortality rate in PICUs is very low since 96% of children were discharged alive for 2011 and 2013.

However, children that are in critical clinical areas are at a higher risk of being subjected to medication administration errors. This is due to the fact these children are bound to be receiving more frequent administrations of medications compared to other acute wards. They are more likely to require narrow therapeutic window medicines and intravenous infusions (Campino et al., 2009; Suresh et al., 2004).

Moreover, medicine administration in the PICU is not allocated to specific time slots. Hence, administration will be frequent at various times. This is an important issue, since there is the potential for administering medicines without clinical checks by a pharmacist. Also, due to the compromised health status of this cohort, they will be more prone to harm and deterioration in event of an error. This will also affect the rate of drug metabolism and excretion (Wilson et al., 1998). Additionally, PICUs are increasingly employing agency and bank staff to address the issue of shortages and it has been

highlighted that only 15% (n= 5) of PICUs met the national standard for level of nursing (7.01 whole time equivalent per critical care bed) in 2013. This is a huge risk since agency and bank staff will not necessary have the knowledge or skills needed for critical care. Furthermore, there is a risk of bringing in uncommon practices that are not routinely performed in certain PICUs or not part of the local procedures and protocols. Additionally, in the PICU it is a 1.5:1 nursing ratio therefore errors must be limited. Since children are in PICUs with life-threating conditions and require constant, close monitoring and support an error can lead to devastating consequences.

The thought of potentially harming children during their care in a hospital environmental is unacceptable and highly sensitive, especially taking into account the fact that the vast majority of potential harm is preventable. Of course this will cause great distress for the patient and their family, but it will also affect the confidence and trust in the healthcare system. Additionally, we cannot ignore the financial implications since patients have the right for compensation through the NHS Litigation Authority for acts of negligence. In turn this will lead to added pressures on healthcare providers. Therefore, it is important to make sure that this process is secured and physical as well as non-physical measures are in place to avoid errors in this process.

This area of research has been extensively studied across the globe. However, the direction of current research has been widely focused on measuring the incidence of MAE in children's hospitals. A limited number of interventional studies was carried out. The majority of these interventional studies tended to be developed and evaluated over a short period of time by the researchers. Therefore, they are not addressing the problem of MAEs realistically from a practice point of view but the research is rushed without taking into consideration the validity, creditability, feasibility and usefulness of these interventions. Hence, the impact of these interventions is questionable and also most of the research is intervening in MAE using a single method. Thus, the primary question for this research is what safety measures are needed to reduce MAEs in PICUs. In order to reach the answer to this research question, the following objectives were developed: 1) to review literature on MAEs in children's hospitals, 2) to characterise existing MAE

interventions used nationally in PICUs, 3) to investigate the nature of MAE in PICUs, and 4) to propose safety measures to reduce MAEs in PICUs.

A pragmatic research method was developed to measure the objectives above. The method was composed of five studies: 1) systematic literature review of MAE in children's hospitals, 2) retrospective analysis of patient safety incidents relating to medication use in PICUs, 3) prospective observation of medication administration practice in PICUs, 4) national survey of MAE interventions used in PICUs, and 5) survey of PICU healthcare professional's thoughts on causes and preventions of MAEs in PICUs.

8.2 Key Research Findings

The systematic literature review of MAE in children's hospitals illustrated the scale of the issue internationally. Although there are basic terminological differences between the definitions used for MAE, the main component of these definitions is the same. This shared component is describing that MAE is related to administration of a medicine deviating from the prescribed instructions or the standard procedures for administration. However, none of the studies recognised errors that related to other medicine processes such as prescribing and that were not intervened in before reaching the patient.

Additionally, the review study found retrospective and prospective methods to investigate hospital MAEs in children. Despite the heterogeneity, the review found cumulatively 12552 reported hospital medication error incidents, MAEs accounted for 50% (n= 6246). Whereas using a prospective method a total of 2537 MAEs (29%) were detected in 8894 dose observations. These findings demonstrate the scale of the problem when providing medicine to children in hospital. Yet data is lacking regarding the level of harm this is causing or the potential for harm. Furthermore, the interventions that were found did not provide enough evidence to support a full-scale impact on MAE. The review identified that MAE is of a multifaceted nature unlike the interventions.

However, the review identified a key gap in literature and that is the limited number of interventions in PICUs, although there have been a number of studies carried out in PICUs to quantify the scale of the problem. Additionally, no study was found that investigated the opinions of PICU healthcare

professionals into the causes of MAE or took their recommendations to improve their administration practice. As far as the researcher is aware, there are only two studies that were carried out in the UK that tried to reduce MAEs (Stewart et al., 2010; Warrick et al., 2011). Both studies did not actually address MAE in the PICU context. Stewart et al. (2010) investigated the use of education and simulation of the administration process with undergraduate nurse students. The study is of less application in real practice since it was carried out over a very short period of time. Also they did not follow up the students' performance in real time clinical situations. On the other hand, Warrick et al. (2011) utilised a clinical information system to provide support for doctors and nurses mainly. However, they only measured MAEs in terms of omitted doses. This is by no means a reflection of the true level of the problem in practice. Especially as they carried out the study in an emergency department where patients are likely to stay for a very short period of time. Hence many of the scheduled doses will have been missed because the patient would either have been discharged to another ward or sent back home. Therefore, there is a serious need for evidence based MAE safety measures in PICUs.

The second study in this research analysed the reported patient safety incidents in the PICU of a London based children hospital. A total of 1686 patient safety incident reports were analysed. Incidents relating to medications accounted for the most (35%). After further exclusion of reports, 412 incidents were specifically associated with the use of medicines. Medication administration incidents were the most reported (n= 176, 43%), followed by prescribing errors that were not intercepted (n= 141, 34%) and near miss incidents (n= 95, 23%). There were 12 incidents classified as severe harm.

The findings of the retrospective analysis were broadly in line with published literature found in the systematic literature review. However, as far the researcher is aware, this is the first study that has identified incidents due to failure in multiple medication processes. It also highlighted the role played by the PICU clinical pharmacist in identifying these incidents. More importantly, it further illustrates the complexity of MAEs and identifies areas for

improvement despite the low reporting rate. Therefore, this led to carrying out a prospective observation study to assess the overall practice of medicine administration.

Hence the third study observed 42 nurses administering 832 doses to 46 patients aged over 1 and under 16 during 28 shifts. It was possible to identify 269 MAEs. Therefore the incidence of MAE in this study is 32.3% of the doses observed which is consistent with the published literature. It was also found that increase in number of interruptions during medicine preparation and administration does correlate positively with increased risk of MAE ($r = 0.7$; $p < 0.5$).

The MAEs categorised into: wrong dose (n= 152, 56.5%), preparation (n= 50, 18.6%), wrong infusion rate (n= 26, 9.7%), wrong time (n= 25, 9.3%), omission (n= 11, 4.1%), and wrong formulation (n= 5, 1.9%). There were also six high-risk medicines that were associated with 56 MAEs cumulatively. In combination with the retrospective analysis study, it was clear that MAEs in PICUs require an intervention. However, both studies highlighted that MAEs are diverse in practice and need multiple interventions in order to reduce them fully. The interventions identified in the systematic literature review were limited and none were focused on the PICU context. Therefore, it was important to identify interventions used nationally in current PICU practices in order to find an evidence-based solution.

Thus, the fourth study aimed to characterise the interventions used in PICUs nationally to reduce medication errors and in particular administration errors. The survey attracted wide interest from 82% of the hospitals that offer PICU services in the UK. As a result, a number of interventions were identified for both prescribing (n= 21) and administration errors (n= 22). The characteristics of the interventions were broadly themed into:

- Education and Training
- Error Monitoring and Reporting
- Prescribing / Administration Policies
- Quality Improvement Tools

- Medication Chart Clinical and Double Checking

The key highlight of this survey is that it illustrates the complexity of dealing with MAEs in practice. It also strengthens the view that a single intervention would not be enough to minimise MAEs in PICU care. Moreover, the participants were asked to identify challenges and barriers for MAE interventions. Their responses were classified into personal, systemic and cultural factors. In summary, for an intervention to be a success it is fundamental to build a culture of safety and a supportive system. This can be achieved by developing a collaborative approach to learn from errors without pointing fingers and assigning blame. This leads to individuals being more open and transparent and improves awareness of the seriousness of medication errors in hospital care. But also the system needs to make the practice of medicine administration easier. This information was not available in the literature. This basic risk management strategy is not always practiced as the observation study found unsafe practices in the system such as: workload, use of child unfriendly formulations, and a constant culture of interruptions and distractions.

Furthermore, it was identified in the systematic literature review that there is a gap in knowledge relating to exploring MAE from PICU frontline staff's perspective. Consequently, a survey was developed to explore MAE contributory factors and reduction methods from their perspective. A total of 125 PICU healthcare professionals took part in this fifth study. Cumulatively, the mean years of post-qualification experience was 10.3 years. Reason's model of error causation was applied to trace contributory factors of MAE. The contributory factors described by the participants were mostly related to latent conditions. This includes failure to have adequate information or resources for healthcare professionals to consult or poor clarity and access to these resources. Additionally, lighting conditions during night shifts is a major risk factor. Other examples include not using pre-prepared medicines and infusions.

Other latent conditions that are error provoking were also found. The constant distractions, disturbances and interruptions are a common contributory factor. Also, increased workloads, low staffing levels and

pressure from peers is putting patients at risk. The effectiveness of double-checking was also questioned.

Contributory factors relating to active failures were also identified. This includes failure to perform pharmaceutical calculations to adjust suitable child doses or infusion rates. Other unsafe acts relate to violations of rules such as administration of unauthorised medicines and prescribers failing to order medicine clearly.

The participants were also asked to describe what interventions they required to reduce MAEs in their practice. A key highlight was the need for standardisation of dosing in bands of age and weight. Another suggestion was the improvement of night-time working conditions. Moreover, a strategy to improve the double-checking process was identified.

Overall, the findings of this survey justify the increasingly high rate of MAEs in PICUs as demonstrated by the retrospective and prospective studies. It further illustrates the need for changes to the system. Some changes are very challenging such as increasing the workforce. This is a national issue as it was mentioned earlier that only 15% of UK PICUs were able to achieve the standard of 7.01 whole time equivalent per critical care bed in 2013. However, there are other factors that can be feasibly changed. As a result of this study, the following safety measures are proposed to reduce MAEs in PICUs:

1. Better lighting on preparation trolley and administration area.
2. Decision support tool with calculation aid, provide direct access to updated guidelines and learning materials.
3. Medicine administration checklist.
4. Pre-prepared infusions.
5. Standardise doses to age and weight bands.
6. Structured open dialogue double checking process.
7. Zero tolerance to interruption policy.

The summary of the key findings of this research represent that the aims and objectives were fulfilled. Therefore, the above list of safety measures provides the answer to the research question based on evidence that was gathered from international, national and local perspectives using a valid research method that included healthcare professionals.

8.3 Research Contribution to Knowledge

Specific research contribution to knowledge was mentioned for each study chapter. However, the key contribution is that it was able to address the gap in literature in relation to PICU specific safety measures to reduce MAE. The research also assessed the potential for harm caused by these errors. It also involved PICU frontline staff in exploring the contributory factors of MAE and reduction strategies.

A major contribution to knowledge also includes evidence of errors that were not picked up before the administration process. This was not explored in any study that investigated MAEs in children's hospitals. The study argued that errors from other medication process such as prescribing not intervened during the administration processes should also be counted as MAE. Since hospital procedures require staff to conduct adequate clinical checks and not blindly administer medicine. This is also an interpretation of MAE definition that generally counts deviation from hospital procedures as MAE. This concept will add a new theoretical dimension to future research.

Furthermore, the method used for the prospective observation study was unique. It builds upon an existing approach developed by Ghaleb (2006). The method used utilised an MAE definition that was validated in a two-round Delphi expert consensus. However, the impact of this research is that it developed a strong methodological approach to identify MAE in practice. This research modified the method of observation practice and the data collection tool. The main modification to the method was that the researcher clinically reviews medication charts before observing the administration process. As far as the researcher is aware, this is the first study that takes this approach. The advantage of this approach is that it allows the observer to anticipate the administration process before it actually takes place. It provides the

opportunity to flag up any potential errors and to be able to be ready to intervene when needed. The second major modification is that the researcher developed an iPad data collection tool rather than the traditional paper-based form. There are many advantages to this, but mainly it can help to maximise the validity of the data since there will be no need for transcription. But it also helps to increase the sensitivity of the observation since less time will be wasted in documentation and therefore this increases the observer's focus.

The contribution of these modifications is that a valid and reliable method for MAE observations is developed. This is becoming increasingly vital since currently it is essential to have valid measurement tools for these types of errors as highlighted by the national patient safety priorities set by NHS England (2014d). This is also required for Quality Improvement programmes funded by the Health Foundation and the Department of Health. Researchers and practitioners can use this method along with the data collection tool. Therefore, providing a new data matrix that can be combined with the reported medication incidents to improve practice.

Another contribution to knowledge is that this research carried out the first national survey of interventions used in PICU to reduce medication errors. Many of these interventions were not known in literature. The results of the survey identified a number of good practices that are in place to reduce avoidable errors. The data generated is now part of a multimillion pounds Quality Improvement programme led by the Royal College for Paediatrics and Child Health. This programme is aiming to develop a one-stop resource for healthcare professionals. This initiative is called Paediatric Care Online. It involves a collaborative component for sharing good practices to improve delivery of medication care. Therefore, this research was able to have a practical input into a national level programme. Finally, a really important contribution to knowledge is that PICU healthcare professionals expressed their view on MAE contributing factors and reduction methods. The key point of this part of the research is that it did not focus on particular staff. Opinions were gathered from everyone and not just the ones that made an error. This adds strength to the study since it presents generalisable findings. Overall, this research was able to propose safety measures to reduce MAE from

different perspectives. The safety measures are also based on evidence gathered from numerous sources that are challenging.

8.4 Research Output

The research findings were presented at the following events:

1. Department of Pharmacy Research Seminar UH. Methodology development for medication administration error research: understanding the problem. March 2012
2. Department of Pharmacy Research Seminar UH. Medication administration in paediatric intensive care unit: Risky practice and solutions. April 2013
3. Health Services Research and Pharmacy Practice Conference. Systematic review: epidemiology, nature and interventions of hospital medication administration errors in paediatrics. May 2013
4. Child Health Research Conference. Interventions and tools used for Used for reduction of Prescribing and Administration Errors in UK & Ireland Paediatric Intensive Care Units. May 2013
5. European Society of Paediatric and Neonatal Intensive Care Annual Meeting. Retrospective analysis of medicine related critical incident reports in paediatric intensive care unit. June 2013
6. Department of Pharmacy Research Seminar UH. Observation of medication administration practice. January 2014
7. School of Life and Medical Sciences Research Conference. Retrospective analysis of medicine related critical incident reports in paediatric intensive care unit. April 2014
8. School of Life and Medical Sciences Research Conference. Interventions and tools used for Used for reduction of Prescribing and Administration Errors in UK & Ireland Paediatric Intensive Care Units. April 2014

9. Department of Pharmacy Research Showcase UH. Medication administration errors in children's hospital: problem that needs solving. June 2014

8.5 Research Limitations

It is important to consider the findings of this research in light of its limitations; the following are the key limitations of the research:

1. The systematic literature review of evidence was restricted to original research presented in English only. It would have been useful to explore non-English written data to identify other perspectives to the problem.

2. The national survey of interventions in PICUs for MAE did not seek to evaluate the true impact of these interventions. Neither did it explore the views of the actual users nor examine the cost effectiveness of the interventions.

3. It was not possible to explore the contributory factors or causes of the MAEs identified retrospectively from the patient safety incidents.

4. It was not possible to find out if a patient suffered any harm or discomfort as a result of the MAE identified during the prospective observation study. Additionally, it is unknown if the nurses observed were aware that they had made an MAE and if they learnt from that error.

5. The final survey of PICU healthcare professionals' questionnaire could have been structured better. The responses received were mostly in the form of key words rather than complete sentences.

8.6 Future Research

The following are the key recommendations for future research in this field:

1. Development of a validated guide based on expert consensus on investigational methods of MAE. This will help to reduce heterogeneity of findings and act as a resource for agreed definition, subtypes of MAE, and numerators/denominators used to represent prevalence of MAE.

2. Evaluation of the impact of the currently used interventions in practice that were identified by the national survey study. This will lead to a better appraisal of effectiveness. Moreover, seek users' opinions on these interventions. Additionally it would be of interest to explore MAE interventions used across Europe PICUs.

3. Carry out a thorough root cause analysis of specific MAEs such as wrong dose or wrong infusion rate. This will lead to a better understanding of the contributory factors and actual causes.

4. Assessment of medicine administration practice in children's hospitals by failure effect mode analysis. This will help to identify risky practices and potential consequences of errors.

5. Implementation of the proposed safety measures in practice. This should include an assessment process of impact and suitability. The findings of this study would provide evidence relating to the impact of multifaceted MAE safety measures.

8.7 Conclusion

Medicine administration in children's hospitals is a complex and risky process. Errors in this process can lead to serious consequences for healthcare providers and more importantly to the patient. Therefore, any mishap is unacceptable and measures should be in place to prevent it. Hence, a series of studies were carried out to propose safety measures for these errors.

A number of interventions were identified that can reduce administration error in practice. This was achieved by a thorough review of published literature and national survey of PICUs. Additionally, the challenges and barriers that hinder the success of these interventions were characterised. This was followed by a retrospective analysis of patient safety incidents and prospective observation of the administration practice.

It was found that a considerable number of patient safety incidents are occurring due to medication use in PICU. Reports relating to failures in administration process are the highest. Medicines that are high risk and those with narrow therapeutic windows are correlated with an increased risk of administration errors. Moreover, the observational study of medication administration practice found a high rate of errors in PICU. The overall findings of the observation study are comparable with the reported errors. Healthcare professionals identified interruptions, workload and calculations as the main contributory factors for administration errors.

Based on the overall findings of the various studies, the following safety measures are proposed to reduce administration errors: standardise dose by bands, improve lighting conditions, develop an electronic tool with calculation aid and access to clinical resources, scale up the use of pre-prepared infusions, enhance the double checking process, adapt a medicine administration checklist, and enforce a culture intolerant to interruption. Future research includes the need to assess the feasibility of the proposed safety measures and implement them in practice. So far, this is the first study of its kind to explore medication administration errors in PICU from different perspectives. It also included practitioners' points of view for improving the safety of medicine delivery in PICU.

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Appendix 1: NHS REC Approval

Health Research Authority

National Research Ethics Service

NRES Committee London - Bloomsbury
HRA NRES Centre Manchester
Barlow House 3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7815
Facsimile: 0161 625 7299

28 August 2012

Mr Ahmed Ameer
University of Hertfordshire
Hillside House
College Lane
AL10 9AB

Dear Mr Ameer

Study title: **Medication Administration Errors in Paediatric Intensive Care Unit**
REC reference: **12/LO/0621**

Thank you for your letter of 15 August 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Other conditions specified by the REC

1. Please amend the poster in the following manner:
    a. Please add the following sentence to the end of the first paragraph 'Ahmed will not be observing your child, just the nursing staff.'
    b. Please replace the word 'child' with 'child's' in the second paragraph so it reads 'The study will not be interfering with your child's current therapy,...'

2. Please check the Study Information Leaflet for the presence of typographical errors.

3. Please rewrite the first sentence of the fifth paragraph so it reads 'The observer will approach you before each observation to ensure it is at a convenient time for you and the patient.'

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

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

Document	*Version*	*Date*
Advertisement	Study Poster - Version 2	01 June 2012
Advertisement	Poster for families - Version 1	24 July 2012
Covering Letter		26 March 2012
Covering Letter		19 June 2012
Covering Letter		15 August 2012
Evidence of insurance or indemnity		02 August 2011
Investigator CV	Ahmed Ameer	
Letter from Sponsor		22 March 2012
Other: CV: Dr Maisoon Ghaleb		

Other: CV: Prof Soraya Dhillon		
Other: CV: Mark John Peter		
Other: CV: Rachelle Booth		
Other: CV: Alison Taberner-Stokes		
Other: Draft Study Invitation Letter	1	01 March 2012
Other: Survey Reply Form		
Other: Draft Survey	1	01 March 2012
Other: Draft Survey Follow-up Letter	1	01 March 2012
Other: Expert Panel Invitation Letter	1	01 March 2012
Other: Observation Schedule	1	01 June 2012
Other: Observation Form	2	10 May 2012
Participant Consent Form	2	01 June 2012
Participant Information Sheet	3	24 July 2012
Protocol		01 March 2012
REC application		28 March 2012
Response to Request for Further Information		04 July 2012
Response to Request for Further Information		15 August 2012
Summary/Synopsis	1	01 March 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/LO/0621	Please quote this number on all correspondence

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

Yours sincerely

Signed on behalf of:
Reverend James Linthicum
Vice-Chair

Email: ashley.totenhofer@northwest.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Dr Maisoon Ghaleb - University of Hertfordshire

Professor Soraya Dhillon - University of Hertfordshire

Mr Subhir Bedi - Joint GOSH/ICH Research & Development Office

John Senior – University of Hertfordshire

NRES Committee London - Bloomsbury

Attendance at Sub-Committee of the REC meeting on 28 August 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor Faith Gibson	Clinical Professor of Children and Young People's Cancer Care	Yes	
Reverend Jim Linthicum	Lay member, Hospital Chaplain	Yes	Vice-Chair

Appendix 2: NHS R&D GOSH Approval

UCL INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS Foundation Trust

Joint Research and Development Office
Division of Research and Innovation

Direct Line: 020 7905 2698
Email: Marice.Lunny@gosh.nhs.uk

12/12/2012

Dr Mark Peters
Reader in PICU
Great Ormond Street Hospital and Institute of Child Health
Great Ormond Street
London
WC1N3JH

Dear Dr Mark Peters

PROJECT TITLE	Medication Administration Errors in Paediatric Intensive Care Unit
Protocol version	1
Protocol date	1 March 2012
REC Reference	12/LO/0621
R&D Reference	12AR24
CSP Reference	N/A
Sponsor	University of Hertfordshire
Chief Investigator (CI)	Mr Ahmed Ameer

Notification of Great Ormond Street Hospital NHS Permission.

The research approval process for the above named study has been completed successfully. I am pleased to issue approval on behalf of Great Ormond Street Hospital for Children NHS Trust (GOSH) for the above study to proceed.

All research carried out within this Trust must be in accordance with the principles set out in the Research Governance Framework for Health and Social Care (April 2005, 2nd edition, Department of Health (DoH)).

This approval is issued on the basis of the project documentation submitted to date. The approval may be invalidated in the event that the terms and conditions of any research contract or agreement change significantly and while the new contract/agreement is negotiated.

The conditions for host site approval are as follows:

- The Principle Investigator (PI) must ensure compliance with protocol and advise the Joint R&D Office of any change(s) to the protocol. Failure of notification may affect host approval status.
- Under the terms of the Research Governance Framework (RGF), the PI is obliged to report any Serious Adverse Events (SAEs) to the Sponsor and the Joint R&D Office in line with the study

UCL INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS Foundation Trust

Joint Research and Development Office
Division of Research and Innovation

protocol and Sponsor requirements. Adverse Incidents (AEs) must also be reported in accordance with the Trust Adverse Incident Reporting Policy & Procedures.

- The PI must ensure appropriate procedures are in place to action urgent safety measures.
- The PI is responsible for the set up and maintenance of the Investigator Site File (ISF) generated to store all documentation relating to this project.
- The PI must ensure that all named staff are compliant with the Data Protection Act (DPA) 1998, Human Tissue Act (HTA) 2005, Mental Capacity Act (MCA) 2005 and all other applicable statutory guidance and legislation.
- The PI must allow monitoring and auditing by the Sponsor and the Joint R&D Office.
- The PI must report any cases of suspected research misconduct and fraud to the Joint R&D Office.
- The PI must provide an annual report to the Joint R&D Office for all research involving NHS patients, staff and/or resources. The PI must notify the Joint R&D Office of any presentations of such research at scientific or professional meetings, or on the event of papers being published and any direct or indirect impacts on patient care.

Failure to comply with the above conditions and regulations will result in the suspension of the research project.

Please contact the Joint R&D Office if you require any further guidance or information on any matter mentioned above. We wish you every success in your research.

Yours sincerely,

Marice Lunny

Marice Lunny
Senior Research Governance Manager
Joint Research and Development Office

cc: Dr Miasoon Ghaleb, Sponsor contact, University of Hertfordshire

Appendix 3: PICU Study Site Approval

Great Ormond Street Hospital for Children NHS Trust

Great Ormond Street
London WC1N 3JH

Tel: 020 7405 9200

24th February 2012

To whom it may concern,

Re: Project Protocol - Neonatal Intensive Care Unit / Paediatric Intensive Care Unit, Great Ormond Street Hospital

I hereby, as risk co-ordinator for PICU and NICU, authorise Ahmed Ameer, PhD student from the University of Hertfordshire to undertake the studies outlined in the project protocol in relation to Medication Administration Errors – observational, interventional and retrospective reviews.

Ahmed will be responsible for observing nursing staff working on the Neonatal and Paediatric Intensive Care Units, carrying out the preparation and subsequent administration of medications to the patients, at previously agreed times. At no point in the study will Ahmed interrupt the nursing staff, unless there is the potential for harm to the patient. Ahmed will notify the relevant personnel of their potential to harm the patient in a non-judgmental and tactful manner.

In agreement with all members of the research team, any member has the right to withdraw / suspend the study, if there has been harm caused to any patients.

Yours sincerely

Alison Taberner-Stokes
Sister / Risk Co-ordinator
PICU - Ext 8808

Appendix 4: Invitation Letter for National Survey of PICU Interventions

University of Hertfordshire
School of Life and Medical Sci
Department of Pharmacy
College Lane
Hatfield
AL10 9AB, UK
Tel: +44 (0)1707284248
Fax: +44 (0)1707284506
herts.ac.uk

6 November 2012

Dear Healthcare Professional

My name is Ahmed Ameer, I am a doctoral candidate at the Department of Pharmacy, University of Hertfordshire. I am investigating interventions and tools used in practice to reduce medication errors in paediatric intensive care units. I would like to invite you to participate in my research and complete an online survey in order to indentify the nature of the interventions used in the UK.

If you decide to participate please complete a short online survey at: tinyurl.com/surveypicu, the survey should not take you more than 10 minutes to complete. Participation is entirely voluntary and data obtained will be kept confidential. NHS ethical approval has been obtained from NRES London Bloomsbury committee to carry out this research.

The results of the study will be published or presented at meetings, but data will be kept anonymous. I will be grateful if you can also nominate any other individuals that you feel have been involved in putting the intervention at your practice. They can follow the same link above to complete the survey.

Thank you very much for your co-operation and participating in this study. If you have any query, you can contact me at 01707284248 or email A.1.Ameer@herts.ac.uk.

With kind regards

Ahmed Ameer

Ahmed Ameer MRPharmS
PhD Candidate

Appendix 5: PICU Medication Error Interventions Survey

Welcome to PICU Medication Error Interventions Survey. The purpose of this survey is to identify interventions and/or tools used to reduce medication errors in PICU.

All data collected in this survey will be anonymised and held securely. The Survey should take 5–10 minutes to complete.

Survey results and feedback will be reviewed within the University of Hertfordshire, Department of Pharmacy. Aggregate data may be retained to benchmark future surveys. This research has been approved by NRES London – Bloomsbury Committee (reference number is 12/LO/0621, Protocol V1).

If you have any questions, please contact Ahmed Ameer on A.1.Ameer@herts.ac.uk.

Thank you very much for completing this survey.

1. Please provide the name of hospital you are representing

Hospital Name ☐

2. Have you carried out an intervention to reduce any of the following at your PICU?

Prescribing Errors ☐Yes ☐No
Administration Errors ☐Yes ☐No

3. If yes, please describe the nature of intervention used?

Prescribing Errors

☐

Administration Errors

4. Have you carried out an audit before and after implementing the intervention?

☐ Yes ☐ No

5. If yes, what are the main outcomes of the audit, was the intervention able to reduce errors?

6. Can you please describe the challenges/barriers you have faced in implementing the intervention?

7. Would you like to participate in future research aiming to develop an intervention to reduce medication errors in PICU or be informed of this research outcome? If yes, please provide the following

Title	
Name	
Profession	
E-mail Address	

Hospital Name	
Job Title	

8. Do you have any other comments in regards to this survey?

Thank you very much for taking time to complete this survey.

Appendix 6: Raw Data of National Survey Responses to Key Questions

Response ID	Nature of intervention used for prescribing errors?
01	Zero tolerance policy – 2 years
02	Zero tolerance prescribing in place
03	ZTP – commenced in 2009 &on-going
04	Staff training, incident reviews: On-going
06	Doctors provided with pocket cards with all the drug infusion guidelines/doses on to help with prescribing
07	Zero tolerance prescribing desks – dedicated and interruptions not allowed for medical staff; no prescribing at end of bed
08	Pharmacist on rounds, feedback daily on errors, prescriber of the week, prescribing desk, no harm policy, induction teaching
09	Junior doctor induction tutorial, daily feedback from PICU pharmacist, Feedback at M&M
10	Redesigned medication chart, instituted distraction management techniques ("Zero Tolerance")
12	Regular feedback to prescribers
13	Induction training for junior doctors on the pitfalls of medical prescribing.
14	Development of an electronic, prescription form for resus drugs. Also implemented use of new drug chart that is aimed at reducing prescription errors.
15	Drug infusion calculator and zero tolerance policy
16	Increased reporting and development of rapid feedback to the prescriber; no blame culture; openness. Improve safety clauses on high risk prescribing in ICU – e.g. K check and K dose limits
17	Prescribing areas– approx 1yr (currently being specifically designed to ensure fit for purpose). Specifically designed questionnaires asking for specific detail of the incident (4yrs to current)
20	Production of labels with prescribing and administration information for a wide range of drugs. Production of a dose calculator for critical drugs
22	Time and motion study over a 3 month period
23	Day to day: on when required – MAX daily dose, antibiotic duration & indication (often), renal dose adjustments
24	Introductory talks to registrars as part of their rotational training
25	Many interventions including introduction of new prescriptions, training and education, standard infusion concentrations, ready-reckoners, emergency drug dose calculators etc
28	Dosing Errors
29	Prescribing at bedside & non-interruption whilst prescribing
30	GOSH Tool

Response ID	Nature of intervention used for prescribing errors?
31	New drug charts
32	PICU safety group have been overseeing RCAs and action plans on drug errors for 5 years
33	Zero tolerance regime, where all errors are documented and chase up.
34	iPad compatible prescribing programme being developed and introduced which produces prescribing stickers
35	Introduced electronic prescribing system
36	Dedicated prescribing area
37	Prescribing training pre job. Pharmacy reviews each prescription chart. Specific PICU training. Feedback tool and discussion post error
38	Prescribing trolleys to reduce interruptions. Incident reporting system. Review of prescribing errors regularly to learn through reflective practice. Prescribers may be required to write a reflective account regarding lessons learnt from prescribing errors.
39	Drug chart redesign; induction training session; on-going "power" sessions; twice yearly audit
40	Continuous intervention
41	Use of standard concentrations of infusions–Prescribing with standard labels
42	Training, human factors (prescribing area), tracking and reviewing with feedback all errors
43	Assisted in the implementation for prescribing areas, and been involved in discussions prior to this for effective actions to take
44	Feedback to the prescriber from Pharmacist and safety team usually as an email if there are any errors.
45	More guidelines writing, particularly unlicensed drugs where no information is provided in BNF. Reviewing procedures for outpatient prescribing.

Response ID	Nature of intervention used for medication administration errors?
3	Reduction of interruptions utilising high visibility disposable red tabards during the preparation & administration process of medications – audit of intervention three months – end 2010 – beginning 2011.
4	staff training, incident reviews: Ongoing
6	Smart IV pumps introduced to help reduce incidents relating to drug infusion administration
7	Silent double checking for nurses
8	redaprons, double check, no harm
9	Daily chart review by pharmacist, non-interruption policy
12	IV infusion rounds &no unnecessary drugs given overnight
14	Double-checking for all drugs. Planning to implement use of 'high-vis' tabards for nurses drawing up drugs, to reduce interruptions.
15	Zero tolerance policy
16	increased reporting and development of rapid feedback to the administrator; standardise algorithms for checking glucose (when on insulin) or K when on repeat dosing; red apron to prevent disturbances; reinforce 5 rights mentality/process; handover drug chart reviews
17	Using a red apron to identify nurses preparing & administering medications (approx 1yr to current). Specifically designed questionnaires asking for specific details of the incident (4yrs to current)
18	send out info for nurses to read then observe administration, ask questions etc
20	Labels as above + IV guidelines to help with information
22	time and motion study over a 3 month period
25	Many interventions including development of IV drug guidelines file, training. pre-filled syringes, ready-reckoners, rationalisation of drugs/formulations stocked etc
29	Red aprons & non interruption policy whilst administering
31	Avoiding handover times
32	PICU safety group have been overseeing RCAs and action plans on drug errors for 5 years
34	As above (iPAD compatible prescribing programme being developed and introduced which produces prescribing stickers), for many drugs, 'mls' of drug are calculated on prescribing. Also many administration drug guides
37	Critical incident forms with feedback. Non punitive approach. Drug rounds. CIVAS ivs where possible
38	All new nurses/staff returning from long term leave: basic and complex drug calculations, infusion devices competency assessments, 12 x administration of medication assessments. All staff: annual medications management update, complex drug calculations, IV update. Medication errors policy. Incident reporting system. Action plans and educational support for staff as required: decision made by Modern Matron
39	multiple training sessions; iv monographs; twice yearly audit; ongoing sessions
41	Use of standard concentrations of infusions
42	Training, human factors, tracking and reviewing with feedback all errors
43	Implemented the use of red aprons for all clinical staff drawing up/administrating

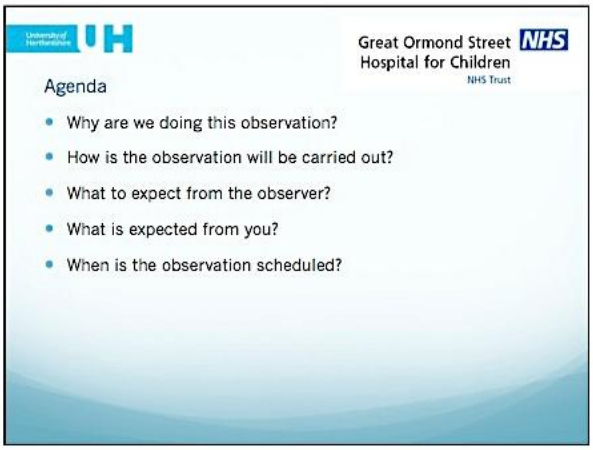
Response ID	Nature of intervention used for medication administration errors?
	medicines
44	Support and retraining.
45	More protocols stating usual practice for nurses to follow. Reviewing stock levels and trying to keep to just one strength.
46	Monthly documents on drug groups, aimed at nursing staff including info on dosing, administration and compatibility

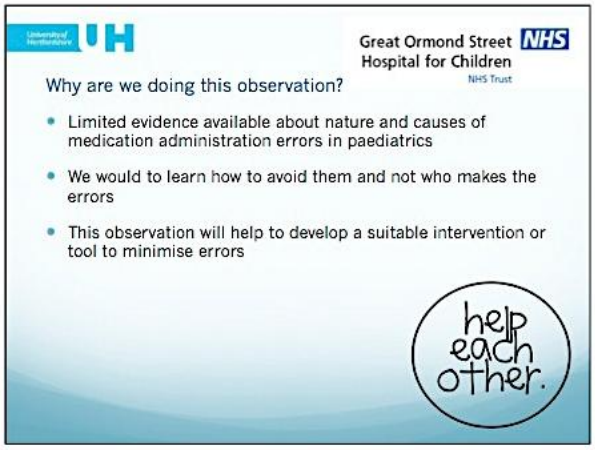
Response ID	Main outcomes of the audit
1	Significant reduction in prescription errors from 45 to 15 %
2	Implementation in its infancy, initial data would suggest more errors are spotted and corrected before reaching the patient.
3	Interruptions continued irrespective of a change in practice during the three month audit process. 100% compliance, demonstrated "buy in" by nursing staff.
4	Not specifically, again Audit is ongoing and continuous
7	Prescribing errors reduced from 1 per occupied bed day to 0.3 per occupied bed day.
8	Interventions reduced errors
15	Audited use of drug calculator (excel program) 2006–7 before and after implementation. Showed reduction in actual errors and near miss events
16	Ongoing reporting. Severity of incidents falling, reporting of incidents increasing – interpreted as a better culture
17	Continuous audit of medication incidents – causes, contributing factors etc. There has been a downward trend in severity of incident reported
18	Showed good knowledge but currently working on change in attitude as to why sometimes cut corners and don't follow policy properly. Improvement initially but now need to re-educate as problems again
20	Errors were reduced following the intervention although not all the improvement was maintained on re-audit.
22	Medication errors reduced
23	Antibiotic audits are carried out monthly in respect to indication and duration ... still not 100% Could install a trigger on electronic prescribing system Change of incident reporting NOW online and daily check possible, therefore also immediate follow-up In respect to administration: Need to write more specific guidance – in respect of too big patients – tube / routes NJ, OG, PEG.
25	Not with all the administration interventions but we undertake monthly audits of prescribing errors
29	Pre audit, post not completed
32	Errors reduced.
34	Waiting to re-audit following introduction of prescribing programme
35	Intervention (e-prescribing) only live very recently – data to be collected and then audited
36	in progress
37	All results not available, pharmacy keep an eye on all errors, plus we use our own critical incident forms to look at such incidents.
38	Planning audit in 2013
39	being rushed and busy leads to errors – take your time and step back – training includes increase self and situational awareness – take that step back
41	Yes, no errors detected in 3 years post implementation. Only 2 errors with miss-selection of infusions
42	Yes
45	We have only done an initial audit, we need to re-audit in one year, but interventions look to be making a difference.

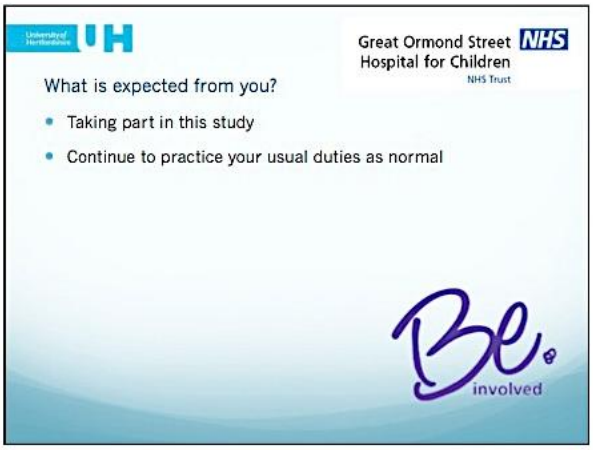
Response ID	Can you please describe the challenges/barriers you have faced in implementing the intervention?
2	Nursing staff attitude towards checking the drug chart. Doctors unwilling to use the dedicated prescribing area, Nurses having their opinion on what is and is not an error (i.e. abbreviations NaCl)
3	Poor "buy in" from members of the MDT. Additional support required from parents & visitors for the success of a change in practice. Disposable high visibility drug tabards alone are not enough to reduce / eradicate interruptions during the drug administration process.
4	Getting staff to participate in the training. Avoiding the 'blame culture'
6	Pocket dose cards very favorably received. Smart pumps received well by nursing staff but has highlighted the need for a 2nd check regarding the information entered into the pumps as some errors have occurred due to human error in data entry into the pump.
7	Sticking to the guidelines and strictly no prescribing at end of bed on ward round and no speaking to prescribers policy all took getting used to
8	lack of motivation and momentum after initial push
10	Unit culture and acuity
12	reluctance from nursing staff to change the way things are done and doctors not taking med errors seriously
15	Cultural – implementing same calculator on three different PICU wards at the time all with different practices. Zero tolerance policy – easier to implement but have not audited to show effect
16	large workforce; difficulty in information distribution and reinforcement; time constraints; availability of space
17	take of staff – poor if it is not easy for them to do the right thing.
18	need nursing staff to be fully on-board. Good team of nurse educators here who led it.
20	Initial resistance to using labels but the greater problem is maintaining the system and ensuring there is administrative staff to print as needed
21	lack of time and staff
23	– time – limitations of the software
24	Challenge: getting registrars to note that as they will now do the majority of the prescribing it is important to acknowledge common mistakes.
25	Errors on PICU are so multi-faceted that it is very difficult to identify whether the changes made have contributed to preventing further errors or not
29	Ensuring staff adherence to rules!
32	Large intensive care unit–communications
33	Upsetting staff as all errors and near misses are recorded. Problems with feedback to the staff on the ground floor.

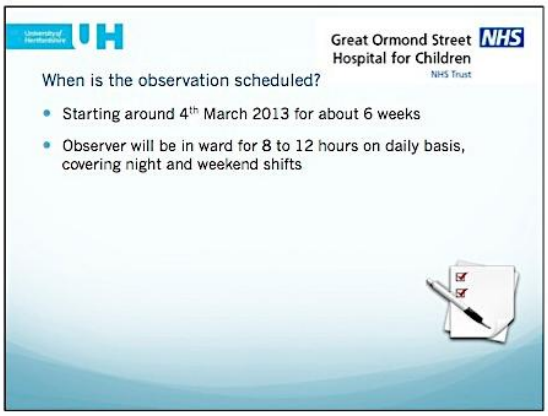
Response ID	Can you please describe the challenges/barriers you have faced in implementing the intervention?
35	Huge project! not designed (other than in minor ways) for paediatrics so huge amount of labor intensive customisation of system required. Major lack of resources for implementation of system, in particular the drug file.
36	people not adhering to non interruption rule
39	acceptance that there is a problem; that they can fall into the traps; drive for more "efficiency" and that being interpreted as speed
41	Many, manufacturing of infusions, design of labels of syringes, prescribing protocols and labels, training of nurses programming of pumps, storage of products and labelling of syringes
42	people felt threatened at first now they help to develop the solution to prevent it happening again
43	Large amount of work force to implement the action, Resistance for change, Communication, Lack of time/patient workload
45	The amount of nurses working on PICU and their shift patterns. The MDT nature of some errors and trying to close all the loop holes in the process (swiss cheese model).
46	Nursing staff shortages, pharmacy staff shortages – I went on maternity leave and the work was not continued in my absence as there was no senior pharmacist cover.

Appendix 7: Observation Study Introductory Presentation

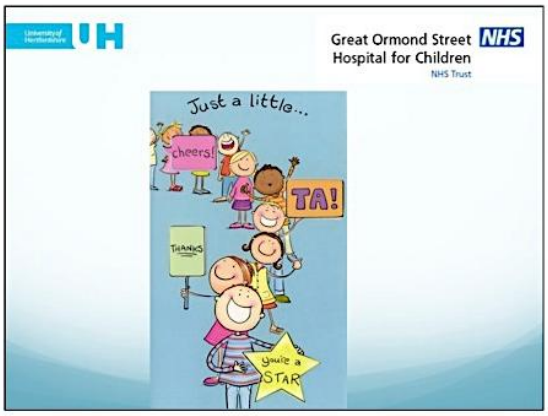







Great Ormond Street Hospital for Children NHS Trust
When is the observation scheduled?
Starting around 4th March 2013 for about 6 weeks
Observer will be in ward for 8 to 12 hours on daily basis, covering night and weekend shifts


Great Ormond Street Hospital for Children NHS Trust
Approvals
Study has been approved by:
NHS Research Ethics Committee – London Bloomsbury (Ref: 12/LO/0621)
GOSH Research & Development Office (Ref: 12AR24)
GOSH PICU Risk Management Team
APPROVED


Great Ormond Street Hospital for Children NHS Trust
Just a little...
cheers!
TA!
THANKS
you're a STAR

Appendix 8: Observation Study Information Sheet

Study Information Leaflet – Version 3 – 24th July 2012

Study Information Leaflet: A Study to Identify Errors in Medication Administration!!!

The aim of the study

The aim of this study is to identify potential medication administration errors that occur in children and to identify their causes, so we can learn how to avoid them. We are not interested in who makes the mistake, just what they are, why they happened, and how we can stop them from happening again.

Why is the study being done?

Limited literature has suggested that medication administration errors may be common in paediatrics and may cause severe harm. We want to understand the nature and the causes of medication administration errors in children. We look beyond blaming individuals for the occurrences of these errors. This will aid in the development of strategies that will help and reduce medication administration errors in this patient group.

Why have you been chosen?

We are asking all healthcare professionals who prepare and administer medicines to help in conducting this study. This study has been approved by NHS Research Ethics and GOSH R&D committees. An approval has also been taken from the ward risk management team.

How is the study being done?

The study will be carried out during your routine work of preparing and administering medicines. The researcher would like to observe this process and will record information about how the drugs are prepared and administered. Our research group has used this method to observe drug rounds in other adult hospitals.

The observer will approach you to take permission prior to each observation in order to check that the observation will be carried out at a suitable time for you and your patient. If you agree, the observer will inform you of what would be carried out during the observation and what information will be recorded. Observation will be carried out routinely during both day and night shifts. The observation schedule will be given to the Nurse in charge.

The observation will be unobtrusive and the researcher will not interfere with patient care or your usual ward routine in any way. The observations will be done during most drug administration rounds. The observation will be documented into a standardised form, the form will record details of medication prescribed, prepared and administered to the patient, also patient's hospital number, age, sex and weight.

The observer will review patient medication chart before administration. Observer will only review patient's medication charts if you have consented for the observation.

Due to the fact that at the PICU medication administration time slot is patient specific unlike other wards where there are specific time slots for administrations, the observation will be carried out in an opportunistic manner, meaning the researcher will be present on PICU at most medicine administration rounds and observe medication administration only if you have agreed and consented for the observation.

If a mistake has occurred, a doctor might have to be contacted if an action is required but it will remain anonymous. We will, of course, intervene to stop any patient harm, in the unlikely event that this is necessary. Any such interventions will be made in an unobtrusive manner.

The researcher will deliver a study presentation in order to clarify any queries you may have and an informed consent will be taken if you wish to participate, prior to observation the researcher will also take a verbal consent from you. If you have missed the presentation the researcher can explain the study to you personally before taking an informed consent.

What are the potential benefits?

Currently little is known about medication administration in paediatric in intensive care unit currently. This study will allow the detection of possible risk factors and good practices in medication administration to children, therefore making medication administration safer.

Who will have access to the research records?

Only the study team will have access to the records kept in this study. The use of some types of personal data is safeguarded by the Data Protection Act 1998 (DPA). The DPA places an obligation on those who record or use personal information, but also gives rights to people about whom information is held. If you have questions about data protection, contact the Data Protection Officer via the switchboard on 0207 405 9200 extension 5217.

Do I have to take part in this study?

No. your participation in the study is entirely voluntary and it is your right to decide whether or not to take part. The researcher will ask you at the beginning of each drug round whether you are happy to be observed as part of the study. If you would prefer not to be included in the study, please let him know.

Who do I speak to if I have further question or worries?

Please contact Mr Ahmed Ameer, who is responsible for this study. You can contact him either by phone 0170 728 4248 or by email on A.1.Ameer@herts.ac.uk. Alternatively, you can contact Dr Mark Peters on Mark.Peters@gosh.nhs.uk.

Mr Ahmed Ameer **Dr Maisoon Ghaleb** **Professor Soraya Dhillon**
University of Hertfordshire, School of Pharmacy, Hillside House, College Lane, AL10 9AB

Dr Mark Peters **Ms Rachelle Booth** **Ms Alison Taberner-Stokes**
PICU 4th Floor, GOSH, Great Ormond Street, London, WC1N 3JH

Appendix 9: Observation Study Consent Form

Consent Form – Version 2 – 1st June 2012

Consent Form

Study Number:

Participant Identification Number:

Title of project: Medication Administration Errors in Paediatric Intensive Care Unit

Name of Researcher:----------

Please tick if you agree:

1. I confirm that I have read and understood the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected ☐
3. I agree to take part in this study ☐

Print Name:----------

Date: dd/mm/yyyy

Signature:----------
(By participant)

Print Name:----------
(Person taking consent)

When completed: 1 for participant; 1 for researcher; 1 (original) for researcher site file

Appendix 10: Observation Study Posters

Study Poster – Version 2 – 1st June 2012

University of Hertfordshire UH

Great Ormond Street Hospital for Children NHS Trust

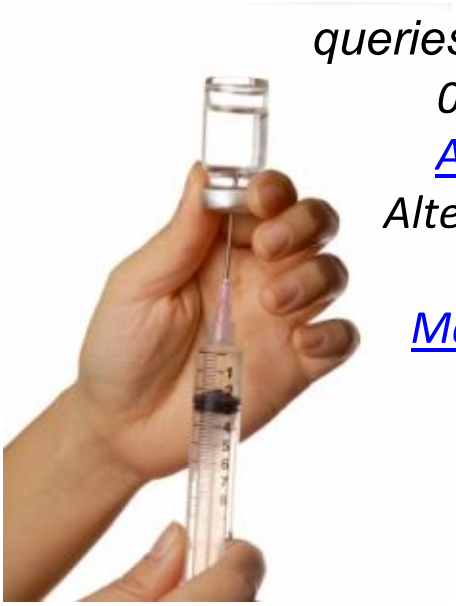
A Study on Medicines Preparation & Administration

We would like to invite you to take part in an observation study aimed to make medication administration safer in children

Study presentation will be given on [DATE] at [TIME] in [ROOM]

Please do come in to find out more about the study, if you have any queries contact Ahmed Ameer on 0170 728 4248 or email A.1.Ameer@herts.ac.uk

Alternatively you can contact Dr Mark Peters on Mark.Peters@gosh.nhs.uk



University of Hertfordshire

Great Ormond Street Hospital for Children NHS Trust

A Study on Medicines Preparation & Administration

[Picture will be inserted here]

We would like to inform you that an observation study aimed to make medication administration safer in children will be carried out in this unit by Ahmed. Observation will be carried out during most drug administration times for example between 6am to 6pm.

The study will not be interfering with your child current therapy, Ahmed will be shadowing the nurse when giving medicines.

Please do contact Ahmed if you want to find out more about the study on 0170 728 4248 or email A.1.Ameer@herts.ac.uk

Appendix 11: Observation Study Pilot Data Collection Form

Observation Form – Version 3 – 20th March 2013

Date		***Patient Age***		***MAE Detected***
Time		***Patient Weight***		☐Yes ☐ No, If Yes specify type ☐Preparation ☐Wrong Medicine ☐Wrong Patient ☐Wrong Route ☐Wrong formulation ☐Admin. Technique ☐Dosage Administered ☐Dosage Prescribed & Administered ☐Extra Dose ☐ IV Rate ☐Time ☐Omission ☐Unauthorised Med. ☐Other
Obsv. Ref.		***Patient Reference***		

Detailed Account of Observation:	***Chart Review***
	Error Identified, if Yes ☐ Dose ☐ Diluent ☐ Formulation ☐ Medicine ☐ Route ☐ Frequency ☐ Illegal ☐ IV Rate ☐ Other
	Error Intercepted ☐ Yes ☐ No
	No .Interruption
	No. Doses

Professional Ref.	☐ Nurse ☐ Sister ☐ Trainee ☐ Other ----------	☐ Bank Staff ☐ NHS Staff	***Experience*** ☐ 0 to 6 months ☐ 7 to 12 months ☐ 1 to 2 years	☐ 2 to 4 years ☐ 5 to 10 years ☐ more than 10 years
MAE Harm	☐ No Harm ☐ Low ☐ Moderate ☐ Severe ☐ Death			

Appendix 12: Case Vignettes for assessment of observed MAE

Dose Errors Case Vignette				
Dose Error is the administration of the correct medicine by the correct route but in a quantity that was not that prescribed. This includes administration of the incorrect number of dose units and the measurement of an incorrect volume of an oral liquid. Using that definition, please circle/choose if you agree that following scenario is indeed containing an error in the dose given or not. Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.				
MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
4, 10, 15	14 y/o (35kg)	Aciclovir 350mg IV Q8hr	Aciclovir 500mg/20mL solution for injection, 15mL (375mg) with NS 100mL @ 100mL/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
19, 22	14 y/o (35kg)	Alimenazine 35mg PO QDS PRN	Alimenazine 30mg/5mL oral solution, 6mL (42mg)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
25	1 y/o (9.2kg)	Cefotaxime 450mg IV Q6hr	Cefotaxime 500mg powder for injection, WFI 2mL, 2mL (500mg) given	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

44	3 m/o (4kg)	Cefotaxime 200mg IV Q6hr	Cefotaxime 500mg powder for injection, WFI 2mL, 1mL (250mg) given	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
47	10 y/o (34kg)	Clarithromycin 255mg IV BD	Clarithromycin 500mg powder for injection, WFI 9.6mL, 4.5mL (225mg) with NS 100mL @ 2mL/min	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
54, 55	2 y/o (12kg)	Dexamethasone 1.2mg IV QDS	Dexamethasone 4mg/mL solution for injection, 0.25mL (1mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
56, 57, 62, 65, 71, 72, 75	3 m/o (4kg)	Dexamethasone 0.6mg IV QDS	Dexamethasone 4mg/mL solution for injection, 0.1mL (0.4mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
76	11 m/o (9kg)	Dexamethasone 1.35mg IV QDS	Dexamethasone 4mg/mL solution for injection, 0.3mL (1.2mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

78	1 y/o (9.2kg)	Flucloxacillin 22mg IV Q6hr	Flucloxacillin 250mg powder for injection, WFI 4.8mL, 5mL (250mg) given over 5min	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
82, 84	1 y/o (10kg)	Furosemide 5mg IV QDS	Furosemide 20mg/5mL Oral solution, 1.2mL (4.8mg) given NGI	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
86	10 y/o (33kg)	Ibuprofen 440mg PO TDS	Ibuprofen 100mg/5mL oral solution, 20mL (400mg) given NGI	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
87, 90	1 y/o (7.5kg)	Ibuprofen 75mg PO QDS	Ibuprofen 100mg/5mL oral solution, 3.8mL (76mg) given NGI	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
91, 92	1 y/o (10kg)	Lansoprazole 10mg NGI OD	Lansoprazole 15mg Dispersable Table in 50mL water, 50mL (15mg) given	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

93	4 y/o (17kg)	Metronidazole 130mg PO Q6hr	Metronidazole 200mg/5mL oral solution, 3.2mL(128mg)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
100, 102, 103, 111, 115, 120	2 m/o (1.6kg)	Morphine 0.33mg PO Q6hr	Morphine 10mg/5mL oral solution, 0.1mL (0.2mg) given	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
121, 122, 123, 126	4 y/o (20kg)	Paracetamol 400mg NGI QDS	Paracetamol 250mg/5mL oral solution, 5mL (500mg)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
129	1 y/o (7kg)	Paracetamol 110mg PO QDS	Paracetamol 120mg/5mL oral solution, 4mL (96mg)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
130, 131, 132	4 y/o (17kg)	Paracetamol 265mg PO Q6hr	Paracetamol 250mg/5mL oral solution, 6mL (300m)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			

Comments				
133, 134	8 y/o (27kg)	Phenyotin 125mg NGI BD	Phenyotin 30mg/5mL oral solution, 18mL (108mg)	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
135	1 y/o (9.2kg)	Phenyotin 45mg IV BD	Phenyotin 250mg/5mL solution for injection, 0.8mL (40mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
136, 137, 138, 139, 140	2 m/o (3.3kg)	Ranitidine 3mg IV TDS	Ranitidine 50mg/2mL solution for injection, 0.2mL (5mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
142, 143, 146	4 y/o (20kg)	Ranitidine 20mg IV TDS	Ranitidine 50mg/2mL solution for injection, 0.6mL (15mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
147	2 y/o (12kg)	Ranitidine 12mg IV TDS	Ranitidine 50mg/2mL solution for injection, 0.6mL (15mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			

Comments				
148, 151, 152, 154, 155, 157	1 y/o (9.6kg)	Ranitidine 9.5mg IV Q8hr	Ranitidine 50mg/2mL solution for injection, 0.5mL (12.5mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
158, 159	4 y/o (16kg)	Ranitidine 16mg IV TDS	Ranitidine 50mg/2mL solution for injection, 0.8mL (20mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
161, 162, 163	1 m/o (3kg)	Ranitidine 3mg IV TDS	Ranitidine 50mg/2mL solution for injection, 0.2mL (5mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
164, 165, 166, 169	1 y/o (9.4kg)	Ranitidine 9mg IV Q8hr	Ranitidine 50mg/2mL solution for injection, 0.3mL (7.5mg) given Neat	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
170, 171, 175, 176, 177, 179, 182	1 y/o (7.5kg)	Salbutamol 1 puff inhalation QDS PRN	Salbutamol 100mcg mouth inhaler, 2 puffs administered	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
183, 184	4 y/o (26kg)	Sodium Valporate 360mg	Sodium Valporate 200mg/5mL oral solution, 8mL (320mg)	Yes / No

		PO BD		
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

Formulation Errors Case Vignette

Formulation error is the administration of the correct medicine by the correct route but in a formulation that was not the prescribed.

Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.

MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
125	7 y/o (19kg)	Co-Trimoxazol 480mg PO Q12hr	Co-Trimoxazol 480mg/5mL solution for injection, 5mL (480mg) in NS 125mL @ 120mL/hr administered,	Yes / No
Severity of Harm		☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10		
Comments				
80, 82, 84, 153	1 y/o (10kg)	Furosemide 5mg IV QDS	Furosemide 20mg/5mL oral solution, 1.2mL (4.8mg) given.	Yes / No
Severity of Harm		☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10		
Comments				

Infusion Rate Errors Case Vignette

Infusion rate error is the administration of the correct medicine and correct dose by the correct route but infused at a rate that falls out side the recommended infusion rate of the medicine per guidelines. Using this definition, please circle/choose if you agree that following scenario is indeed containing an infusion rate error or not.

Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.

MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
2	2 y/o (12kg)	Cefotaxime 600mg IV QDS	Cefotaxime 1g powder for injection, WFI 3.5mL, 2.4mL (600mg) given over 2min	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
16, 20, 21	10 y/o (30kg)	Clarithromycin 255mg IV BD	Clarithromycin 500mg powder for injection, WFI 9.6mL, 5mL (250mg) in 100mL NS @ 2mL/min	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
28	2 y/o (12kg)	Clarithromycin 90mg IV QDS	Clarithromycin 500mg powder for injection, WFI 9.6mL, 1.8mL (90mg) in 50mL NS @ 100mL/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
33, 34	8 y/o (26kg)	Furosemide 5mg IV BD	Furosemide 10mg/mL solution for injection, 0.5mL (5mg) given Neat Bolus	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

36, 40	4 y/o (20kg)	Furosemide 10mg IV Q6hr	Furosemide 10mg/mL solution for injection, 1mL (10mg) given Neat Bolus	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
41, 42	1 y/o (10kg)	Metronidazole 75mg IV Q8hr	Metronidazole 500mg/100mL solution for injection, 15mL (75mg) in G5W 85mL @ 400mL/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
47	1 y/o (9.6kg)	Midazolam 50mg (0-4 mcg/ kg/min) Continuous IV @ 0 - 2mL/hr, 50mL G5S	Midazolam 50mg/10mL solution for injection, 10mL in G5S 40mL @ 1mL/hr as 2mcg/kg/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
53, 60, 64, 70, 77, 79	14 y/o (41kg)	Ranitidine 40mg IV Q8hr	Ranitidine 50mg/2mL Solution for injection, 1.6mL (40mg) given in less than 2min	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

108	3 y/o (14kg)	Ranitidine 14mg IV Q8hr	Ranitidine 50mg/2mL solution for injection, 0.6mL (14mg) Neat Bolus	Yes / No
110, 112	15 y/o (50kg)	Ranitidine 50mg IV TDS	Ranitidine 50mg/2mL solution for injection, 2mL (50mg) Neat Bolus	Yes / No
145, 149	1 y/o (10kg)	Ranitidine 10mg IV QDS	Ranitidine 50mg/2mL solution for injection, 0.4mL (10mg) Neat Bolus	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
150	11 m/o (9kg)	Vancomycin 150mg IV TDS	Vancomycin 500mg powder for injection, WFI 9.7mL, 3mL (150mg) @ 1mL/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
178	1 y/o (10kg)	Vecuronium 30mg (0-4mcg/kg /min) Continuous IV @ 0-2mL/hr in 25mL NaCl 0.9%	Vecuronium 10mg powder for Injection, WFI 5mL x3 (30mg), NaCl 0.9% (10mL), infused @ 1mL/hr as 2mcg/kg/hr	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

Omission Errors Case Vignette

Omission error is a dose of medication that had not been administered by the time of the next scheduled dose. Doses omitted according to doctors' instructions, according to a nurse's clinical judgement or because the patient was not on the ward were not considered opportunities for error. If a dose omitted was documented in medication chart, it would not be considered as an omission error.

Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.

MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
5	4 y/o (20kg)	Furosemide 10mg IV Q6hr	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
9	10 m/o (9.5kg)	Furosemide 9mg IV BD	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
12	10 m/o (9.5kg)	Ranitidine 10mg IV TDS	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
17, 35, 39	1 y/o (10kg)	Paracetamol 150mg IV Q6hr	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

98	1 y/o (9.2kg)	Ranitidine 9mg IV TDS	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
117	1 y/o (7.5kg)	Chloral 225mg PO Q6hr	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
118	1 y/o (7.5kg)	Morphine 1.5mg PO Q6hr	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
144	2 m/o (1.6kg)	Furosemide 1mg IV TDS	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
160	11 m/o (9kg)	Disopyramide 20mg PO Q6hr	Dose not given, omission not documented	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

Preparation Errors Case Vignette

Preparation error is an incorrect preparation of the medication dose, an example incorrect dilution or reconstitution, not shaking a suspension, not keeping a light-sensitive drug protected from light, and mixing drugs that are physically or chemically incompatible. Not following aseptic preparation technique is also considered a preparation error. Also not administering a medicine without double checking is a preparation error or use of wrong diluent than that prescribed or recommended in guidelines.

Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.

MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
11	7 y/o (26kg)	Aciclovir 475mg IV Q8hr	Aciclovir 500mg/20mL solution for injection, 19mL (475mg) in 100mL NS @ 100mL/hr, Dose spillage occurred when withdrawing the 19mL into 100mL of NS	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
3	2 y/o (12 kg)	Aciclovir 280mg IV TDS	Aciclovir 500mg/20mL solution for injection. 11.2mL (280mg) in NS 56mL @1.2mL/min administered but no aseptic preparation followed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

23	1 y/o (10kg)	Benzylpencillin 500mg IV Q8hr	Benzylpencilin 600mg powder for injection, NS 5.6mL, 5mL (500mg) to NS 15mL @ 30mL/hr, Dose spillage occurred when withdrawing from syringe containing drug.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
46	1 y/o (10kg)	Benzylpencillin 500mg IV Q8hr	Benzylpencilin 600mg powder for injection, NS 5.6mL, 5mL (500mg) to NS 15mL @ 30mL/hr, Dose spillage occurred and not following aseptic technique	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
27, 52, 49,	1 y/o (10kg)	Cefotaxime 500mg IV Q6hr	Cefotaxime 500mg powder for injection, NS 2mL, 2mL (500mg) over 5min. Powder not fully dissolved.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
174	1 y/o (9kg)	Cefotaxime 450mg IV Q6hr	Cefotaxime 500mg powder for injection, NS 2mL, 1.8mL (450mg) over 5min. No double check.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
30, 31	5 y/o (18kg)	Ceftazidime 2g IV TDS	Ceftazidime 2g powder for injection, WFI 10mL, 10mL (2g) Neat Bolus given. Powder not fully dissolved.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

37	5 y/o (18kg)	Co-Amoxiclav 125/31mg PO TDS	Co-Amoxiclav 125/31mg/5mL oral solution, 5mL given using oral syringe, dose spillage noticed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
180	15 y/o (60kg)	Co-Amoxiclav 1.2g IV Q8hr	Co-Amoxiclav 600mg powder for injection, WFI 10mL x2. 20mL(1.2g) neat given without double check.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
43	1 y/o (9.2kg)	Flucloxacillin 225mg IV Q6hr	Flucloxacillin 250mg powder for injection, WFI 4.8mL, 4.5mL(225mg) neat over 5min given. Dose spillage	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
48	10 y/o (33kg)	Ibuprofen 440mg PO TDS	Ibuprofen 100mg/5mL oral solution, 20mL(400mg) given. Not shaken.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
51	1 y/o (7.5kg)	Ibuprofen 75mg PO QDS	Ibuprofen 100mg/5mL oral solution, 3.8mL(76mg) given. Not shaken.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

93	4 y/o (17kg)	Metronidazole 130mg PO Q6hr	Metronidazole 200mg/5mL oral solution, 3.2mL (128mg) given but not double checked	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
6, 45, 63	8 y/o (27 kg)	Midazolam 0 – 4 mcg/kg/min continuous IV @ 0 – 2mL/hr	Midazolam 50mg/10mL solution for injection, 32.4mL in NS 17.6mL @ 20mcg/kg/min (1mL/hr). Dose spillage noticed and wrong diluent used, G5W prescribed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
172	1 y/o (12kg)	Midazolam 0 – 4 mcg/kg/min continuous IV @ 0 – 2mL/hr	Midazolam 50mg/10mL solution for injection, 14.4mL in NS 35.6mL @ 20mcg/kg/min (1mL/hr). Wrong diluent used, G5W prescribed.	Yes/No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
66, 68	1 y/o (10kg)	Morphine 0 – 4 mcg/kg/hr continuous IV @ 0 – 2mL/hr	Morphine 10mg/mL solution for injection, 1mL in NS 49mL @ 20mcg/kg/min (1mL/hr). Dose spillage noticed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
173	1 y/o (12kg)	Morphine 0 – 4 mcg/kg/hr continuous IV @ 0 – 2mL/hr	Morphine 10mg/mL solution for injection, 1.2mL in NS 48.8mL @ 20mcg/kg/min (1mL/hr). No aseptic technique followed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

7	8 y/o (27kg)	Morphine 0 – 4 mcg/kg/hr continuous IV @ 0 – 2mL/hr	Morphine 10mg/mL solution for injection, 2.7mL in NS 47.3mL @ 20mcg/kg/min (1mL/hr). Wrong diluent used, G5W prescribed.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
69, 73, 67	4 y/o (26kg)	Oramorph 2.5mL PO QDS	Oramorph 10mg/5mL oral solution, 2.5mL (5mg) given but not shaken. Poor aseptic technique	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
74, 81	14 y/o (41kg)	Paracetamol 500mg PO QDS PRN	Paracetamol 250mg/5mL oral solution, 10mL(500mg) given but not shaken using oral syringe.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
85	8 y/o (27kg)	Paracetamol 500mg NGI QDS	Paracetamol 250mg/5mL oral solution, 10mL(500mg) given but not shaken using oral syringe.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
86	1 y/o (7.5kg)	Paracetamol 120mg PO QDS	Paracetamol 120mg/5mL oral solution, 5mL (120mg) given but not shaken & spillage using oral syringe.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

90, 94	1 y/o (10kg)	Paracetamol 150mg IV Q6hr	Paracetamol 500mg/50mL solution for injection, 15mL (150mg) @ 1mL/min Neat. Dose spillage	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
95, 104	2 m/o (3.3kg)	Paracetamol 60mg IV QDS	Paracetamol 500mg/50mL solution for injection, 6mL (60mg) in NS 54mL @ 1mL/min. Dose spillage	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
119	4 y/o (20kg)	Paracetamol 400mg NGI QDS	Paracetamol 250mg/5mL oral solution, 8mL(400mg) given but not shaken	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
124	4 y/o (17kg)	Paracetamol 265mg PO Q6hr	Paracetamol 250mg/5mL oral solution, 6mL (300mg) given but not shaken	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
127, 128	4 y/o (26kg)	Phenytoin 150mg NGI BD	Phenytoin 30mg/5mL oral solution, 25mL (150mg) given but not shaken	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

132	8 y/o (27kg)	Piperacillin/Tazobactam 2475mg IV Q6hr	Piperacillin/Tazobactam 4/0.5g powder for injection, NS 16.6mL, 11mL (2475mg) neat, dose spillage & no aseptic technique followed	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
141	11 m/o (9kg)	Propranolol 9mg PO TDS	Propranolol 10mg/5mL oral solution, 4.5mL (9mg) given but not shaken	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
32	15 y/o (47kg)	Rifampicin/Isoniazid 450/300mg PO OD	Rifampicin/Isoniazid 150/100mg tablets crushed and dissolved in water x3. 50mL (450/300mg) given but poor aseptic technique followed.	Yes/No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
156, 167, 168	14 y/o (41kg)	Salbutamol 100mcg 2puffs QDS PRN	Salbutamol 100mcg Inhaler, 2 puffs administered but inhaler not shaken	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
181	14 y/o (35kg)	Vancomycin 2g IV TDS	Vancomycin 1g powder for injection, WFI 20mL x2. 40mL (2g) in NS 400mL @ 200mL/hr. Powder not fully dissolved in vial.	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

Time Errors Case Vignette				
Time error is the administration of a medication ± 1 hour of the prescribed dosage regime. Please rate severity of harm for the following scenarios in terms of **potential clinical significance** by choosing a number between **zero** to **ten**, where zero should be given to a case which will have **no effects** on the patient, and ten should be given to a case that would result in **death**. Please assess the cases based on the information available, but feel free to look up any information you need in the BNF or elsewhere. Please state any comments you have in the space provided.				
MAE Ref	Patient	Prescribed Medicine	Administered Medicine	Error Occurred
101	14 y/o (35kg)	Aciclovir 350mg IV Q8hr	Aciclovir 500mg/20mL solution for injection, 14mL (350mg) in NS 100mL @ 100m/hr given 1hr:45min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
61	1 y/o (10kg)	Aciclovir 245mg IV TDS	Aciclovir 500mg/20mL solution for injection, 9.8mL (245mg) in NS100mL @ 100mL/hr given 1hr:30min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
18	1 y/o (10kg)	Benzylpencillin 500mg IV Q8hr	Benzylpencillin 600mg powder for injection, NS5.6mL, 5mL(500mg) in NS 15mL @ 30mL/hr given 1hr:50min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
13	2 y/o (12kg)	Cefotaxime 600mg IV QDS	Cefotaxime 1g powder for injection WFI 3.5mL, 2.4mL (600mg) given 1hr:15min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

59	1 y/o (10kg)	Cefotaxime 500mg IV Q6hr	Cefotaxime 500mg powder for injection, WFI 2mL, 2mL (500mg) given 1hr:20min late	Yes / No
113	1 y/o (9.1kg)	Cefotaxime 450mg IV Q6hr	Cefotaxime 500mg powder for injection, WFI 2mL, 1.8mL (450mg) given 1hr:30min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
114	11 m/o (9kg)	Ciprofloxacin 90mg IV Q8hr	Ciprofloxacin 250mg/5mL oral solution, 1.8mL (90mg) was given orally 1hr:10min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
58	1 y/o (10kg)	Clarithromycin 75mg IV BD	Clarithromycin 500mg powder for injection, WFI 9.6mL, 1.5mL (75mg) in NS 50mL @ 50mL/hr given 2hrs late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
76	11 m/o (9kg)	Dexamethasone 1.35mg IV QDS	Dexamethasone 4mg/mL solution for injection, 0.3mL (1.2mg) given neat 2hr:10min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
99	1 y/o (9.2kg)	Flucloxacillin 225mg IV Q6hr	Flucloxacillin 250mg powder for injection, WFI 4.8mL, 4.5mL (225mg) neat given 2hr late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

87	1 y/o (7.5kg)	Ibuprofen 75mg IV QDS	Ibuprofen 100mg/5mL oral solution, 3.8mL (76mL) given 1hr:45min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
89	4 y/o (17kg)	Meropenem 340mg IV Q8hr	Meropenem 0.5g powder for injection, WFI 9.5mL, 6.8mL(340mg) in NS 17mL given 1hr:15min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
1, 38	1 y/o (10kg)	Metronidazole 75mg IV Q8hr	Metronidazole 500mg/100mL solution for injection, 15mL (75mg) in G5W 85mL @ 5mL/min given 1hr late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
83, 88, 109	4 y/o (26kg)	Oramorph 2.5mL PO QDS	Oramorph 10mg/5mL oral solution, 2.5mL(5mL) given 1hr:50 late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
97	14 y/o (41kg)	Paracetamol 1g NGI QDS	Paracetamol 250mg/5mL oral solution,20mL(1g) given 1hr:30min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

105	1 y/o (9.2kg)	Piperacillin/Tazobactam 810mg IV Q6hr	Piperacillin/Tazobactam 2g/0.25g powder for injection, WFI 8.3mL, 3.5mL (810mg) given 2hr:15min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
8, 26, 29	8 y/o (27kg)	Piperacillin/Tazobactam 2475mg IV Q6hr	Piperacillin/Tazobactam 4g/0.5g powder for injection, NS 16.6mL, 11mL (2475mg) given 1hr:50min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
116	11 m/o (9kg)	Propranolol 9mg PO TDS	Propranolol 10mg/5mL oral solution, 4.5mL(9mg) given 2hrs:30min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
106	3 y/o (14kg)	Ranitidine 14mg IV Q8hr	Ranitidine 50mg/2mL solution for injection, 0.6mL (14mg) given 1hr:10min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				
24	1 y/o (10kg)	Ranitidine 10mg IV QDS	Ranitidine 50mg/2mL solution for injection, 0.4mL (10mg) given 1hr:30min late	Yes / No
Severity of Harm	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10			
Comments				

Appendix 13: MAE Safety Measures Survey Invitation Letter for GOSH PICU Staff

University of Hertfordshire
School of Life and Medical Science
Department of Pharmacy
College Lane
Hatfield
AL10 9AB, UK
Tel: +44 (0)1707284248
Fax: +44 (0)1707284506
herts.ac.uk

16 July 2014

Dear Healthcare Professional

My name is Ahmed Ameer, I am a doctoral candidate at the Department of Pharmacy, University of Hertfordshire. I would like to invite you to participate in an online survey to identify an intervention to reduce the possibility of medication administration errors in paediatric intensive care unit.

If you decided to participate please complete a short online survey at: http://tinyurl.com/interventiondesign, the survey should not take you more than 10 minutes to complete. Participation is entirely voluntary and data obtained will be kept confidential.

The results of the study will be published or presented at meetings, but data will be kept anonymous. I will be grateful if you can also nominate any other individuals that you feel have been involved in putting the intervention at your practice. They can follow the same link above to complete the survey.

Thank you very much for your co-operation and participating in this study. If you have any query, you can contact me at 01707284248 or email A.1.Ameer@herts.ac.uk.

With kind regards

Ahmed Ameer

Ahmed Ameer MRPharmS
PhD Candidate

Appendix 14: MAE Safety Measures Survey Invitation Letter for PICU Staff Nationally

University of Hertfordshire
School of Life and Medical Science
Department of Pharmacy
College Lane
Hatfield
AL10 9AB, UK
Tel: +44 (0)1707284248
Fax: +44 (0)1707284506
herts.ac.uk

16 July 2014

Dear Healthcare Professional

My name is Ahmed Ameer, I am a doctoral candidate at the Department of Pharmacy, University of Hertfordshire. I would like to invite you to participate in an online survey to identify an intervention to reduce the possibility of medication administration errors in paediatric intensive care unit.

If you decide to participate please complete a short online survey at: https://www.surveymonkey.com/s/CFHGNF3 The survey should not take you more than 10 minutes to complete. Participation is entirely voluntary and data obtained will be kept confidential.

The results of the study will be published or presented at meetings, but data will be kept anonymous. I will be grateful if you can also nominate any other individuals that you feel have been involved in putting the intervention at your practice. They can follow the same link above to complete the survey.

Thank you very much for your co-operation and participating in this study. If you have any query, you can contact me at 01707284248 or email A.1.Ameer@herts.ac.uk.

With kind regards

Ahmed Ameer

Ahmed Ameer MRPharmS
PhD Candidate

Appendix 15: MAE Safety Measures Survey

Survey to Design Medication Administration Error Intervention in PICU

Thank you for taking part in in this medication administration error intervention design survey. The purpose of this survey is to identify interventions and/or tools that can help to reduce the possibility of medication administration errors in your practice.

All data collected in this survey will be anonymised and held securely. The survey should take 5–10 minutes to complete.

Survey results and feedback will be reviewed within the University of Hertfordshire, Department of Pharmacy.

If you have any questions, please contact Ahmed Ameer on A.1.Ameer@herts.ac.uk.

Thank you very much for completing this survey.

1. Can you please choose one of the following that best describe you:
   ☐ Doctor

   ☐ Nurse

   ☐ Pharmacist

2. How many years of post registration experience do you have?
   ☐

3. What factors do you believe could lead to making a mistake during medication administration in your current practice?

4. In your opinion, what would reduce the possibility of medication administration errors in current practice?

5. Please rate the usefulness of the following interventions/tools in reducing medication administration errors in your current practice?

Intervention/Tool	Scale					
	Don't Know	Not Useful At All	Not Very Useful	Somewhat Useful	Very Useful	Extremely Useful
Centralised Intravenous Additive Service (CIVAS) for high risk drugs and drugs with difficult concentrations	☐	☐	☐	☐	☐	☐
Barcode medication administration technology combined with smart infusion pumps	☐	☐	☐	☐	☐	☐
Zero Tolerance Policy towards interruptions during administration	☐	☐	☐	☐	☐	☐
Use of electronic calculator to help with preparation of dose e.g. calculate the actual volume needed to withdrawal, the amount of diluent and work out the rate of infusion	☐	☐	☐	☐	☐	☐
Extensive eLearning modules on medication administration process with demonstration videos	☐	☐	☐	☐	☐	☐
Step by Step flow chart easily accessible describing medication administration process and tips with pharmaceutical dose calculations for Intravenous medications	☐	☐	☐	☐	☐	☐

6. Would you like to participate in future research aiming to develop an intervention to reduce medication errors in PICU or be informed of this research outcome? If yes, please provide the following

Name	
Job Title	
E-mail Address	

7. Do you have any other comments?

Thank you very much for taking time to complete this survey.